

ST. MARY'S COLLEGE OF MARYLAND POLICY AND PROCEDURES
FINANCIAL CONFLICT OF INTEREST
Effective Date: October 15, 2016

I. Purpose

St. Mary's College of Maryland ("St. Mary's") adopts this Policy and Procedures (the "Policy") as required to implement and to comply with U.S. Public Health Service ("PHS") regulations on Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 C.F.R. Part 50, Subpart F), regulations on Responsible Prospective Contractors (45 C.F.R. Part 94), and provisions of the National Science Foundation ("NSF") (60 FR 35820). The purpose of this Policy is to comply with NSF provisions and PHS regulatory requirements and their goal of promoting objectivity in federally funded research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under NSF and PHS grants, cooperative agreements and contracts will be free from bias resulting from Investigators' Financial Conflicts of Interest.

II. Applicability

This Policy applies to any application for or receipt of federally funded research ("Funded Research") from PHS, including the National Institutes of Health ("NIH"), or NSF, whether such funding is by means of a grant, cooperative agreement or contract. This Policy applies to any investigator of Funded Research. This Policy, however, shall only apply to Funded Research with an issue date of the Notice of Award on or after the Effective Date of this Policy. Notwithstanding anything contained herein, this Policy does not apply to any Small Business Innovation Research Program ("SBIR") or Small Business Technology Transfer ("STTR") Program Phase I applications.

III. Definitions

- A. Effective Date:** This Policy was presented to the St. Mary's College of Maryland Board of Trustees for approval at its meeting on October 15th, 2016.
- B. Family:** Any member of the Investigator's immediate family, specifically, any dependent children and spouse or partner.
- C. Funded Research:** Any research funded by or proposed to be funded by PHS, including the National Institutes of Health ("NIH"), and NSF by means of a grant, cooperative agreement, or contract.
- D. Financial Conflict of Interest ("FCOI"):** A Significant Financial Interest that could directly or significantly affect the design, conduct, or reporting of Funded Research.
- E. Financial Interest:** Anything of monetary value, whether or not the value is readily attainable.
- F. Institution:** St. Mary's College, generally referred to as St. Mary's.

- G. Institutional Official:** The individual within the Institution who has been designated to solicit and review disclosures from Investigators (and their families) of significant financial interests related to the Investigator's institutional responsibilities. For purposes of this Policy, the Institutional Official will be the Provost, or a designated representative.
- H. Institutional Responsibilities:** An Investigator's professional responsibilities on behalf of St. Mary's, and as defined by its Policy, to include (but may not be limited to): research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as institutional review boards.
- I. Investigator:** The project director, the principal investigator, co-principal investigators, co-project directors and any other person, regardless of title or position at St. Mary's, who is responsible for the design, conduct, or reporting of Funded Research or proposed for such funding, including but not limited to collaborators or consultants.
- J. Public Health Service (PHS):** 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).
- K. Research:** A systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to science and 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 NSF or a PHS Awarding Component through a contract, whether authorized under the PHS Act or other statutory authority.
- L. Significant Financial Interest:** A significant financial interest includes one or more of the following financial interests of the Investigator or an Investigator's family member, that reasonably appears to be related to the Investigator's institutional responsibilities, and that which was received in the prior (12) twelve months:
- 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);
- c. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests; or
 - d. 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.
2. The term “Significant Financial Interest” does **not** include the following:
- a. Salary, royalties, or other remuneration paid by St. Mary’s to the Investigator if the Investigator is currently employed or otherwise appointed by St. Mary’s, including intellectual property rights assigned to St. Mary’s and agreements to share in royalties related to such rights;
 - b. 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;
 - c. An asset in a blind trust, but only if (i) the asset is not known to the Investigator (e.g. it was purchased by the trust with proceeds from assets originally placed in the trust), and (ii) the trust is managed by an independent fiduciary;
 - d. 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;
 - e. Income from service on advisory committees or review panels of: 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

IV. Disclosures

- A. All investigators are required to disclose their financial conflicts of interest to St. Mary’s on an **annual basis**, as described below, using the St. Mary’s Financial Conflict of Interest Disclosure Form (click [here](#) to obtain form). There may be instances where **ad hoc** disclosures are required (see section E below).
- B. As required by federal regulations, all significant financial interests must be disclosed *prior* to the time a proposal is submitted to the relevant federal government agency (*i.e.*, NIH, NSF). All financial disclosures must be updated by investigators during the period

of the award, either on an annual basis or as new reportable significant financial interests are obtained.

