



Objectivity in Research and Investigator Financial Disclosure

Scope

This policy applies to Mount Mary University employees who serve as investigators and who apply for funding through Mount Mary University from the Public Health Service (PHS), which includes: the National Institutes of Health (NIH) the Centers for Disease Control and Prevention (CDC), the Health Resources and Services Administration (HRSA), the Substance Abuse and Mental Health Services Administration (SAMHSA), the Food and Drug Administration (FDA) and the Agency for Healthcare Research and Quality (AHRQ) or the National Science Foundation (NSF) or other funding agencies with similar requirements. This policy may also be extended to any federal sponsor that has similar requirements with regard to investigator financial disclosure according to the scope of their regulation. The term "investigator" includes the principal investigator, co-principal investigator, and any other person at Mount Mary University who is responsible for the design, conduct, or reporting of research (this may include, for example, consultants and unpaid collaborators) funded by the above funding agencies or an agency with similar requirements as the Public Health Service agencies.

Policy

Overview

The University complies with Public Health Service, National Science Foundation and other federal agency disclosure regulations in order to maintain eligibility to submit applications for grant, cooperative agreement or contract funding to those agencies. Additionally, and most importantly, the regulations are designed to promote objectivity in research and to ensure that the design, conduct and reporting of research conducted at Mount Mary University and sponsored with federal funds are not biased by any perceived or real financial conflict of interest (FCOI) of an investigator. The NIH Office of Extramural Research Conflict of Interest Website contains more information at <http://grants.nih.gov/grants/policy/coi/> as well as a link to the current regulation "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought" ([42 C.F.R. Part 50, Subpart F](#)) which is the basis for this policy and provides a more extensive definition of what a Significant Financial Interest (SFI) includes. The National Science Foundation's Award and Administration Guide has more information for NSF investigators at <http://www.nsf.gov>. The body which will determine if a Significant Financial Interest (SFI) constitutes an FCOI and be responsible for management plans and review of FCOIs

will be the Office of the Vice President of Academic and Student Affairs in conjunction with the Development Office, specifically Corporate & Foundation Relations (CFR). As disclosed, FCOIs will be shared with the appropriate Dean and an annual report on all FCOIs will be provided to the University President.

Training

The Mount Mary University Research Compliance Committee (RCC), comprised of the Vice President of Academic and Student Affairs, Director of CFR, Dean, PI on the project, and the President or President's designee, shall be responsible for ensuring that each investigator is informed about this policy and made aware of the required training through the university's Collaborative Institutional Training Initiative (CITI). The IRB will ensure that each investigator has completed the CITI FCOI training prior to engaging in research related to any PHS or NSF-funded grant, cooperative agreement, or contract and at least every (4) years thereafter, and immediately when any of the following applies: (1) this Objectivity in Research Policy, the SFI Disclosure Form, or the University's procedures are materially revised in any manner that affects the requirements of the investigators; (2) an investigator is newly appointed to the University; or (3) the University RCC finds that an investigator is not in compliance with this policy or their FCOI management plan. "Immediately" shall mean the training is provided or made available and the investigators participate in the training expeditiously following the event that triggers the training requirement. Mount Mary University's IRB will be responsible for maintaining the CITI subscription, ensuring access to CITI training, and retaining records of training completed on behalf of the University.

Disclosure, Review and Monitoring

Disclosure

- a. The Development Office will be responsible for collecting the initial disclosure of SFIs via the customary Fundraising Initiation Form. This initial disclosure shall be provided prior to the submission of all proposals to federal agencies or other sponsors with similar requirements. This initial disclosure will apply to the investigator and any other personnel who would be responsible for the design, conduct, or reporting of research to be funded by the project, which may include, for example, consultants and unpaid collaborators. If an SFI is disclosed, the lead Principal Investigator (PI) on the proposed project will be responsible for completing for themselves and then obtaining an SFI Disclosure Form from all participating investigators.
- b. The SFI Disclosure Form shall ask the investigator to list all of the investigator's Significant Financial Interests (and those of the investigator's spouse or domestic partner and dependent children) that reasonably appear to be related to the investigators Institutional responsibilities (as defined below).
- c. "Significant Financial Interest" means (subject to the exclusions listed below):

(i) Publicly Traded-Entities - 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.

(ii) Privately Held Entities - 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 domestic partner and dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest).

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

(iv) Travel Reimbursements - 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 in the twelve months preceding the disclosure; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, and 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.

