

Introduction

The Department of Health and Human Services amended its regulations related to financial disclosure on 8/25/2011. All institutions applying for U.S. Public Health Service (PHS) funding for research, including the National Institutes of Health (NIH), are required to have a policy that complies with these amended regulations; this PHS/NIH Financial Conflict of Interest Policy is designed to comply with the federal regulations and hereby incorporates by reference 42 CFR Chapter I, Subchapter D, Part 50.

These guidelines define general Moravian University policy and procedures regarding conflicts of interest in relationship to sponsored projects funded by PHS (including the NIH). Their purpose is to protect the credibility and integrity of Moravian's faculty and staff so that public trust and confidence in Moravian's PHS-funded sponsored activities is ensured.

This policy applies to all Investigators (as defined by the policy) who are involved with PHS-funded research. The Provost is responsible for ensuring implementation of this policy and may suspend all relevant activities until the financial conflict of interest is resolved or other action deemed appropriate by the Provost is implemented. Violation of any part of these policies may also constitute cause for disciplinary or other administrative action pursuant to Moravian University policy.

Definitions

Family means any member of the Investigator's immediate family, specifically, any dependent children, spouse, or registered domestic partner.

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 Moravian University;
- b) income from the authorship of academic or scholarly works;
- c) income from seminars, lectures, or teaching engagements sponsored by—or from service on advisory committees or review panels for—U.S. Federal, state or local governmental agencies; U.S. institutions of higher education; U.S. 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 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. institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers.

Financial Conflict of Interest (FCOI) means a Significant Financial Interest (or, where the Provost requires disclosure of other Financial Interests, a Financial Interest) that Moravian University reasonably determines could directly and significantly affect the design, conduct or reporting of PHS-funded research.

Institutional Responsibilities means the Investigator's responsibilities on behalf of Moravian University, which are defined by Moravian as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as institutional review boards (e.g., HSIRB, IACUC).

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.

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 agencies of the PHS include, but are not limited to, the National Institutes of Health, the Agency for Healthcare Research and Quality, the Food and Drug Administration, the Health Resources and Services Administration, the Substance Abuse and Mental Health Services Administration, and the Centers for Disease Control and Prevention.

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).

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 by the Investigator and his or her family during the 12-month period preceding the disclosure, and the value of any equity interest held by the Investigator and his or her family 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 by the Investigator and his or her family during the 12-month period preceding the disclosure exceeds \$5,000; or
- c) if with a non-publicly-traded company, is an equity interest held by the Investigator and his or her family of any value during the 12-month period preceding or as of the date of disclosure; or
- d) is income to the Investigator and his or her family related to intellectual property rights and interests not reimbursed through Moravian University.

Conflict of Interest

This policy is predicated on the expectation that Investigators should conduct their affairs so as to avoid or minimize conflicts of interest, and must respond appropriately when conflicts of interest arise. To that end, this policy informs faculty and staff about situations that generate conflicts of interest related to research, provides mechanisms for Investigators and Moravian University to manage those conflicts of interest that arise, and describes situations that are prohibited. Every Investigator must become familiar with, and abide by, the provisions of this policy. If a situation arises raising questions of conflict of interest, an Investigator should discuss the situation with the Provost.

Disclosure of Financial Interests

All Investigators are required to disclose their outside financial interests to Moravian University no later than the time of application for PHS-funded research, and on an annual and an ad hoc basis thereafter, as described below, using the PHS/NIH Financial Conflict of Interest Disclosure Form. This form is available from the Director of Foundation Relations. The Provost is responsible for the receipt, processing, review and retention of disclosure forms.

Regardless of the minimum disclosure requirements, a faculty or staff member, in his or her own best interest, may choose to disclose any other financial or related interest that could present an actual conflict of interest or be perceived to present a conflict of interest. Disclosure is a key factor in protecting one's reputation and career from potentially embarrassing or harmful allegations of misconduct.

Investigators provide the following information for all Significant Financial Interests: name of the entity, nature of the financial interest, the monetary value of the financial interest or its approximate value, and any supporting documentation needed to make a determination of whether a Financial Conflict of Interest (FCOI) exists.

1. Initial Disclosure

All Investigators must disclose their Significant Financial Interests and those of their family to Moravian University, through the Provost or designee, no later than the time of application for PHS-funded research.

2. Annual Disclosures

All Investigators must disclose their Significant Financial Interests and those of their family to Moravian University, through the Provost or designee, at least annually during the grant period in conjunction with filing the required annual report.

3. Ad hoc Disclosures

In addition to annual disclosure, certain situations require ad hoc disclosure.

a. New Hires

All Investigators involved with PHS-funded research must disclose their Significant Financial Interests to Moravian University, through the Provost, within 30 days of being appointed or employed.

b. New Significant Financial Interest

All Investigators must submit to the Provost an updated disclosure of any Significant Financial Interests within thirty (30) days of discovering or acquiring a new Significant Financial Interest.

Investigators must also disclose reimbursed or sponsored **travel** related to their Institutional Responsibilities, as defined above in the definition 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 Provost will determine if additional information is needed (e.g., the monetary value if not already disclosed) to determine whether the travel constitutes an FCOI with the Investigator's research.