C. Required Disclosures Include:

1. Any significant financial interest of the investigator that would reasonably appear to be affected by the research or educational activities funded, or proposed for funding, by an external sponsor; or
2. Any significant financial interest of the investigator in an entity whose financial interest would reasonably appear to be affected by the research or educational activities funded, or proposed for funding, by an external sponsor.

D. Procedures for Reporting Disclosures:

1. Each investigator who has a significant financial interest requiring disclosure shall complete a Financial Interest Disclosure Form.
2. The completed disclosure form must be submitted with the NSF or PHS grant proposal and the St. Mary's College proposal approval form (PAF) to the research & sponsored programs office.

E. Ad Hoc Disclosures – The following circumstances require ad hoc disclosures:

1. New Hires

All Investigators involved with PHS- or NSF-funded research, must disclose their Significant Financial Interests to the St. Mary's Institutional Official, within 30 days of being appointed or employed.

2. New Grant Proposal or Sub-award

Before submitting grant proposals for PHS or NSF funding or entering into sub-award agreements for PHS or NSF funded research, each Investigator must submit to the Institutional Official an *ad hoc* updated disclosure of his or her Significant Financial Interests.

3. New Significant Financial Interest

Investigators must update their most recently filed disclosure form within thirty (30) days of *acquiring* (e.g., through purchase, marriage or inheritance) a Significant Financial Interest; as well as after or discovering a Significant Financial Interest that was improperly omitted from a prior disclosure form.

4. Travel

Investigators must update their most recently filed disclosure form within thirty (30) days of the event for which Travel Payments were or are expected to be sponsored or reimbursed. When describing applicable reimbursed or sponsored travel, the Investigator must include at a minimum, a description of: the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

V. Institutional Review of Disclosures

- A. The provost, or her/his designated representative, shall perform an initial review of all financial disclosures to determine whether an actual or potential conflict of interest

- exists. An actual or potential conflict of interest exists when the review reasonably determines that a significant financial interest could directly affect the design, conduct, or reporting of the proposed sponsored project. The provost 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.
- B. Prior to consideration by the provost, the investigator in collaboration with the research and sponsored programs office shall develop and present a Conflict of Interest Resolution Plan that details proposed steps that will be taken to manage, reduce, or eliminate any actual or potential conflict of interest presented by a significant financial interest in accordance with this Policy and the PHS Regulations.
 - C. At a minimum the resolution plan shall address such issues as:
 - 1. Public disclosure of significant financial interests (e.g., when presenting or publishing the Research);
 - 2. Review of research protocol by independent reviewers; and
 - 3. Monitoring of research by independent reviewers.
 - D. The provost shall approve the resolution plan after review and consideration of additional conditions or restrictions that may include any of the following:
 - 1. Modification of the research plan;
 - 2. Disqualification from participation in all or a portion of the research funded;
 - 3. Divestiture of Significant Financial Interests; or
 - 4. Severance of relationships that create actual or potential conflicts of interest.
 - E. An approved resolution plan shall be incorporated into a Memorandum of Understanding (MOU) between St. Mary's College of Maryland and the investigator that details the conditions or restrictions imposed upon the investigator in the conduct of the project or in the relationship with the business or entity. The MOU shall be signed by the investigator, department chair (or equivalent supervisor) and provost.
 - F. The provost, or a designated representative will certify that actual or potential conflicts of interests will be satisfactorily managed, reduced, or eliminated in accordance with these guidelines prior to expending any funds from the applicable federal award or that such conflict will be disclosed to the sponsored agency for action.

VI. External Reporting of Financial Conflicts of Interests

- A. The provost, or a designated representative, is responsible for ensuring that all significant Financial Conflict of Interest reports and other information are submitted to the PHS Unit or NSF, as required by the PHS and NSF Regulations.
- B. Such FCOI reports must be filed:

1. Prior to St. Mary's College of Maryland expenditure of funds under a NSF/PHS Funded Research project;
2. Within sixty (60) days, with respect to any Significant Financial Interest that is identified as a Financial Conflict of Interest subsequent to the initial FCOI report during an ongoing NSF/PHS Funded Research project (e.g. upon the participation of an Investigator who is new to the PHS Funded Research project); and
3. Annually with respect to any Financial Conflict of Interest previously reported with regard to an ongoing NSF/PHS Funded Research project.