The term "Significant Financial Interest" does not include: salary, royalties, or other remuneration paid by Mount Mary to the investigator if the investigator is currently employed or otherwise appointed by Mount Mary, including intellectual property rights assigned to Mount Mary and agreements to share in royalties related to such rights; 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.

With respect to human subjects research, the term "Significant Financial Interest" shall include cases involving any type of remuneration and any type of equity ownership.

"Institutional Responsibilities" means an investigator's professional responsibilities on behalf of Mount Mary, including activities such as research, teaching, clinical or other professional practice, academic activities, scholarly events, institutional committee memberships, and service on panels such as Institutional Review Boards or Compliance Committee.

- d. The SFI Disclosure Form must conform to the requirements of the FCOI Regulations and shall include a link to the FCOI Regulations and the NIH Conflict of Interest Website. The form must include, at a minimum, the name of the entity, the nature of the financial interest (e.g., equity, consulting fee), the monetary value of the financial interest or its approximate value if the interest is one whose value cannot readily be determined, and any supporting documentation determined necessary to make a determination of whether a FCOI exists (such as a copy of the applicable consulting agreement or stock purchase agreement). For travel reimbursements, the disclosure must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and the approximate monetary value. In addition, the investigator must cooperate with all requests for additional information as needed. All such internal disclosures shall be treated as confidential personnel information with all necessary precautions to protect any sensitive proprietary company or sponsor information.
- e. The investigator shall update the SFI Disclosure Form during the period of the award at least annually. Should an SFI be determined to also be an FCOI, the reporting and requisite FCOI management plan shall be required to be completed prior to the expenditure of any funds under a PHS or NSF-funded grant, cooperative agreement, or contract. In addition, an updated SFI Disclosure Form must be submitted within thirty (30) days of discovering or acquiring (e.g. through purchase, marriage, or inheritance) a new SFI. An investigator who is new to participating in PHS or NSF-funded research projects, shall submit an SFI Disclosure Form at the time the investigator is identified as a possible participant in the PHS or NSF-funded project, such that training can be completed and timely reporting of a FCOI (if any) can be made to the respective funding agency.

The SFI Disclosure Form shall notify the investigator of this requirement to provide updated disclosures.

- f. All disclosures are required to be reviewed in a prompt manner such that within sixty (60) days of receipt of the SFI Disclosure Form an assessment of the SFI can be made, a management plan can be developed and the necessary reviews and approvals can be secured, such that any required report to the applicable PHS or NSF funded agency is submitted within sixty (60) days of the determination that a FCOI exists. The investigator's timely cooperation with the efforts of the SFI and FCOI reviewers is needed to ensure timely reporting. Upon a failure to make timely reporting to a PHS funding agency of an FCOI, the University is required under FCOI Regulations to conduct a retrospective review of the investigator's activities and the research project

Management of Financial Conflicts of Interest

- a. The Vice President of Academic and Student Affairs shall review SFI Disclosure Forms from each investigator to determine if the research is funded by NSF, PHS, or other funding agencies with similar requirements. All participants in the review committee shall sign a confidentiality agreement related to all information disclosed as part of the review committee's work.
- b. The review committee must review SFI Disclosure Forms to determine whether the SFI is a FCOI. The review committee will be overseen by the Vice President of Academic and Student Affairs Office. The review committee will be comprised of the respective Dean overseeing the PI on the project, a representative from the Development Department and the Vice President of Academic and Student Affairs (or the President's designee if the Vice President of Academic and Student Affairs is an investigator on the project). The review committee will determine whether the SFI could be affected by the PHS or NSF-funded research; or whether the SFI is an entity whose financial interest could be affected by the research. Also, an FCOI exists when the review committee reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS or NSF-funded research. In making the determination, the review committee can take into account financial interests in that same entity related to PHS, NSF or other federal funded research disclosed in an earlier disclosure by the investigator. The review committee may consult with appropriate governmental officials in making its deliberations.
- c. Following initial review by the RCC, all cases involving the disclosure of an SFI having a value greater than \$5,000 (measured by aggregating the various categories of interests reported) shall be submitted to the next meeting of the RCC for its consideration for expedited review or full review (depending upon the level of financial interests involved) in accordance with the Disclosure section of this policy. The RCC will decide upon one of the following dispositions of the case: approval, approval with conditions or restrictions, or prohibition. All

conflicts which are approved shall include a management plan which shall be implemented by an oversight committee designated by the RCC.

