

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

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Introduction

This policy sets forth University of New England's general policy and procedures regarding financial conflicts of interest in relationship to research or externally sponsored projects. Its purpose is to protect the credibility and integrity of the University, thereby ensuring public trust and confidence in the University's sponsored research activities.

In accordance with Federal regulations, the University has a responsibility to manage, reduce, or eliminate any actual or potential conflicts of interest that may be presented by a financial interest of an Investigator. Thus, the University requires that Investigators disclose any significant financial interest that may present an actual or potential conflict of interest in relationship with a sponsored project. Unless otherwise indicated in the relevant section below, investigator **disclosure requirements** of this policy apply to all externally sponsored projects, regardless of funding source. Institutional **reporting requirements**, if any, will vary according to the requirements of the funding entity.

Background

On June 28, 1994, the National Science Foundation (NSF) issued notice of its policy on financial disclosure by scientific Investigators in sponsored research (59 Fed. Reg. 33308). This policy is designed to protect the integrity of NSF-funded research and at the same time to promote sharing and publication of research results. The notice, entitled *Investigator Financial Disclosure Policy*, became effective October 1, 1995.

Placing primary responsibility on the institution to develop information-gathering and reporting procedures, the National Science Foundation requires that grantee institutions employing more than 50 persons maintain "an appropriate written and enforced policy on conflict of interest." Researchers and institutional representatives must comply with the institutional requirements.

Also on June 28, 1994, the Public Health Service (PHS) published a proposed rulemaking entitled *Objectivity in Research*. Under its proposed rules, PHS would require that applicant institutions ensure there is no reasonable expectation that the design, conduct, and reporting of the research to be funded will be biased by any significant financial interest of the Investigator responsible for the design, conduct, and reporting of the research. The final rule was published in the Federal Register of July 11, 1995 with an effective date of October 1, 1995.

On August 25, 2011, PHS published a Final Rule substantially revising the 1995 Rule. These revisions apply to both individuals and institutions engaged in research, and contain new and amended definitions as well as policy and procedural requirements. This amended UNE policy document implements those regulatory changes.

Requirements

Federal regulations require institutions to have policies and procedures in place to ensure objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under Public Health Service (PHS) grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest. To achieve this goal, UNE is required to assess potential Investigator financial conflicts of interest related to the Investigator's institutional responsibilities. UNE must also develop

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 means an Investigator's disclosure of significant 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 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.

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 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 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.

¹ At UNE, the PI is generally the individual best able to decide who meets this definition. The UNE PI **must** ensure that all personnel who meet this definition be apprised of the Investigator Significant Financial Disclosure Policy and prepare the UNE Financial Interests Disclosure Form, if applicable.

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, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, 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 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 funders by the Institution under this subpart.

Significant financial interest means any of the following:

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](#):
 - a. 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;
 - b. 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
 - c. Intellectual property rights and interests (*e.g.*, patents, copyrights), upon receipt of income related to such rights and interests.
2. PHS funded [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 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, 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; or income from service on advisory committees or review panels for 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.

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

Applicability

This policy has two distinct components: internal disclosure of [Significant Financial Interests](#) and external reporting of [Financial Conflicts of Interest](#). All UNE [Investigators](#) **must** disclose [Significant Financial Interests](#) when submitting a “pink sheet” to the Office of Sponsored Programs and within thirty (30) days of acquiring or discovering a [Significant Financial Interest](#).

As required by the individual funding entity reporting requirements, UNE will report [Financial Conflicts of Interest](#) to the funder. For PHS, UNE will be subject to the August 25, 2011 Final rule, including its disclosure requirements, as to any Notice of Award issued on or after August 24, 2012 and all award renewals, made by PHS or any subsidiary entity, including but not limited to:

1. NIH;
2. National Cancer Institute (“NCI”);
3. Centers for Medicare and Medicaid Services (“CMMS”);

4. Agency for Healthcare Research and Quality (“AHRQ”);
5. Centers for Disease Control and Prevention (“CDC”); and
6. Food and Drug Administration (“FDA”).

This overall policy applies to the following entities and individuals:

1. The University of New England;
2. Any [Investigator](#), as defined above, planning to participate or participating in the research;
3. Any individual applying for or receiving research funding; and
4. SBIR/STTR Phase II applicants and awardees. Phase I SBIR/STTR applicants and awardees are exempt.
5. Subcontractors and sub-awardees are subject to the same disclosure and reporting requirements.

