



Policies and Procedures for Grants Administration

5.8 Conflict of Interest: Promoting Objectivity in Research

Policy Statement

Pursuant to [Title 42 CFR Part 50 Subpart F](#), as well as other funding agency requirements, Olivet maintains and disseminates written standards of conduct covering organizational conflicts of interest within all externally funded grants and sponsored programs, regardless of the funding mechanism used to issue an award. Investigators and others involved in the design, conduct, or reporting of such awards are required by policy and federal law to disclose, at least annually, any conflict of interest utilizing ONU's Conflict of Interest Disclosure Form to enable the review and development of a Management Plan. Olivet utilizes the regulations of [Title 42 CFR Part 50 Subpart F](#) as the framework for the administration of conflicts for any externally funded research or sponsored program, regardless of the source of funding or type of funding mechanism for the purpose of ensuring consistency.

Applicability

This policy applies to any employee, student, or other individual participating in any externally funded research or sponsored program awarded to Olivet Nazarene University as PI/PD, Senior/Key Personnel, or other role in which compensation for services is received, referred to as a Covered Individual. This policy also applies to any individual who receives a notification from the OGA that disclosures shall be required.

Definitions

The following definitions taken from [Title 42 CFR § 50.603](#) apply specifically to this policy:

- [*Disclosure of significant financial interests*](#) means an Investigator's disclosure of significant financial interests to an Institution.
- [*Financial conflict of interest \(FCOI\)*](#) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.
- [*FCOI report*](#) means an Institution's report of a financial conflict of interest to a PHS Awarding Component.
- [*Financial interest*](#) means anything of monetary value, whether or not the value is readily ascertainable.
- [*HHS*](#) [or DHHS] means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.
- [*Institution*](#) means any domestic or foreign, public or private, entity or organization (excluding a federal agency) that is applying for, or that receives, PHS research funding.
- [*Institutional responsibilities*](#) means an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on financial conflicts of interest, which may include for example: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.
- [*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, for example, collaborators or

consultants.

- Manage means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.
- PD/PI means a project director or principal Investigator of a PHS-funded research project; the PD/PI is included in the definitions of senior/key personnel and Investigator under this subpart.
- 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 involved may be delegated, including the National Institutes of Health (NIH).
- PHS Awarding Component means the organizational unit of the PHS that funds the research that is subject to this subpart.
- Public Health Service Act or PHS Act means the statute codified at [42 U.S.C. 201](#) *et seq.*
- Research means a systematic investigation, study or experiment designed to develop or 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). As used in this subpart, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.
- Senior/key personnel means the PD/PI and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS by the Institution under this subpart.
- Significant financial interest means: (1) A financial interest consisting 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: (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); or (c) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests; (2) 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; 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. The Institution's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the Institution's FCOI policy, the institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research; (3) The term *significant financial interest* does not include the following types of

financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; 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.

Policy and Procedure

Publicly Available Policy, Procedure, and Disclosure Form

Olivet complies with [Title 42 CFR § 50.604](#) by developing, maintaining, and enforcing a policy on conflicts of interest that complies with [Title 42 CFR Part 50 Subpart F](#). The policy, along with other ONU policies governing the administration of externally funded programs or projects, is provided to the campus community, including all institutional Investigators and SKPs, within the institutional SharePoint page for the Office of Grants Administration. ONU also makes the written policy available to any requestor within five business days of any request.

Required Training for Investigators

Investigators are responsible to comply with ONU's Conflict of Interest Policy and file disclosures at least annually (or update disclosures when circumstances require). In addition, and as required under [Title 42 CFR 50.604\(b\)](#), Investigators are required to complete ONU-administered Conflict of Interest training prior to engaging in PHS- or other externally funded research and at least every four years thereafter throughout the award and closeout lifecycle, and immediately when any of the following circumstances apply:

- (1) ONU revises its Conflict of Interest Policy in any manner that affects the requirements of Investigators;
- (2) An Investigator is new to ONU; or
- (3) ONU finds that an Investigator is not in compliance with ONU's Conflict of Interest Policy or Conflict of Interest Policy Management Plan.