VII. Required Disclosures by Collaborators

All collaborators from other institutions paid as sub-recipients of federal PHS or NSF funds must provide certification that their institutions are in compliance with federal policies regarding Significant Financial Interest disclosure and that their portion of the project is in compliance with their institutional policies.

VIII. Required Training for Investigators

- A. Each Investigator who is planning to participate in, or is participating in, NSF and PHS Funded Research must complete training related to financial conflicts of interest (regardless of whether or not a Financial Conflict of Interest exists).
- B. Such training must be completed prior to engaging in NSF and PHS Funded Research and:
 1. At least every four (4) years if participating in NSF and PHS Funded Research;
 2. If the Investigator is new to St. Mary's College of Maryland, within sixty (60) days of the commencement of employment but not later than the beginning of NSF/PHS Funded Research by the Investigator;
 3. If Institutional Financial Conflict of Interest policies change in a manner that affects Investigator requirements; or
 4. When so directed as a result of an Investigator's non-compliance with this Policy or any Management Plan.
- C. Training, or access to training, shall be facilitated by St. Mary's College and shall include information regarding this Policy, PHS regulations, and the Investigator's responsibilities under this Policy and the PHS Regulations to disclose Significant Financial Interests of the Investigator (and of the Investigator's spouse and dependent children). As part of this training investigators need to complete training, such as the on-line training certificate program Collaborative Institutional Training Initiative (CITI) module on FCOI, or equivalent training.

IX. Institutional Retention of Records of Financial Disclosures

Records of the investigator's financial disclosures, training completion reports, and of actions taken to manage actual or potential conflicts of interest shall be retained by the office of research & sponsored programs until three (3) years after the termination or completion of the award to which they relate, or the resolution of any government action involving those records, whichever comes later.

X. Policy Violations

Whenever an investigator has violated this policy or the terms of the MOU, the provost shall recommend actions consistent with PHS regulation and St. Mary's College of Maryland research misconduct policy.

XI. Confidentiality

To the extent permitted by law, including but not limited to the Maryland Public Information Act, Maryland Code Annotated, State Government, Title 10, subtitle 6, as amended from time to time, all disclosure forms and related information will be kept confidential.

XIII. Regulatory Authority

This policy implements the requirements 42 CFR 50, subpart F – Promoting Objectivity in Research for Which PHS Funding is Sought; and 45 CFR 94 – Responsible Prospective Contractors. Where there are substantive differences between this policy and the requirements set forth in 42 CFR 50 and 45 CFR 94, those requirements shall take precedence.

Possible Financial Conflict of Interest Disclosure Form

Project Title:

Funding Agency and Program:

Principal Investigator(s):

St. Mary's College of Maryland (St. Mary's) investigators who receive funding from NIH/NSF (or any other funding agency requiring FCOI disclosure) need to determine what constitutes a reportable FCOI and truthfully disclose any such conflict. To this end, investigators need to read the provided [St. Mary's FCOI Policy](#) and complete the [NIH FCOI tutorial](#) (<http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>) **or** the [CITI FCOI tutorial](#) available to all St. Mary's employees (contact Adam Malisch, Research Administrator, for details: ajmalisch@smcm.edu). If, after taking the FCOI tutorial(s), you have questions about a potential FCOI, please contact Adam Malisch. After taking the tutorial, please indicate if you have a reportable FCOI as defined in either the NIH or CITI tutorial:

Yes: _____ No: _____

Once you have completed this form and an FCOI tutorial, please send the completed Possible Financial Conflict of Interest Disclosure Form to Adam Malisch (ajmalisch@smcm.edu) **and** Director of Research and Sponsored Programs Sabine Dillingham (sldillingham@smcm.edu) for review. If you completed the NIH FCOI tutorial, please also send the NIH Completion Certificate. If you completed the CITI FCOI tutorial, there is no need to send a completion certificate; we can confirm completion directly through CITI.

By signing this form, you confirm that you have a) read the St. Mary's FCOI Policy, b) taken an FCOI tutorial, and c) truthfully disclosed any FCOI.

_____ Date

PI Name

_____ PI Signature