

Promoting Objectivity in Research for which PHS Funding is Sought

Effective Date: August 24, 2012

Responsible University Official: Vice President for Research (VPR)

Conflict of Interest Official: Director of Grants and Contracts (OGC)

PROCEDURE

These procedures relate to the 2011 revised PHS requirements as outlined in 42 CFR Part 50 Subpart F and 45 CFR Part 94 (collectively, referred to as the “PHS Regulations”) which deal with significant financial interest, financial conflict of interest, management of such conflicts, and the responsibilities of NMSU and NMSU Investigators who are responsible for the design, conduct, and/or reporting of research funded by PHS. NMSU requires that the University and all applicable employees comply with the PHS Regulations.

APPLICABILITY

1. The PHS regulations and this procedure apply to all NMSU employees, subawardees, consortium participants, collaborators, and consultants who are responsible for the design, conduct, and/or reporting of research funded by PHS.
2. The PHS regulations and this procedure apply to all PHS proposals submitted on or after August 24, 2012.
3. The PHS regulations and this procedure apply to all awards with a Notice of Award (NoA) that is issued on or after August 24, 2012.
4. The PHS regulations do not apply to PHS-funded Phase I SBIR or STTR funding.
5. The PHS regulations do not apply to procurements, purchases of goods or services from vendors, or consultant services if the consultant does not meet the definition of an investigator.

DEFINITIONS

Authorized Institutional Official(s) The Vice President for Research is authorized by the Board of Regents of NMSU to sign proposals, awards and other agreements; the VPR has delegated this authority to the Director of Grants and Contracts.

Conflict of Interest (COI) may take many forms and exists whenever personal (including those of family members), professional, commercial, or financial interests or activities outside of the University have the possibility of compromising an individual’s judgment, biasing the nature or direction of scholarly research, influencing an individual’s behavior with respect to teaching,

service, student affairs, appointments and promotions, use of University resources, interactions with human subjects, or other matters of interest to the University resulting in personal gain or advancement

Conflict of Interest Committee is the committee that advises the Vice President for Research (VPR) on conflict of interest matters relating to sponsored projects.

Conflict Management Plans are designed to afford a reasonable expectation that the design, conduct, and reporting of research, training or service activities will be free from bias or personal gain resulting from Investigator FCOI. Conflict Management Plans also provide oversight to ensure adherence to the highest scientific and academic standards and protect the interests of other University employees or students who may be involved in the sponsored project.

Disclosure is reporting of financial interests related to the Investigator's Institutional Responsibilities, including Significant Financial Interests (SFI).

Financial Conflict of Interest (FCOI) means a Significant Financial Interest (SFI) that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

FCOI report means an Institution's report of a financial conflict of interest to a PHS Awarding Component.

Financial Interest means anything of monetary value, whether or not the value is readily ascertainable. ONLY financial interests that arise to the level of SFI represent potential FCOI.

Institution means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, PHS research funding.

Institutional Responsibilities means an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on financial conflicts of interest, which may include for example: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Investigator means any person, regardless of *title, position, or employment status* who is responsible for the design, conduct, or reporting of PHS-funded or proposed research at, on behalf of, or in collaboration with NMSU.

Institutional (or Designated) Official means the individual within the Institution, or his/her designee, that is responsible for the solicitation and review of disclosures of SFI including those of the Investigator's family related to the Investigator's Institutional Responsibilities; determination of whether any SFI is related to PHS-funded research and could be affected by the PHS-funded research or is in an entity whose financial interest could be affected by the

research; development and oversight of the management plan; and retention of disclosures, and related documents. The Director of Grants and Contract Services is the VPR's designee to serve as the Institution Official.

Manage means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

Principal Investigator (PI) or Project Director (PD) means a project director or principal Investigator of a PHS-funded research project; the PD/PI is included in the definitions of senior/key personnel and Investigator.

Public Health Service or PHS means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority of the PHS may be delegated. The components of the PHS include, but are not limited to, the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), the Health Resources and Services Administration (HRSA), the Substance Abuse and Mental Health Services Administration (SAMHSA), the Food and Drug Administration (FDA), the Indian Health Service (IHS), the Agency for Toxic Substances and Disease Registry (ATSDR), the Centers for Medicare and Medicaid Services (CMS), the Administration for Community Living (ACL), and the Agency for Healthcare Research and Quality (AHRQ).

Research is defined by PHS as a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social sciences research. The term encompasses basic and applied research, and development, and includes any such activity for which research funding is available from a PHS Awarding Component through a grant, cooperative agreement, or contract, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

Senior/Key Personnel means the Project Director/Principal Investigator (PD/PI) and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS-awarding component by the Institution.

Significant Financial Interest (SFI) has been redefined in the revised 2011 regulations:

A financial Interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's family members) that reasonably appears to be related to the Investigator's Institutional Responsibilities:

- With regard to any publicly traded entity, the aggregate value of any salary or other payments for services received during the twelve-month period preceding the disclosure, and the value of any equity interest during the twelve-month period preceding or as of the date of disclosure, exceeds \$5,000. For purposes of this definition, services include, but are not limited to, consulting fees, honoraria, or 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.