Policy

1. University of New England requires each [Investigator](#) submitting a proposal for external funding to submit all required financial disclosures at the time of proposal submission and to update this information at least annually. However, [Investigators](#) must submit an updated disclosure of significant financial interests within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.
 - a. **Initial disclosure** of significant financial interests shall be made to the Director of Research Administration by submitting a packet of information consisting of the [UNE Financial Interest Disclosure Form](#), all required supporting documentation (in a sealed envelope marked *confidential*), the proposal, and the University of New England routing form for grant and contract transmittal form ("the UNE pink sheet").
 - b. **Annual disclosure** of significant financial interests shall be made to a responsible institutional representative by submitting [UNE Financial Interest Disclosure Form](#).
 - c. **Thirty (30) day disclosure** of new significant financial interests, and all Reportable Travel, shall be made to a responsible institutional representative by submitting [UNE Financial Interest Disclosure Form](#).
 - d.
2. In accordance with Federal regulations, a complete initial disclosure must be made by the [Investigator](#) prior to submission of the proposal.
3. The procedure to review disclosures, assess their potential for conflicts of interest, and develop resolution strategies to "manage, reduce or eliminate" such conflicts shall be incorporated with the standard proposal signature process and integrated into the normal proposal submission process.
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 conflicts of interest; and as necessary, recommend sanctions.

5. The Office of Sponsored Programs shall be responsible for appropriate follow-up reporting and records management procedures.
6. By law, information regarding the UNE FCOI policy and its implementation must be publically available.
 - a. UNE will make this policy available to the general public by posting it on the University's [Research-Sponsored Programs](#) website.
 - b. As required, UNE will make certain information about FCOIs related to PHS-funded research by Senior/Key Personnel available to the public. UNE will do so by responding to any request for information about these specifically covered FCOIs within five (5) business days. The Requestor will be informed that the information a) is up to date as of the date of disclosure and b) is subject to update as follows:
 - i. at least annually; or
 - ii. within 60 days of a newly discovered FCOI; and
 - iii. will remain available for 3 years after the most recent update.
 - c. Information that must be made available is:
 - i. Investigator's name;
 - ii. Investigator's title and role with respect to a research project;
 - iii. Name of the entity in which the SFI is held;
 - iv. The nature of the SFI;
 - v. and the approximate dollar value of the SFI (dollar ranges are permissible:\$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,000; \$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 references of public prices or other reasonable measures of fair market value).
7. UNE will make available FCOI training to all [Investigators](#) and Senior/Key personnel, as defined above. This training is **required** for all UNE personnel engaged in research funded or sponsored by PHS and is **recommended** for all UNE personnel engaged in research. The Conflict of Interest training **must** be completed prior to engaging in research related to any PHS funded grant or contract and at least every four years thereafter. In addition, training must be completed immediately by PHS funded [Investigators](#) under the following circumstances:
 - a. UNE FCOI policies change in a manner that affects [Investigator](#) requirements;
 - b. A PHS funded [Investigator](#) is new to UNE and brings current PHS funding to UNE; or
 - 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 University 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 ("pink sheet") to the Office of Sponsored Programs according to normal University 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 an equivalent policy at the subrecipient's home institution. These steps include, but are not limited to:
 - a. Incorporating as part of a written agreement with the subrecipient terms that establish whether UNE's financial conflicts of interest policy or that of the subrecipient will apply to the subrecipient's Investigators;
 - b. If the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the subrecipient shall certify as part of the agreement referenced above that its policy complies with current PHS standards. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to UNE's financial conflicts of interest policy for disclosing significant financial interests that are directly related to the subrecipient's work for UNE;
 - c. If the subrecipient's Investigators must comply with the subrecipient's financial 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. Alternatively, if the subrecipient's [Investigators](#) must comply with UNE's financial 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 shall conduct an initial review of all financial disclosures (Initial, 30 day and Annual) to determine if any disclosed significant financial interest could affect the design, conduct, or reporting of the proposed sponsored project. If the initial review indicates that there may be a potential for conflict of interest covered by this policy, the investigator will be notified and the disclosure will be referred to the FCOIRC.
 6. **Review of Untimely Disclosure:** Within sixty days of learning that a) an [Investigator](#) failed to make a timely disclosure, or b) UNE had not previously reviewed an [Investigator's](#) disclosure in a timely manner, the Director of Research Administration shall review the disclosure of the significant financial interest in order to:
 - a. Determine whether it is related to PHS-funded research;
 - b. Determine whether a financial conflict of interest exists; and, if so,
 - c. Implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest.

Depending on the nature of the significant financial interest, the Director of Research Administration may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date of disclosure and the completion of the Institution's review.

