

**University of New England
Investigator Significant Financial Interest Disclosure
Policy
for Sponsored Projects**

Originally Adopted March 2005

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appropriate specific mechanisms by which conflicts of interest will be satisfactorily managed, reduced, or eliminated, prior to award or acceptance of an award. The institution must also maintain appropriate records. If a new reportable significant conflict of interest arises at any time during the period after the submission of the proposal through the period of the award, the filing of a disclosure is also required. Furthermore, UNE must require certain Investigators to complete an appropriate training at least once every four (4) years.

Definitions

Disclosure of significant financial interests
financial interests to an Institution.

Financial conflict of interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of funded research.

FCOI report a PHS Awarding
Component.

Financial interest means anything of monetary value, whether or not the value is readily ascertainable.

HHS means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

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

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 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 funded research or research proposed for such funding, which may include, for example, collaborators, consultants and subcontractors¹.

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.

PD/PI 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 under this subpart.

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 involved may be delegated, including the National Institutes of Health (NIH).

PHS Awarding Component means the organizational unit of the PHS that funds the research that is subject to this subpart.

Public Health Service Act or PHS Act means the statute codified at 42 U.S.C. 201 *et seq.*

Research means 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 (*e.g.*, a published article, book or book chapter) and product development (*e.g.*, a diagnostic test or drug). As used in this policy

related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an 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 an Institution of higher education. For UNE, the details of this disclosure will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with this 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.

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 within the U.S., a U.S. Institution of higher education as defined at 20 U.S.C. 1001(a), a U.S. academic teaching hospital, medical center, or research institute that is affiliated with a U.S. Institution of higher education; or income from service on advisory committees or review panels for a Federal, state, or U.S. local government agency, a U.S. Institution of higher education as defined at 20 U.S.C. 1001(a), a U.S. academic teaching hospital, medical center, or research institute that is affiliated with a U.S. Institution of higher education.
4. [Investigators](#), including subrecipient Investigators, must disclose all financial interests received from a foreign Institution of higher education or the government of another

4. The Director of Research Administration, or official designee, will review [UNE Investigator FCOI Disclosure Forms](#) to determine whether an actual or potential conflict of interest exists. If an actual or potential conflict of interest is found, the matter will be referred to the UNE [Financial Conflict of Interest Review Committee](#) to determine what conditions or restrictions, if any, should be imposed by the institution to manage, reduce, or eliminate such

- c. UNE finds an [Investigator](#) noncompliant with the institutional policy or his/her Management Plan.

This training requirement may be satisfied through face to face sessions offered by UNE and/or through online training modules approved by UNE.

Procedure & Implementation

1. Financial Conflict of Interest Review Committee: UNE will maintain a Financial Conflict of Interest Review Committee (FCOIRC). Committee members will be appointed by the President. The committee shall contain, at a minimum, researchers representing a cross section of disciplines, a research administrator, and other appropriate UNE personnel. The committee shall determine what conditions or restrictions, if any, should be imposed by the institution to manage actual or potential conflicts of interest arising from disclosed significant financial interests. Recommendations for committee members will be made to the President by the Director of Research Administration.
2. Investigator Disclosure: When making a new, annual, or 30-day disclosure under this policy, each [Investigator](#) is required to complete the [UNE Financial Interests Disclosure Form](#) and attach any required supporting documentation. For initial disclosures, the completed disclosure form must be submitted with the proposal and the University of New England Proposal Transmittal Form to the Office of Sponsored Programs according to normal UNE procedures.

Regardless of the above minimum requirement, a faculty or staff member, in his or her own best interest, may choose to disclose any other financial or related interest that could present an actual conflict of interest or be perceived to present a conflict of interest. Disclosure is a key factor in protecting one's reputation and career from potentially embarrassing or harmful allegations of misconduct.

3. Timeframe for Investigator Disclosure: As required by federal regulation, all significant financial interests must be disclosed to UNE prior to the time a proposal is submitted to the funding agency. All financial disclosures must be updated by [Investigators](#) while the award is pending, either on an annual or thirty (30) day basis, as described above.
4. Subawards: If UNE carries out PHS-funded research through a subrecipient (e.g., subcontractors or consortium members), UNE as the awardee Institution must take reasonable steps to ensure that any subrecipient [Investigator](#) complies with this Policy or

- c. [Investigators](#)
conflicts of interest policy, the agreement referenced above shall specify time period(s) for the subrecipient to report all identified financial conflicts of interest to UNE. Such time period(s) shall be sufficient to enable UNE to provide timely FCOI reports, as necessary, to PHS;
 - d. [Investigators](#)
conflicts of interest policy, the agreement referenced above shall specify time period(s) for the subrecipient to submit all [Investigator](#) disclosures of significant financial interests to UNE. Such time period(s) shall be sufficient to enable UNE to comply timely with its review, management, and reporting obligations under this subpart.
 - e. UNE will provide FCOI reports to the PHS Awarding Component regarding all financial conflicts of interest of all subrecipient [Investigators](#) according to the timeframe for reporting UNE Investigator FCOIs set forth below (e.g. prior to the expenditure of funds and within 60 days of any subsequently identified FCOI).
5. Disclosure Form Review: The Director of Research Administration or official designee

