

UNI Office of Research and Sponsored Programs
Policy on Conflicts of Interest Involving Research Funded by the Public Health Service
8-22-12

Purpose of Policy

The purpose of this policy is to ensure that university employees engaged in research funded by the Public Health Service (PHS), including the National Institutes of Health (NIH), comply with the 42 CFR 50, the 2011 regulation addressing Financial Conflicts of Interest in research.

All UNI employees must be able to act and make decisions that are free from bias engendered by unmanaged conflicts of interest and commitment, and to act with integrity and transparency in academic and business activities. While faculty, staff, and administrators are encouraged to develop external activities and relationships, they must maintain those in a way that does not adversely affect their duties and obligations to the university. This policy therefore provides a framework for identifying potential or perceived conflicts of interest that may affect Public Health Service-funded research, disclosing and reporting them, and managing them so that all interests are appropriately addressed. Every investigator has an obligation to become familiar with, and abide by, the provisions of this policy.

Applicability of Policy

This policy applies to all individuals at UNI who are involved in projects that are sponsored by the U.S. Public Health Service (PHS), consistent with the 2011 Revised Financial Conflict of Interest (FCOI) regulations (42 CFR 50 Subpart F). This policy and related requirements also apply to contractors, grantees, and sub-recipients of Public Health Service funds from the university, although they may also maintain and adhere to stricter policies of their own.

Policy Statement

All investigators involved in PHS-funded projects are required to disclose their Significant Financial Interests to the university on an annual and on an ad hoc basis, as described below. The UNI Conflict of Interest Officer (COIO) is responsible for the distribution, receipt, processing, review and retention of [disclosure forms](#). This includes reviewing investigator disclosure forms to determine if a Financial Conflict of Interest (FCOI) exists, and if so, reporting it as required by the PHS and working with the investigator to resolve the conflict appropriately. The COIO may suspend all relevant activities until the Financial Conflict of Interest is resolved or other action deemed appropriate by the COIO is implemented. Violation of any part of these policies may also constitute cause for disciplinary or other administrative action pursuant to university policy.

Definitions

Family means any member of the investigator's immediate family, specifically, any dependent children and spouse.

Financial Interest means anything of monetary value received or held by an investigator or an investigator's family, whether or not the value is readily ascertainable, including, but not limited to: salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works); any equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights), upon receipt of royalties or other income related to such intellectual property rights and interests.

Financial Interest does NOT include:

- a) salary, royalties, or other remuneration from UNI;
- b) income from the authorship of academic or scholarly works;
- c) income from seminars, lectures, or teaching engagements sponsored by or from advisory committees or review panels for U.S. Federal, state or local governmental agencies; U.S. universities of higher education; U.S. research institutes affiliated with universities of higher education, academic teaching hospitals, and medical centers; or

- d) equity interests or income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions made in these vehicles.

Financial Interest also includes any reimbursed or sponsored travel undertaken by the investigator and related to his/her university responsibilities. This includes travel that is paid on behalf of the investigator rather than reimbursed, even if the exact monetary value is not readily available. It excludes travel reimbursed or sponsored by U.S. Federal, state or local governmental agencies, U.S. universities of higher education, research institutes affiliated with universities of higher education, academic teaching hospitals, and medical centers.

Significant Financial Interest means a Financial Interest that reasonably appears to be related to the investigator's university responsibilities, and:

- a) if with a publicly traded entity, the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure, and the value of any equity interest during the 12 month period preceding or as of the date of disclosure, exceeds \$5,000; or
- b) if with a non-publicly traded entity, the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure exceeds \$5,000; or
- c) if with a non-publicly-traded company, is an equity interest of any value during the 12 month period preceding or as of the date of disclosure; or
- d) is income related to intellectual property rights and interests not reimbursed through the University.

Financial Conflict of Interest means a Significant Financial Interest that the university reasonably determines could directly and significantly affect the design, conduct or reporting of university research.

