

II-3.10-UMCES Policy on Conflict of Interest and Conflict of Commitment Addendum for Public Health Service (PHS) Financial Conflict of Interest (FCOI)

Approved by the Administrative Council as Interim Policy 9/4/2013

Approved by the President November 15, 2013

Purpose: The purpose of this addendum is to incorporate the changes in the Health and Human Services, Public Health Service (PHS) Policy on Financial Conflict of Interest (FCOI) in the UMCES policy. The requirements outlined in this Addendum apply to individuals supported by grants or cooperative agreement funded by the PHS (typically National Institutes of Health) only.

Summary of NIH Requirements: The basic requirement is parallel to the existing UMCES conflict of interest policy, however, PHS is very specific regarding the types of activities which must be reported and the value of the financial interest. Reporting specific to PHS (in addition to what is required by the UMCES policy) is required at the time of proposal submission and at least annually if funded. Training on the PHS FCOI regulations is required.

Definitions:

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 the Institution;
- 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. institutions of higher education; research institutes affiliated with institutions 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.

For Investigators, *Financial Interest* also includes any reimbursed or sponsored travel undertaken by the Investigator and related to his/her institutional responsibilities. This **includes** travel that is paid on behalf of the Investigator as well as travel that is 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. institutions of higher education, research institutes affiliated with institutions 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 Institutional 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 exceeding \$5,000 related to intellectual property rights and interests not reimbursed through the Institution, or
 - e) is reimbursed or sponsored travel related to their institutional responsibilities.

Financial Conflict of Interest means a Significant Financial Interest (or, where the Institutional official requires disclosure of other Financial Interests, a Financial Interest) that the Institution reasonably determines could directly and significantly affect the design, conduct or reporting of PHS-sponsored research.

Investigator means any individual who is responsible for the design, conduct, or reporting of PHS sponsored research, or proposals for such funding. 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.

Research 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).

Disclosure of Financial Interests: Every Investigator submitting a proposal to NIH or who will receive funding through NIH has an obligation to become familiar with, and abide by, the provisions of this policy. If a situation raising questions of conflict of interest arises, an Investigator should discuss the situation with the Institutional official.

a) Annual Disclosures

All Investigators must disclose their Significant Financial Interests that are related to the investigator's institutional responsibilities to the Institution, through the Institutional Official, on an annual basis. All forms should be submitted to the Institutional official or designee by March 1 for the previous calendar year.

b) Ad hoc Disclosures

In addition to annual disclosure, certain situations require ad hoc disclosure. All Investigators must disclose their Significant Financial Interests to the Institution, through the Institutional Official, within 30 days of their initial appointment or employment.

Prior to entering into PHS-sponsored projects or applications for PHS-sponsored projects, where the Investigator has a Significant Financial Interest, the Investigator must affirm the currency of the annual disclosure or submit to the Institutional Official an ad hoc updated disclosure of his or her Significant Financial Interests with the outside entity. The

Institution will not submit a research proposal unless the Investigator(s) have submitted such ad hoc disclosures.

In addition, all Investigators must submit to the Institutional official an ad hoc disclosure of any Significant Financial Interest they acquire or discover during the course of the year within thirty (30) days of discovering or acquiring the Significant Financial Interest.

c) Travel

Investigators must also disclose reimbursed or sponsored travel related to their institutional responsibilities, as defined above in the definition of Financial Interest and Significant 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 Institutional Official 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.

Review of the Institutional Official

If the disclosure form reveals a Significant Financial Interest, it will be reviewed promptly by the Institutional Official or designee for a determination of whether it constitutes a Financial Conflict of Interest. A Financial Conflict of Interest will exist when the Institutional Official or designee determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of PHS-sponsored research. In such cases, the Investigator will complete the UMCES COI form which will be submitted to and reviewed by the COI Committee. The affected Investigator must formally agree to the proposed management strategies and sign the written management plan before any related PHS-sponsored research goes forward.

The Institutional Official will periodically review the ongoing activity, 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.

Reporting to PHS

The institutional official will report financial conflicts of interest or non-compliance to PHS in accordance with PHS regulations. If the funding for the Research is made available from a prime PHS-awardee, such reports shall be made to the prime awardee prior to the expenditure of any funds and within 60 days of any subsequently identified financial conflict of interest such that the prime awardee may fulfill their reporting obligations to the PHS.

Investigator Non-Compliance

In the event of an Investigator's failure to comply with this Policy, the Institutional official may suspend all relevant activities or take other disciplinary action until the matter is resolved or other action deemed appropriate by the Institutional official is implemented. A Institutional Official'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 Institutional official, will be described in a written explanation of the decision to

the investigator, COI Committee, and, where applicable, the IRB, and will notify the individual of the right to appeal the decision. The institution will promptly notify the PHS Awarding Component of the action taken or to be taken. If the funding for the research is made available from a prime PHS awardee, such notification shall be made promptly to the prime awardee for reporting to PHS.

In addition, if the Institutional Official 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, the COI committee will complete a retrospective review of the Investigator's activities and the PHS-sponsored 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 Institutional official 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. The mitigation report will identify elements documented in the retrospective review, 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

Each Investigator must complete training on this Policy, the investigator's responsibilities regarding disclosure and the PHS regulations prior to engaging in research funded by PHS, and at least every four years thereafter. To meet the requirement for training, UMCES will maintain a membership in the Collaborative Institutional Training Initiative (CITI) web-based training programs. At the time of registration in the course, new users should associate themselves with the University of Maryland Center for Environmental Science. The course can be found at: <http://www.citiprogram.org>.

Public Accessibility

Prior to the expenditure of funds, the Institution will 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 senior and key personnel;
- 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.

The information to be made available shall be consistent with the requirements of the PHS regulation.