- With regard to any non-publicly traded entity, the aggregate value of any salary or other payments for services received during the twelve-month period preceding the disclosure exceeds \$5,000; or is an equity interest of any value during the twelve-month period preceding or as of the date of disclosure.
- Intellectual property rights and interests (e.g., patents, copyrights) upon receipt of income related to such rights and interests.
- 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 U.S. Federal, state or local governmental agencies, U.S. institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers. In accordance with the Institution's FCOI policy, the institutional official 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.

The term *significant financial interest* does not include the following types of financial interests: salary, royalties, or other remuneration received from or through the University, including intellectual property rights assigned to the University and agreements to share in royalties related to such rights; income from the authorship of academic or scholarly works; income from seminars, lectures, or teaching engagements sponsored by or from advisory committees or review panels for U.S. Federal, state, or local government agencies, U.S. institutions of higher education, academic teaching hospitals, medical centers, or U.S. research institutes that are affiliated with institutions of higher education, academic teaching hospitals, and medical centers; financial interests arising solely by reason of investment in a business by a mutual, pension or other institutional investment fund over which the employee does not exercise direct control.

Sponsored Project: Research, training, or service activity funded by an outside agency, either through a grant, contract, or other transaction.

Small Business Innovation Research (SBIR) Program means the extramural research program for small businesses that is established by the Awarding Components of the Public Health Service and certain other Federal agencies under Public Law 97–219, the Small Business Innovation Development Act, as amended. For purposes of the revised FCOI Regulation, the

term SBIR Program also includes the Small Business Technology Transfer (STTR) Program, which was established by Public Law 102–564.

MANDATORY TRAINING

The PHS mandates that Investigators complete FCOI training prior to participating in PHS-funded research, at least every four years thereafter, and immediately when any of the following circumstances apply:

1. NMSU procedure for PHS is revised in any manner that affects the requirements of the Investigators.
2. An Investigator is new to NMSU.
3. NMSU finds that an Investigator is not in compliance with these requirements.

This educational requirement includes training on the PHS Regulations as well as additional training regarding the Investigator's responsibilities for disclosure of SFI and the policies and procedures set forth in this procedure. PHS training is provided by the Director of Grants and Contracts, and NMSU Investigators must complete the workshop before submitting a proposal to PHS.

DISCLOSURE, REVIEW, AND MONITORING PROCEDURES

A. Disclosure of Significant Financial Interests

All NMSU employees are required to complete an annual Conflict of Interest form located at <https://accounts.nmsu.edu/eds/docserve/central/login.php>. The form allows all employees to disclose any significant financial interests, including those of family members, that reasonably appear to be related to an Investigator's institutional responsibilities.

Special attention is paid to employees who work on a sponsored program. If Investigators have any questions about a potential SFI, they are encouraged to call Ms. Alisha Giron at 575-646-1590. She can help the Investigator if there is a true SFI that needs to be disclosed.

Additionally, before a proposal to PHS is submitted, all Investigators on the proposal must complete the sign NMSU's form titled PHS Financial Conflict of Interest (FCOI) Certification located at <http://coi.research.nmsu.edu/sites/coi/files/images/FCOI%2001-PHS%20FCOI%20Certification.pdf> certifying no conflict exists or is handled with a management plan and all reimbursed travel conflicts are disclosed. In the case of a new Investigator or disclosure of a new FCOI, NMSU will submit to the PHS agency a report showing the conflict and implementation of a management plan within 60 days.

Investigators must submit new or updated disclosures without thirty (30) days of discovering or acquiring a new SFI.

B. Review of Disclosures

All disclosures on the annual Conflict of Interest form that involve sponsored programs will be forwarded to the Conflict of Interest Officer. She will review each disclosure and determine whether SFI is related to a PHS sponsored award and if so, does a FCOI exist.

The Conflict of Interest Officer will look closely at all disclosures of SFIs or reimbursed or sponsored travel related to PHS funded research. She will classify an SFI as a FCOI when:

- The SFI could be affected by the PHS-funded research or is in an entity whose financial interest could be affected by the research; and
- The SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded research

The Conflict of Interest Officer will consult with and solicit other pertinent information from the Investigator and/or the Investigator's Chair, Director, Dean, and any other individuals who may be involved with the research. After gathering all pertinent information, she determines if the Conflict of Interest Committee should convene to discuss the potential FCOI. If she determines there is no FCOI, the Conflict of Interest Officer shall make a notation on the disclosure form and then store the form in a manner to protect confidentiality. If she determines there is a potential FCOI, she will convene a committee meeting to discuss further the situation, and to develop a management plan when feasible.

If and when NMSU identifies an SFI or reimbursed or sponsored travel that was not disclosed in a timely manner by the Investigator or, for whatever reason, was not reviewed by NMSU during an ongoing PHS research project, NMSU shall within sixty (60) days:

1. Review the SFI or reimbursed or sponsored travel.
2. Determine whether the SFI or reimbursed or sponsored travel relates to PHS-funded research and if so, whether a FCOI exists.
3. Develop and implement, on at least an interim basis, a management plan that shall specify the actions that have been, or will be, taken to manage the FCOI.
4. Submit required reports to the PHS agency.