University responsibilities refers to the investigator's responsibilities associated with his or her university appointment or position, such as research, teaching, clinical activities, administration, and university, internal and external professional committee service.

Investigator in this policy means ***key personnel*** - any individual who is responsible for the design, conduct, or reporting of PHS sponsored research, or proposals for such funding. Thus, this definition is not limited to those titled or budgeted as principal investigator or co-investigator on a particular proposal, and may include postdoctoral associates, senior scientists, or graduate students. The definition may also include collaborators or consultants as appropriate.

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 Administration for Children and Families, Administration on Aging, Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Federal Occupational Health, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, and Substance Abuse and Mental Health Services Administration.

Research, for purposes of this policy, means a systematic investigation, study, or experiment designed to 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).

Methods and Timing of Financial Disclosures

Initial. All UNI investigators and other key personnel involved in PHS-funded projects must disclose their Significant Financial Interests to the university, using the [UNI COI form](#) prior to the submission of an application for PHS funding (42 CFR 50.604c(2)e(1)), or within 30 days of their initial appointment or employment on the PHS-funded project (for those who become involved at award and/or during the course of the project). Consultants and collaborators who are involved in the project as independent contractors will be required to

disclose directly to UNI as well, if they are not already covered under an employer policy that is consistent with the PHS regulations.

Annual. In addition, all PHS-funded investigators and other key personnel must disclose their Significant Financial Interests to the University, through the COIO on an annual basis, using the [UNI COI form](#) due no later than **January 1st of each year**.

Ad Hoc. All PHS-funded investigators and other key personnel must submit to the COIO an ad hoc disclosure of any Significant Financial Interest they acquire during the course of the year within 30 days of discovering or acquiring the Significant Financial Interest. This includes disclosing reimbursed or sponsored travel related to their university responsibilities, as defined above as one type of Financial Interest. Such disclosures must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and, if known, the monetary value. The COIO will determine if additional information is needed (e.g., the monetary value if not already disclosed) to determine whether the travel constitutes a Financial Conflict of Interest with the Investigator's research.

Sub-recipient Requirements

Sub-recipients of PHS funds must provide certification prior to the awarding of any funds that they either have a conflict of interest policy in place that is consistent with 42 CFR 50, or otherwise certify that their employees, collaborators, and sub-recipients will comply with this policy. The certification regarding which policy applies, and the methods and time frames for providing FCOIs to UNI, will be specified in the sub-recipient agreement.

Sub-recipients who have their **own** policy must use their own process for identifying and resolving any investigator Financial Conflicts of Interest (conflicts meeting the definition for an SFI and related to PHS-funded research) and must make reports to that effect to the UNI COIO in sufficient time for UNI to review the information and meet its obligations to report the required information to PHS (prior to award, annually, and otherwise within **30 days** of an FCOI being acquired).

If sub-recipients certify they do **not** have their own policy and thus will be relying on UNI's policy, the sub-recipient investigators must submit an initial UNI disclosure form regarding their Significant Financial Interests to their university's designated person, and that person must forward those forms to the UNI COIO before the award document will be signed by UNI (ensuring that this occurs prior to any expenditure of funds on the project, as required by PHS). They must also certify that their investigators will submit such forms on an ad hoc basis within **30 days** of acquiring a Significant Financial Interest and as well as annually by January 1st.

The disclosure form to be used will depend on whether the sub-recipient is choosing to follow the UNI policy or their own in satisfying the PHS regulatory requirements. Among the possible sanctions for sub-recipients who do not comply with this policy may include an immediate termination in the flow of funds and repayment of funds already expended on the project.

Disclosure Review and Reporting

If the disclosure form reveals a Significant Financial Interest, it will be reviewed promptly by the COIO or designee for a determination of whether it constitutes a Financial Conflict of Interest. If a Financial Conflict of Interest exists, the COIO will work with the investigator to eliminate, reduce, or manage the conflict, as appropriate. A Conflict of Interest does not have to be resolved prior to the submission or awarding of a grant or contract, but the conflict **must** be resolved before any expenditure of funds from the sponsor.

