

The College of William and Mary
FINANCIAL CONFLICT OF INTEREST PROCEDURE

The following information is attributable to 42 CFR 50*:

http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf

Each Institution that applies for PHS grants or cooperative agreements for research must maintain and enforce a written Financial Conflict of Interest procedure. This updated regulation promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research under PHS funding will be free from bias from Investigator Financial Conflict of Interest.

Per the Code of Federal Regulations (CFR), The College of William and Mary has a responsibility to inform each Investigator of the policy, the Investigator's reporting responsibilities, and the regulations. This procedure governing the financial conflict of interest applies to all PHS-sponsored Investigators of the College of William and Mary.

The Institutional Official is responsible for ensuring implementation of this procedure and may suspend all relevant activities until the financial conflict of interest is resolved or other action deemed appropriate by the Institutional Official is implemented. Violation of any part of the procedure may constitute cause for disciplinary action or other administrative action pursuant to College policy.

DEFINITIONS:

Disclosure Statement: a statement of financial interests of the Investigator (spouse and dependent children).

Financial Conflict of Interest: A significant financial interest that the College reasonably determines could directly and significantly affect the design, conduct, or reporting of PHS funded research.

Financial Conflict of Interest Working Group (FCOI Working Group): the College's working group that advises the Institutional Official, Vice Provost Manos, on conflict of interest matters and management plans. The working group consists of the Institutional Official along with four faculty members appointed by the Provost along with an Ex-Officio member.

Institutional Official: The Vice Provost for Research has been appointed by the Provost as the College's Institutional Official for PHS Federal Conflict of Interest matters.

Investigator: 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 research funded by the PHS, or proposed for such funding, which may include collaborators or consultants.

Public Health Service or PHS: 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. Agencies under the operating division of the Public Health Service include, but are not limited to, the following:

[Agency for Healthcare Research and Quality](#) (AHRQ)

[Agency for Toxic Substances and Disease Registry](#) (ATSDR)

[Centers for Disease Control and Prevention](#)(CDC)

[Food and Drug Administration](#) (FDA)

[Health Resources and Services Administration](#) (HRSA)

[Indian Health Service](#)(IHS)

[National Institutes of Health](#) (NIH)

[Substance Abuse and Mental Health Services Administration](#) (SAMHSA)

Significant Financial Interest: Significant Financial interest means anything of monetary value, including but not limited to salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights, and royalties from such rights).

“A Significant Financial Interest may consist 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:

- 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 **\$5000.00**. 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;
- 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 **\$5000.00**, 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

- Intellectual Property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.”

(Dean, Diane; Hancock, Kathy, 2012) NIH Division of Grants Compliance and Oversight, Office of Policy for Extramural Research Administration, OER, NIH, DHHS, NIH Regional Seminar, Indianapolis, IN, April 2012.

Investigators must disclose any reimbursed or sponsored travel (i.e., *travel 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, A travel disclosure will include the purpose of the trip, the identity of the sponsor, the destination, the duration and the monetary value. The Institutional Official, along with the FCOI working group, will determine whether the travel constitutes a Financial Conflict of Interest with the Investigator’s research.

Significant Financial Interest does not include the following:

- a) Salary, royalties or other remuneration from The College of William and Mary
- b) Intellectual Property Rights assigned to The College and agreements to share in royalties related to such rights
- c) 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
- d) 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, academic teaching hospitals, and medical centers
- e) An equity interest that when aggregated for the Investigator and the Investigator’s spouse and dependent children, meets **both** of the following tests: 1) does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of air market value, **and** 2) does not represent more than a five percent ownership interest in any single entity
- f) Salary, royalties, or other payments that when aggregated for the Investigator and the Investigator’s spouse and dependent children over the next twelve months, are not expected to exceed \$10,000 (Dean, Diane; Hancock, Kathy, 2012)

STEPS:

The Office of Sponsored Programs liaison on behalf of the Institutional Official is tasked to solicit financial disclosure statements from each Investigator planning to participate in PHS-funded research.

Two weeks prior to the due date of application to a PHS funded program, The College requires two action items from each Investigator who plans to participate in PHS-funded research:

- 1) The Investigator must submit to the Institutional Official, via the Office of Sponsored Programs FCOI liaison, a disclosure listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children):
 - a) That would reasonably appear to be affected by the research for which PHS funding is sought, and
 - b) In entities whose financial interests would reasonably appear to be affected by the research.

- 2) In addition to a disclosure statement, Investigators must provide a certificate of completion of CITI online training for Conflict of Interest to the Office of Sponsored Programs liaison prior to engaging in research related to PHS funding, at least every four years, and immediately when
 - a) The College revises its FCOI procedure
 - b) An Investigator is new to The College
 - c) The College finds an Investigator is not in compliance with The College procedure or management plan.