SUBRECIPIENT REQUIREMENTS

- a. Subrecipients or Subcontractors must certify that they have in effect a policy which is compliant with the PHS Regulations, or that they will comply with NMSU's procedure.
- b. Subrecipients or Subcontractors who rely on their FCOI policies must report identified FCOIs to the NMSU Institutional Official in sufficient time to allow NMSU to report the FCOI to the PHS Awarding Component.
- c. Agreements will specify time period(s) for the subrecipient or subcontractor to report all identified FCOIs to NMSU. Agreements may not be executed until the awardee certifies compliance with the PHS Regulations, including reporting requirements.

REPORTING FINANCIAL INTERESTS TO PHS

A. Initial Reports

1. Prior to any funds being expended on a PHS-funded project, the Institutional Official will submit to the PHS agency a report regarding any conflicts or reimbursed travel determined by NMSU that have not been managed through a management plan. NMSU will work diligently to either eliminate all conflicts or to implement a management plan approved by the Conflict of Interest Committee and involved parties; this results in no report required to PHS. NMSU will report to the PHS agency any FCOI of a subrecipient or subcontractor Investigator prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.
2. At the time of proposal submission, all Investigators will complete and sign NMSU's form titled PHS Financial Conflict of Interest (FCOI) Certification located at <http://coi.research.nmsu.edu/sites/coi/files/images/FCOI%2001-PHS%20FCOI%20Certification.pdf> certifying no conflict exists or is handled with a management plan and all reimbursed travel conflicts are disclosed. In the case of a new Investigator or disclosure of a new FCOI, NMSU will submit to the PHS agency a report showing the conflict and implementation of a management plan within 60 days.
3. In the case of a retrospective review where bias has been found, NMSU shall notify the PHS agency promptly and submit a mitigation report as described in the new PHS regulations.

4. NMSU will prepare reports with sufficient information for the PHS agency to understand the nature of the FCOI and to assess the appropriateness of NMSU's management plan. The report will include the following items:
 - a. Sponsor Award ID
 - b. Principal Investigator
 - c. Name of Investigator with the FCOI
 - d. Name of the entity with which the Investigator has a FCOI
 - e. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium)
 - f. Value of the financial interest 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
 - g. A description of how the financial interest relates to the PHS-funded research and why NMSU determined that the financial interest conflicts with such research
 - h. A description of the key elements of the management plan.
- B. Annual Reports
 1. For previously reported FCOI, NMSU will submit to the PHS agency an annual FCOI report that addresses the status of the FCOI and any changes to the management plan for the duration of the project.
 2. The annual FCOI report will specify whether the financial conflict is still being managed or explain why the FCOI no longer exists.
 3. NMSU will submit annual FCOI reports to the PHS agency for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS agency.
 - a. Annual FCOI reports shall not be submitted as part of the annual progress report for a PHS-funded project.

MAINTENANCE OF RECORDS

NMSU shall retain records relating to all Investigator disclosures of financial interests and NMSU's review of, and response to, such disclosures (whether or not a disclosure resulted in a determination of a FCOI), and all actions under the procedures set forth in this document for a period of five years from the date of the final expenditure report submitted to the sponsor, or until resolution of any action involving the records, whichever is longer.

ENFORCEMENT MECHANISMS

NMSU expects all Investigators to comply fully and promptly with the guidelines and procedures regarding conflicts of interest in PHS-funded projects. The University will comply with all sponsor requirements, including sanctions and other administrative actions to ensure

compliance. Failure to comply with the procedure may result in disciplinary action and/or sanctions by NMSU.

PUBLIC ACCESSIBILITY REQUIREMENTS

The procedure will be posted on the NMSU VPR/OGC Website at <http://www.research.nmsu.edu/ogc.html>

NMSU will ensure public accessibility by providing a written response within five (5) business days of a request for information concerning any disclosure of a significant financial interest on a PHS-funded project determined to be a FCOI. The information will include the Investigator's name, title and role with respect to the project, name of entity involved, nature of SFI and the approximate dollar value, or a statement that the interest is one whose value cannot readily be determined through reference to public prices or other reasonable measures of fair market value.

NMSU will note in our written response that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and with 60 days of NMSU's identification of a new potential FCOI, which should be requested subsequently by the requestor.

Information concerning disclosed SFIs will remain available for responses to written requests for at least five years from the date that the information was most recently updated.

Written requests for information concerning any FCOIs can be sent to Ms. Alisha Giron at agiron@nmsu.edu.

INSTITUTIONAL CERTIFICATIONS

NMSU will certify through its Authorized Institutional Official in each application for PHS funding, that NMSU:

- a. Has in effect an up-to-date, written, and enforced administrative process to identify and manage FCOIs with respect to all research projects for which funding is sought or received from the PHS.
- b. Shall promote and enforce Investigator compliance with PHS Regulations.
- c. Shall manage FCOIs and provide initial and ongoing reports to the PHS agency as required.
- d. Agrees to make FCOI and SFI information (including related institutional reviews and determinations) available to PHS, promptly, upon request.
- e. Shall fully comply with requirements of the PHS regulations.