Investigators and other affected personnel engaged in any NIH or other PHS award are required to complete the Financial Conflict of Interest (FCOI) virtual training session which have been designed by NIH specifically to meet federal requirements. NIH FCOI training may currently be found at the following website: https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html. Personnel completing the training session are required to retain the completion certificate.

Subawards from Partner Institutions or Agencies

In the performance of programs funded as passthrough funding (subawards from another institution or organization), ONU remains responsible for ensuring ongoing compliance with its own Conflict of Interest Policy and Conflict of Interest Policy Management Plan unless ONU, through the Office of Grants Administration, has agreed to comply with the passthrough entity's policy and procedures and has established clear beginning and ending dates for ONU's reporting requirements under the subaward(s).

Institutional Official

As aligned with [Title 42 CFR 50.604\(d\)](#), ONU has designated the Director of Grants Administration as the institutional official responsible for the administration of the COI process for grants and PHS awards.

The Director of Grants Administration has numerous responsibilities for the administration of this policy, as required and stated by PHS, with additional requirements imposed by ONU. The Director of Grants Administration is responsible to:

- Develop the COI policy
- Maintain the COI policy and all records, for at least three (3) years after the date of the final expenditure report submitted to the funding agency, relating to: Investigator disclosures; ONU's review of disclosures; ONU's response to disclosures; ONU action or activity under the Institution's policy
- Make the COI policy publicly available online or providing it promptly upon request pursuant to policy.
- Provide records promptly to funding agencies upon receipt of a lawfully written request.
- Distribute the COI policy to existing and new faculty and staff members in the research and grant campus community.
- Solicit disclosures from faculty to ensure disclosures are submitted at least annually
- Review all Investigator disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in, the PHS-funded research.
- Determine whether any significant financial interests relate to PHS- or other funded programs to ultimately determine whether a financial conflict of interest exists
- Develop and implement an FCOI and/or COI Management Plan that identifies any actions that have been, and will be, taken to manage any financial conflict of interest.
- Distribute disclosures to administrators
- Establish institutional enforcement mechanisms, with support from the VPAA/Provost.
- Reinforce decisions and enforce compliance made by the VPAA/Provost regarding employee sanctions or other administrative actions.
- Provide training at least annually to the campus community
- Ensure that all conflicts are publicly available online, and other related activities involving disclosures, communication, review, and compliance.
- Provide initial and ongoing FCOI reports to PHS as required by [Title 42 CFR § 50.605\(b\)](#), or other funding agency requirement or regulation.
- Liaise with PHS and other funding agencies by supporting reporting requirements:

Investigator Disclosures

Every ONU Investigator that is presently or is planning to engage PHS or any other public, state, or private funding agency, regardless of the purpose of the program is required by ONU policy and by [Title 42 CFR 50.604\(e\)\(1\)](#) to submit an accurate disclosure, at least annually, to the Institutional Official. In any circumstance when the Institutional Official is also potentially involved, a disclosure may be made to the VPAA/Provost. Disclosures must include real or perceived financial, significant financial interests, and those of the Investigator's spouse and dependent children.

- Disclosures must be filed no later than the time of application for PHS- or other externally funded award (or at the time of transfer of a PHS- or other externally funded award into ONU from another institution or organization).
- Annual disclosures must be submitted at least prior to July 1 of the subsequent fiscal year, or earlier as deemed appropriate by the Director of Grants Administration to align with the period of the award.
- Updated disclosures must be submitted within 30 days of discovering or acquiring any new significant financial interest. This includes interests acquired through acquisition/purchase, marriage, inheritance, filing of intellectual property (patent, copyright, trademark, or license), or through any activities of a spouse or dependent child.

Submission of a Disclosure with No Conflicts to Report

If any Investigator completes, signs, and submits a disclosure form to the Director of Grants Administration which does not identify any real or perceived conflicts of interest, the Investigator may proceed normally unless otherwise directed.