- d. The management plan shall be implemented by an oversight committee designated by the RCC and comprised of members designated by the Assistant Dean, Graduate School Curriculum, Policy, and Operations and the Chair of the RCC. Ordinarily, the oversight committee will be comprised of one member of the RCC, the Department Chair of the investigator, and the Dean of the College of the investigator. Management plans shall include reporting three times a year on the first day of September, December, and April or the next business day should that date fall on a weekend or University holiday.
- e. Mount Mary University has two policies that are related to conflict of interest. The [University's Conflict of Interest Policy](#) and this policy (Objectivity in Research). The standard for review under this policy is whether or not an actual or potential conflict between the personal interests of a University employee and the interests of the University or the public exists, or simply the reasonable appearance of such a conflict to the public (defined as a Conflict of Interest). The standard for review under the Conflict of Interest policy is whether an FCOI exists. In regard to these two policies, the Objectivity in Research policy shall govern the disclosure, management and reporting of FCOIs for the University in relation to PHS or NSF-funded research.
- f. For all management plans, examples of conditions or restrictions that might be imposed to manage conflicts of interest include, but are not limited to: (1) public disclosure of significant financial interests; (2) appointment of independent monitor(s) capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest; (3) modification of the research plan; (4) change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research; (5) reduction or elimination of the financial interest (e.g., sale of an equity interest); or (6) severance of relationships that create financial conflicts. Additional conditions and restrictions (including a lower threshold for review) shall apply to cases involving human subjects as provided for under Mount Mary's Protection of Human Subjects in Research Projects.
- g. For all management plans, the University is required to monitor investigator compliance with the management plan on an on-going basis until the completion of the PHS-funded research project

Reporting

- a. Prior to expending any funds under an PHS or NSF funded grant, cooperative agreement or contract, the University, through the Development Office, must report to the applicable funding agency the existence of any FCOI (as defined above) and assure that the University has implemented a management plan in accordance with the FCOI Regulations and this policy. If the University identifies a FCOI and eliminates it prior to the expenditure of any awarded funds, the

University is not required to submit a FCOI report to the respective agency. The requirements of the FCOI Regulations do not apply to PHS funded Phase I SBIR or STTR funding, instead those financial interests are subject to disclosure and management under the University's Conflict of Interest Policy ([link](#)) and any other applicable campus procedures.

- b. For any FCOI reported to the respective agency relating to an on-going PHS or NSF funded research project, an annual report that conforms to the requirements of the applicable FCOI Regulations shall be made to the applicable funding agency by the Principal Investigator for the duration of the research project in the time and manner specified by the applicable funding agency.
- c. For any SFI that the University identifies as being a FCOI subsequent to the University's initial FCOI report under the award, the report will be made to the applicable funding agency and a management plan shall be implemented, at least on an interim basis, within sixty (60) days of that identification. Such a disclosure could include a new SFI Disclosure Form received by the investigator during the on-going research project, or a SFI held by an investigator who is new to the research project. However, if that FCOI is one that was not made in a timely manner to the applicable funding agency, for whatever reason, the ORC is required under the FCOI Regulations to conduct a retrospective review of the investigator's activities and the research project. If bias is found during the course of this review, a mitigation report will also be required to be submitted. These reviews and reports must be made in accordance with the requirements of the FCOI Regulations.
- d. The elements of such a report shall include, at least, the items enumerated under the FCOI Regulations. The FCOI Regulations provide that, to the extent permitted by law, the Government will maintain the confidentiality of all records of financial interests.
- e. Prior to expending any funds under a PHS-funded grant, cooperative agreement or contract, the University, through the RCC, shall ensure public accessibility of information about the FCOI, via a written response to any requestor within five (5) business days of a request, of information concerning a SFI which was disclosed and is still held by the senior/key personnel on the project, which is determined to be related to the PHS-funded research, and which is determined to be a FCOI. The information shall consist of the information required to be provided under the FCOI Regulations

Subrecipient Requirements:

- a. All proposed subrecipients under a PHS-funded research of the University shall have a financial conflicts of interest policy that conforms to the requirements of the FCOI Regulations. With respect to these subgrantees, subcontractors, and collaborators, Contracts and Purchasing must either: 1) confirm that these entities are listed on the Federal Demonstration Project (FDP) FCOI Clearinghouse, or 2) require these entities to enter into a written agreement and

make a certification to the University at the time of award that its financial conflicts of interest policy complies with the FCOI Regulations. Provision of their FCOI policy certifying that the entity's policy conforms to the [PHS FCOI policy checklist](#) found on the Office of Extramural Research website will be sufficient evidence of compliance with this policy.