NOTE: FCOI applies to sub-awardees as well as prime recipients. If the College issues a sub-award, the sub-awardee must certify the entity **a)** will follow W&M Policy, or **b)** has their own institutional FCOI policy to ensure compliance with 45 CFR 50.

All financial disclosures must be updated during the period of the award, either on an annual basis by January 15, or within 30 days as new reportable Significant Financial Interests are acquired.

After a preliminary evaluation, any identified potential FCOI will be forwarded to the FCOI working group for review and development of a management plan to be implemented in regard to the conflict. The management plan will identify actions as necessary to ensure a conflict of interest is managed, reduced or eliminated.

The College will maintain records of all financial disclosures and all actions taken by the College in regard to each conflict of interest for at least three years from the date of submission of the final expenditure report, or where applicable, from other dates specified in 45 CFR 74.53 (b) for different situations.

The College has established enforcement mechanisms and provides for sanctions where appropriate (see section on "Management of Conflicting Interests"): PHS funding will not be drawn down without a Certificate of completion of CITI Training for Investigators and a completed and institutionally reviewed Financial Disclosure form from Investigators.

Prior to the expenditure of any funds under the award, the College will report to the PHS Awarding Agency the existence of a conflicting interest (but not the nature of the interest or other details) found by the College and assure that the interest has been managed, reduced or eliminated in accordance with 42 CFR 50 Subpart G; and, for any interest that the College identifies as conflicting subsequent to the College's initial report under the award, the report will be made and the conflicting interest managed, reduced, or eliminated; at least on an interim basis, within sixty days of that identification.

The College will make information available upon request to HHS regarding any Investigator disclosure of financial interest and the College's review of, and response to such disclosure, whether or not the disclosure resulted in the College's determination of a FCOI.

The College will certify by means of the Assurance Statements in Grants/Contracts, that the College of William and Mary has a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which funding is sought from PHS agencies.

Management of Conflicting Interests:

A "conflict of interest" exists when the Institutional Official with concurrence of the FCOI working group, reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the PHS funded research.

Possible conditions or restrictions that may be imposed to manage conflicts of interest include, but are not limited to:

Public disclosure of significant financial interest

Monitoring of research by independent reviewers

Modification of the research plan

Disqualification from participation in all or a portion of the research funded by the PHS agency

Divestiture of significant financial interest

Severance of relationships that create actual or potential conflicts

An investigator who has been deemed to have a significant FCOI will be advised by the FCOI working group as to the means determined by the group to manage, reduce, or eliminate the conflict. The Investigator is to abide by the management plan and provide timely reports to the FCOI working group.

If a management plan is required, the plan will cover the following: it will enumerate the role and duties of the conflicted Investigator in the research project, state the conditions of the management plan, state how the management plan is designed to safeguard objectivity in research, confirm the Investigator's agreement to the plan, and advise how the plan will be monitored to ensure compliance.

The investigator will update the FCOI working group on management plan every 6 months until completion of the PHS funded activity.

If the failure of an investigator to comply with the FCOI management plan has biased the design, conduct, or reporting of the PHS-funded research, the College must promptly notify PHS of the corrective action taken or to be taken. The PHS agency will consider the situation and, as necessary,

take appropriate action or refer the matter to the College for further action which may include directions to the College on how to maintain appropriate objectivity in the funded project.

The HHS may at any time inquire into the College's procedures and actions regarding conflicting financial interests in PHS-funded research, including a requirement for submission of, or review on site, all records pertinent to compliance with the 45 CFR 50.606. The College is **required** to submit or permit on site review of records pertinent to compliance with the regulation.

To the extent permitted by law, HHS will maintain the confidentiality of all records of financial interests. On the basis of its review of records and/or other information that may be available, the PHS Agency may decide that a particular conflict of interest will bias the objectivity of the PHS funded research to such an extent that further corrective action is needed or that the College has not managed, reduced, or eliminated the conflict of interest in accordance with 45 CFR 50.606. The PHS agency may determine that suspension of funding under 45 CFR 74.62 is necessary until the matter is resolved.

If the College identifies a SFI that was not disclosed or reviewed in a timely manner, the Institutional Official shall within sixty days review the SFI, determine if an FCOI exists, and implement an interim management plan if necessary.

In cases of non-compliance, the College will complete a retrospective review within 120 days of the determination of non-compliance and submit a mitigation report to HHS if bias is found.

*(Government Printing Office, 2012)