Review and Decision of the Provost

If an initial, annual, or ad hoc disclosure reveals a Significant Financial Interest, the Provost will, within sixty (60) days, review the Significant Financial Interest, determine whether it is related to PHS-funded research, determine whether an FCOI exists, and, if so, implement at least on an interim basis a management plan that specifies the actions that have been and will be taken to manage the FCOI. The Provost will consult as appropriate with administrative colleagues.

An FCOI will exist when the Provost or designee determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of PHS-supported research. If the Provost determines that there is an FCOI that can be managed, he or she must require and approve a written management plan before any related research goes forward. The affected Investigator, in consultation with the Provost, is responsible for developing and submitting a proposed management plan.

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) for research projects involving human subjects research, disclosure of an FCOI directly to participants; (3) appointment of independent monitor(s) capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI; (4) modification of the research plan; (5) change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research; (6) reduction or elimination of the financial interest (e.g., sale of an equity interest); or (7) severance of relationships that create financial conflicts.

For all management plans, Moravian University will monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project.

To address complex situations, oversight committees may be established by the Provost to review periodically the ongoing activity, to monitor how the activity is conducted (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

Before expending any funds under an PHS-funded grant, cooperative agreement or contract, or subaward under which the primary award is funded by a PHS entity, Moravian University must report to the applicable PHS funding agency (or to the primary awardee) the existence of any FCOI and assure that Moravian has implemented a management plan in accordance with PHS regulations.

If Moravian University identifies an FCOI and eliminates it prior to the expenditure of any PHS-awarded funds, Moravian is not required to submit a FCOI report to the respective agency.

If the failure of an Investigator to comply with Moravian's FCOI Policy or a FCOI management plan appears to have biased the design, conduct, or reporting of the PHS-funded research, Moravian will promptly notify the PHS Awarding Component of the corrective action taken or to be taken. If the funding for the Research is a subaward from a primary PHS awardee, reports will be made to the primary awardee such that they may fulfill their reporting obligations to PHS.

Investigator Non-Compliance

Disciplinary Action

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

The Provost'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 Provost, will be described in a written explanation of the decision to the Investigator and, where applicable, the HSIRB or IACUC, and will notify the individual of the right to appeal the decision.

Retrospective Review

In addition, if the Provost determines that an FCOI 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 an FCOI, or failure by an Investigator to materially comply with a management plan for an FCOI, a committee appointed by the Provost will complete within 120 days 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 will include the project number, project title, PI, name of Investigator with the FCOI, name of the entity with which the Investigator has the FCOI, reason(s) for the retrospective review, detailed methodology used for the retrospective review, and findings and conclusions of the review.

The Provost will update any report previously submitted to the PHS or the primary PHS awardee relating to the research, specifying the actions that will be taken to manage the FCOI going forward. If bias is found, the report will include a mitigation report in accordance with 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

Each Investigator must complete training on this Policy prior to engaging in research funded by PHS, and at least every four years thereafter. Investigators must also complete training within a reasonable period of time as determined by the Provost in the following situations: if this Policy is substantively amended in a manner that affects the requirements of Investigators, if the Investigator is new to Moravian University, or if it is determined that the Investigator has not complied with this policy or with a management plan related to their activities.

Subrecipients

If Moravian University carries out PHS-funded research in collaboration with or through a subrecipient, Moravian as the awardee institution will take reasonable steps to ensure that any subrecipient Investigators comply with FCOI Policy by (1) incorporating as part of a written agreement with the subrecipient terms that establish whether Moravian's FCOI Policy or that of the subrecipient will apply to the subrecipient's Investigators, and (2) providing FCOI reports to the PHS Awarding Component regarding all FCOIs of all subrecipient Investigators prior to the expenditure of funds and within sixty (60) days of any subsequently identified FCOI.

Record Retention

The Provost 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 primary PHS awardee.

Confidentiality

To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be confidential. However, Moravian University may make such information available to an agency funding an Investigator's research, to a requestor of information concerning an FCOI related to PHS funding or to the primary entity that made the funding available to Moravian, if requested or required. If Moravian University provides disclosure forms, conflict management plans, and related information to an outside entity, the Investigator will be informed of this disclosure.

Public Accessibility

Prior to the expenditure of funds, Moravian University will ensure public accessibility of information about any FCOI, via response to requestor within five business days of the request, information concerning any Significant Financial Interest that meets the following criteria:

- The Significant Financial Interest was disclosed and is still held by the Investigator;
- A determination has been made that the Significant Financial Interest is related to the PHS-funded research; and
- A determination has been made that the Significant Financial Interest is an FCOI.

The information to be made available will be consistent with the requirements of PHS regulations.

Regulatory Authority

This policy implements the requirements of 42 CFR 50 and 45 CFR 94; where there are substantive differences between this policy and the requirements, the requirements will take precedence.

This policy has been reviewed and accepted by the President's Council (October, 24 2017).

Origination Date: 9/28/2017
Last Amended Date: 2/20/2023 (College to University only)
Last Review Date: 10/24/2017