7. **Retrospective Review:** In addition to the above described prospective review, UNE shall conduct retrospective reviews whenever the University becomes aware of any [Investigator](#) non-compliance. Retrospective reviews will be completed and documented within 120 days of the date non-compliance is discovered.
8. **Resolution Plan:** Prior to consideration by the FCOIRC, the [Investigator](#), in cooperation with the [Investigator's](#) department and school or college, shall develop and present to the FCOIRC a resolution plan that details proposed steps that have or will be taken to manage, reduce, or eliminate any actual or potential conflict of interest presented by a significant financial interest.

At a minimum the resolution plan shall address such issues as public disclosure of significant financial interests, review of research protocol by independent reviewers, and monitoring of research by independent reviewers.

Within a reasonable time period, the FCOIRC shall review the resolution plan and approve it, add conditions or restrictions, including but not limited to the following:

- (i) Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
- (ii) For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
- (iii) Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
- (iv) Modification of the research plan;
- (v) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- (vi) Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
- (vii) Severance of relationships that create financial conflicts.

The approved resolution plan shall be incorporated into a memorandum of understanding that details the conditions or restrictions imposed upon the [Investigator](#) in the conduct of the project or in the relationship with the business enterprise or entity. The memorandum of understanding shall be developed by the Office of Sponsored Programs and signed by the [Investigator](#) and the [Investigator's](#) chair and dean. Actual or potential conflicts of interest will be satisfactorily managed, reduced, and eliminated in accordance with these guidelines prior to accepting any award, or they will be disclosed by the Office of Sponsored Programs to the sponsoring agency as may be required.

9. **Record Retention:** Records of [Investigator](#) financial disclosures and actions taken to manage actual or potential conflicts of interest shall be retained by the Office of Sponsored Programs until three (3) years after the later of 1) the submission of the final expenditures report to PHS or 2) the resolution of any government action involving those records. All records, forms, correspondence, and all copies thereof shall be returned to the [Investigator](#) at the determination of award or resolution of government action involving those records.
10. **UNE Reporting to PHS:** UNE shall report any identified FCOI to the PHS Awarding Component. Timeframes for filing reports are as follows:
 - a. Prior to the expenditure of any funds;
 - b. Within sixty (60) days of identifying an [Investigator](#) who is newly participating in the project;
 - c. Within sixty (60) days of identifying any new, or newly identified FCOIs, for existing [Investigators](#);
 - d. At least annually until the completion of the project; or
 - e. Following a [retrospective review](#) to update a previous report, if indicated.

Such reports shall contain the following information:

- a. Grant Number;
- b. Project Director/Principal Investigator or designated contact person;
- c. Name of the [Investigator](#) with FCOI;
- d. Whether FCOI was managed, reduced or eliminated;
- e. The name of the entity with which the [Investigator](#) has the FCOI;
- f. The nature of the FCOI (e.g. equity, consulting fees, travel reimbursement, honoraria);

- g. The value of the financial interest in the following manner:
 - i. \$0-\$4,999;
 - ii. \$5,000-\$9,999;
 - iii. \$10,000-\$19,999;
 - iv. \$20,000-\$99,999 in increments of \$20,000;
 - v. More than \$100,000 in increments of \$50,000; or
 - vi. A statement that a value cannot be readily determined.

In the case of either prospective or [retrospective reviews](#), if UNE determines that that the FCOI resulted in bias in the conduct of the project, UNE will promptly notify the PHS awarding component and submit an appropriate mitigation report, setting forth at a minimum the following:

- a. the key elements documented in the review;
- b. a description of the impact of the bias on the research project; and
- c. UNE's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable).

11. **Monitoring:** The Director of Research Administration, or designee, will monitor PHS funded [Investigator](#) compliance with any management plans until the completion of the project.
12. **Non-Compliance/Violations:** Whenever an [Investigator](#) has violated this policy or the terms of the memorandum of understanding, the conflict of interest review committee shall recommend sanctions which may include disciplinary action ranging from a public letter of reprimand to dismissal and termination of employment. The committee's recommendations on sanctions shall be presented to the [Investigator's](#) chair and dean who, in consultation with the University President, shall enforce any disciplinary action in accordance with the University procedures then in force.

If the failure of an [Investigator](#) to comply with UNE's financial conflicts of interest policy or a financial conflict of interest management plan appears to have biased the design, conduct, or reporting of the PHS-funded research, UNE shall promptly notify the PHS Awarding Component of the corrective action taken or to be taken.

In any case in which the HHS determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an [Investigator](#) with a financial conflict of interest that was not appropriately managed or reported by UNE, UNE shall require the [Investigator](#) involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

13. **UNE Internal Reporting:** The Director of Research Administration or official designee shall report annually to the Associate Provost for Research and Scholarship about the status and workings of this policy and the actions of the conflict of interest review committee.