- b. The University, through the Development Office, will report to the funding agency any FCOI which are identified by any subgrantee, subcontractor, or collaborator to the University in the manner required under the FCOI Regulations, prior to the expenditure of funds and within sixty (60) days of any subsequently identified FCOI

Remedies

- a. If an investigator fails to comply with this policy or a management plan and the non-compliance appears to have biased the design, conduct or reporting of the PHS- funded research, the Director of CFR (through the RCC) shall promptly notify the agency of the corrective action taken or to be taken. In every respect, the RCC shall ensure compliance with the requirements for retrospective review and prepare a mitigation report, if needed, for submission to the applicable funding agency as required under the FCOI Regulations. The agency may take its own action as it deems appropriate, which may include suspension of funding, or require the University to take further action to maintain the objectivity of the research.
- b. For clinical research projects supported by the PHS, if the Department of Health and Human Services 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, was designed, conducted, or reported by an investigator with a FCOI that was not properly disclosed or managed as required under the FCOI Regulations, the University, through the , must require the investigator(s) to disclose the FCOI in each public presentation (such as articles, manuscripts and oral presentations, including classroom materials) of the results of the research and to request an addendum to previously published presentations.

Enforcement and Sanctions

- a. All persons subject to University's Conflict of Interest Policy ([link](#)) and this policy are expected to comply with it fully and promptly. Whenever an investigator has violated either policy, for example by a failure to disclose a SFI, the matter will be referred RCC who may recommend disciplinary or other appropriate action.
- b. Violations of this policy and the FCOI Regulations that constitute falsification in proposing, performing, reporting or reviewing research shall be handled in accordance with the [Institutional Integrity](#) policy and procedures governing allegations of research misconduct.

Records

The University, through the RCC, is required pursuant to the PHS and NSF FCOI Regulations to maintain all SFI Disclosure Forms and all related records of actions taken by the University with respect to disclosures of financial interests for a period of three years from the date of submission of the final expenditures report to the PHS as governed by Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought ([42 C.F.R. Part 50, Subpart F](#)) or the NSF Award Administration Guide . The Development Office will maintain records of the initial disclosure of SFIs via the Fundraising Initiation Form. The IRB will maintain records related to training. The Development Office will retain records related to annual SFI disclosures. The RCC will maintain records related to SFIs determined to be FCOIs, subsequent management plans, and any other related materials connected to oversight of the management plan.

Approved by: *Mount Mary University Administration*

Definitions

Acronyms, Terms, and Definitions

Approval - A conflict has been identified for which a management plan can be developed by the RCC and implemented by an oversight committee designated by the ORC.

Approval with Conditions or Restrictions - A conflict has been identified, and a management plan can be developed only for parts of the conflict with conditions or restrictions. The management plan with conditions or restrictions will be implemented by an oversight committee designated by the RCC.

Prohibition - A conflict has been identified for which a management plan cannot be developed.

CITI / Collaborative Institutional Training Initiative - The CITI Program is a subscription service providing research ethics education to all members of the research community. Learners must be affiliated with a CITI participating organization such as Gallaudet University. CITI is a subscription based service and includes an FCOI course among other responsible conduct of research topics.

FCOI / Financial Conflict of Interest - A significant financial interest that the University's designated official has reasonably determined could directly and significantly affect the design, conduct, or reporting of research project.

FCOI report - An Institution's report of a financial conflict of interest to a PHS Awarding Component or to another agency with similar requirements or regulations such as the NSF.

Financial Conflict of Interest (FCOI) - A significant financial interest that could directly and /or significantly affect the design, conduct, or reporting of PHS-funded research.

Financial interest - Anything of monetary value, whether or not the value is readily ascertainable.

Institutional Responsibilities - "Institutional Responsibilities" means an investigator's professional responsibilities on behalf of Mount Mary, including activities such as research, teaching, clinical or other professional practice, academic activities, scholarly events, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Compliance Committees.

RCC / Research Compliance Committee - The RCC is comprised of the Vice President of Academic and Student Affairs, Director of CFR, Dean, PI on the project, and the President or the President's designee. The RCC shall be responsible for ensuring that each investigator is informed about this policy and made aware of the required training.

SFI / Significant Financial Interest - See section Disclosure C.