A Financial Conflict of Interest will exist when the COIO or designee determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of PHS-supported research. If the COIO determines that there is a Financial Conflict of Interest that can be managed, he or she must require and approve a written management plan before any related research goes forward.

To address complex situations, oversight committees may be established by the COIO to periodically review the ongoing activity, to monitor the conduct of the activity (including use of students and postdoctoral appointees), to ensure open and timely dissemination of the research results, and to otherwise oversee compliance with the management plan.

Should any reported conflict or non-compliance require reporting to PHS, the COIO will report in accordance with PHS regulations (prior to the expenditure of funds and otherwise within **60 days** of the disclosure). If the funding for the research is made available from a prime PHS-awardee, such reporting shall be made available to the prime awardee such that they may fulfill their reporting obligations to the PHS.

Investigator Noncompliance

In the event of an investigator's failure to comply with this policy, the COIO may suspend all relevant activities or take other disciplinary action until the matter is resolved or other action deemed appropriate by the COIO is implemented.

A COIO's decision to impose sanctions on an investigator because of failure to comply with this policy, or failure to comply with the decision of the COIO, will be described in a written explanation of the decision to the investigator, and, where applicable, the IRB, and will notify the individual of the right to appeal the decision through the designated administrative channels appropriate to the status of the individual (e.g., faculty, staff, student).

Retrospective Review

If the COIO determines that a Financial Conflict of Interest was not identified or managed in a timely manner, including but not limited to an investigator's failure to disclose a Significant Financial Interest that is determined to be a Financial Conflict of Interest, or failure by an investigator to materially comply with a management plan for a Financial Conflict of Interest, a committee appointed by the COIO will complete a retrospective review of the investigator's activities and the research project to determine whether the research conducted during the period of non-compliance was biased in the design, conduct or reporting of the research.

Documentation of the retrospective review shall include the project number, project title, PI, name of investigator with the Financial Conflict of Interest, name of the entity with which the investigator has the Financial Conflict of Interest, reason(s) for the retrospective review, detailed methodology used for the retrospective review, and findings and conclusions of the review.

The COIO will update any previously submitted report to the PHS or the prime PHS-awardee relating to the research, specifying the actions that will be taken to manage the Financial Conflict of Interest going forward. If bias is found, the report will include a mitigation report in accordance with the PHS 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.

Training and Notification

This policy will be posted online at and all investigators involved in an application for PHS funding will be notified of the policy, procedures, and relevant regulations through the Office of Research and Sponsored Programs application review and approval process. In addition, each investigator will be required to complete training on this policy prior to engaging in research funded by PHS, and at least every four years thereafter. Information on how to obtain this training can be found on the [RSP Conflicts of Interest webpage](#). Investigators must also complete additional training within a reasonable period of time as determined by the COIO in the event that this policy is substantively amended in a manner that affects the requirements of investigators, or if it is determined that the investigator has not complied with this policy or with a management plan related to their activities.

Record Retention

The COIO will retain all disclosure forms, conflict management plans, and related documents for a period of three years from the date the final expenditure report is submitted to the PHS or to the prime PHS awardee, or three years following the resolution of any civil, government, or university action involving those records.

Public Accessibility

Prior to the expenditure of funds, the university will publish on a publicly-accessible website or respond to any requestor within five business days of the request, information concerning any Significant Financial Interest that meets the following criteria: a) the Significant Financial Interest was disclosed and is still held by the investigator; b) a determination has been made that the Significant Financial Interest is related to the PHS-funded research; and c) a determination has been made that the Significant Financial Interest is a Financial Conflict of Interest. This information will be posted within 60 days of disclosure and updated at least annually, and will remain available on the web for at least three years from the most recent update. Sub-recipients will be required to post such information for their own investigators, regardless of which policy (theirs or UNI's) is applicable.

Related Policies and References

If the requirements in this policy are found to conflict with any federal or state law or regulation, UNI or Board of Regents policy, or policy maintained by the Public Health Service, the policy or regulation with the stricter requirements will prevail.