Disclosures with Real or Perceived Conflicts, and ONU's Conflict of Interest Management Plan

If any Investigator completes, signs, and submits a disclosure form to the Director of Grants Administration which identifies any real or perceived conflict(s) of interest, the Investigator shall not proceed until all signatories and the Director of Grants Administration have:

- Determined if the conflict is related to the PHS or other externally funded program and determine whether any significant financial interest may be a financial conflict of interest (note: ONU may require continued dialogue or information from any Investigator for the purpose of making any determination)
- Developed a Conflict of Interest Management Plan, which may be permanent (or until other circumstances require a change) or interim.

Reporting of Financial Conflicts of Interest to PHS and other Agencies with Reliance on 42 CFR

The purpose of reporting is to enable the Institutional Official, Institutional executives, and funding agency representatives to identify, assess, and respond to a Conflict of Interest and Management Plan. All reports, whether final or interim, and whether they are retrospective or mitigation reports, must document specific details, as show in the attached Conflict of Interest Report Template.

Prior to the any expenditure of funds under a PHS-funded research project or other project funded by an agency with reliance upon the PHS regulations, ONU is required to provide to the awarding agency an FCOI report regarding any significant financial interest found by ONU to be conflicting and ensure that ONU has implemented a Conflict of Interest and Management Plan in accordance and compliance with Title 42 CFR 50 Subpart F. However, should ONU identify a financial conflict of interest and eliminate it prior to the expenditure of any awarded funds, ONU is not required to submit an FCOI report.

Public Disclosure

Pursuant to [Title 42 CFR 50.605\(a\)\(5\)\(i\)](#), prior to ONU's expenditure of any funds under a PHS funded research project [or other award utilizing the regulations of 42 CFR 50 Subpart F], ONU shall ensure that disclosures are available to the public via a public facing website, or by providing a written response to any requestor within five (5) business days of a request for information concerning any significant financial interest disclosed to ONU that: 1) the significant financial interest was disclosed and is still held by the SKP; and 2) ONU determined that the significant financial interest is related to the PHS funded research; and 3) ONU determined that the significant financial interest is a financial conflict of interest. While disclosures are required to be submitted by all Investigators pursuant to this policy, public disclosure shall only be provided for PHS awards or other agencies which utilize PHS regulations for conflict-of-interest management.

Any information made publicly available by ONU will only include answers to the five questions provided below as required under [Title 42 CFR 50.605\(a\)\(5\)\(ii\)](#). Any information in addition to responses to the below questions shall only be provided with the approval of the Director of Grants Administration and with the approval of ONU legal counsel without a lawful written order.

- 1) The Investigator's name
- 2) The Investigator's title and role with respect to the research project
- 3) The name of the entity in which the significant financial interest is held
- 4) The nature of the significant financial interest; and
- 5) The approximate dollar value of the significant financial interest
☐ \$0-\$4,999

- ☐ \$5,000-\$9,999
- ☐ \$10,000-\$19,999
- ☐ \$20,000-\$100,000 by increments of \$20,000
- ☐ \$100,000 and above by increments of \$50,000)
- ☐ The value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

Table of Responsibilities

Institution Responsibilities	Investigator Responsibilities
Appoint an Institutional Official	
Develop and disseminate policy	Comply with policy
Provide annual training campus-wide	Complete training and every 4 years
Administer disclosures	Disclose prior to submission of PHS Disclose annually Disclose within 30 days of discovery
Develop COI Management Plan and monitor	Comply with COI Management Plan
Develop Mitigation Reports	
Publicly post FCOI details, updated annually	
Submit FCOI reports to PHS and agencies	

Sources and Resources

- [Title 2 CFR § 200.318\(c\)\(2\)](#)
- [Title 42 CFR Part 50 Subpart F—Promoting Objectivity in Research](#), et. seq.

Consequences of Non-Compliance

A PHS funding agency may 1) require specific award conditions under [Title 45 CFR § 75.207](#); 2) suspend funding; or 3) implement one or more additional enforcement actions under [Title 45 CFR § 75.371](#) until non-compliance is resolved. Institutionally, ONU may take other appropriate actions to ensure compliance. ONU's Policy seeks to wholly comply with [Title 42 CFR Part 50 Subpart F](#); however, it is the responsibility of the Investigator to review all Federal requirements required of the granting agency.

History

Policy Approved By:

Policy Effective Date:

Annual Review: