

LOYOLA UNIVERSITY OFFICE OF GRANTS AND SPONSORED PROGRAMS CONFLICT OF INTEREST POLICY FOR PHS-FUNDED SPONSORED PROJECTS

Revised October 4, 2017

A. Introduction

The Loyola University Conflict of Interest policy (“university-wide policy”) applies to all faculty and staff. As specified in Section II.B of that policy, those faculty and staff who are participating in government-supported sponsored projects are subject to additional requirements as specified by the sponsor. The current policy aims to protect the university and individuals participating in Public Health Service (PHS)-funded sponsored projects by specifying additional responsibilities and establishing procedures for complying with the federal regulation Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought and Responsible Prospective Contractors (42 CFR Part 50). These responsibilities and procedures complement, rather than replace those established through the university-wide policy.

B. Scope

1. This policy pertains to all sponsored projects for research activities that are funded, in whole or in part, by the PHS, which is part of the Department of Health and Human Services and which includes the following agencies:
 - 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
 - National Institutes of Health (NIH)
 - Substance Abuse and Mental Health Services Administration (SAMHSA)

This policy applies to both prime awards and sub-awards (award subcontracts).

2. This policy applies to all Investigators associated with PHS-funded sponsored projects, whether they are full- or part-time employees or regular or exceptional faculty, to Office of Grants and Sponsored Programs staff administering PHS awards, and to members of the University’s Conflict of Interest Committee.

C. Definitions

“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.

“Financial interest” means anything of monetary value, whether or not the value is readily ascertainable.

“Investigator” means the Principal Investigator or any other person who is responsible for the design, conduct, or reporting of research (or, in the case of PHS contracts, a research project) that is either funded by PHS or proposed for such funding. For purposes of the regulatory requirements relating to financial interests, the term “Investigator” includes the Investigator’s spouse and dependent children.

“Manage” means taking action to address a **financial conflict of interest (FCOI)**, which can include reducing or eliminating the FCOI, to ensure, to the extent possible, that the design, conduct, and reporting of the research will be free from bias.

“PHS regulation” refers to the federal regulation Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought and Responsible Prospective Contractors (42 CFR Part 50).

“Principal Investigator” is the individual at the University who is most responsible for the development and completion of a sponsored project.

“Significant Financial Interest (SFI)” 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:

(i) With regard to any publicly traded entity, an **SFI** 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) With regard to any non-publicly traded entity, an **SFI** exists (a) if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or (b) when the Investigator (or the Investigator’s spouse or dependent children) holds any equity interest (*e.g.*, stock, stock option, or other ownership interest) [regardless of value]; or

(iii) Intellectual property rights and interests (*e.g.*, patents, copyrights), upon receipt of income related to such rights and interests [regardless of value].

(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;
- Loyola University or another 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.

(3) The term **significant financial interest (SFI)** 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.

“Sponsored Project” is an organized activity that is supported by external funding from a grant, contract, or cooperative agreement and for which there is a level of accountability to the sponsor that is characterized by three things: 1) a pre-defined work plan or scope of work, 2) a budget, and 3) reporting requirements. All projects funded, in whole or in part, by the federal or state governments are sponsored projects.

“Subrecipient” means an institution or other entity that receives federal assistance passed through from a prime award recipient or another subrecipient to carry out or administer a program with the responsibility for programmatic decision making. When applying for the federal award, the prime institution and this entity often sign a letter of intent to form a consortium. This entity is often referred to as a consortium partner or federal subcontractor.

D. Statement of Policy and Procedures

The University is committed to the pursuit of truth, wisdom, and virtue. In consultation with the University's Conflict of Interest Committee, the Office of Grants and Sponsored Programs will work actively with all Investigators to maintain the excellence and objectivity of the University's research enterprise.

Disclosures, Review, and Monitoring

- The Director of Grants and Sponsored Programs, hereinafter referred to as the Director, will solicit and review disclosures of all Investigator SFIs related to institutional responsibilities. If the Director will be away from the office or otherwise unable to review disclosures, he or she will designate in writing another member of his or her office or the University's Conflict of Interest Committee to perform this function on his or her behalf.
- Prior to the submission for a new sponsored project or competitive renewal application for PHS funding, the Principal Investigator will provide the Office of Grants and Sponsored Programs with a list of all Investigators to be associated with the project. This list is requested at least two (2) weeks prior to the agency's application deadline and must include the associated institution for each Investigator who is not primarily affiliated with the University. The Director may, but is not required to, accept lists submitted after this deadline.
- Each Investigator is required to disclose all SFIs that are related to his or her institutional responsibilities by submitting a completed and signed SFI Disclosure and Certification Form (1) prior to the submission of an application for PHS funding, (2) at least annually during the period of an award, and (3) within five (5) days of the Investigator discovering or acquiring a new SFI. The SFI disclosure process is designed to complement the university-wide policy and, in part, to capture any interests that are not disclosed as per that policy. If Loyola is proposing to serve a subrecipient, then the prime's form may be used in place of the SFI Disclosure and Certification Form, at the Director's discretion.
- It is the Principal Investigator's responsibility to submit a signed SFI Disclosure and Certification Form for each Loyola Investigator to the Office of Grants and Sponsored Programs at least two weeks prior to the agency's application due date.
- The Principal Investigator must also provide a signed SFI Disclosure and Certification Form for each Investigator associated with each collaborating Institution that is listed in the application and intended to be a subrecipient of the intended award.
- The Investigator disclosures are requested no later than two (2) weeks prior to the agency's application deadline; failure of the Principal Investigator to provide all disclosures in a timely manner may prevent the application from being submitted. The Director may, but is not required to, accept forms submitted after this deadline.
- Prior to the expenditure of PHS funds, the Director of Grants and Sponsored Programs will:
 - Review all Investigator SFI disclosures;
 - Determine if any SFIs are related to the PHS-funded research;
 - Determine if an FCOI exists; and

- Develop and implement management plans as needed to manage all identified FCOIs.
- The Director will perform a preliminary review of all disclosures and will forward to the Committee those that may reasonably involve an FCOI.
- The Office of Grants and Sponsored Programs has posted and will maintain guidelines that the Director and the Conflict of Interest Committee, hereinafter referred to as the Committee, will use in determining whether an Investigator's SFI is related to PHS-funded research and, if so related, whether the SFI is an FCOI.
- The Director and the Committee will review disclosures of SFIs, make determinations of FCOIs, and implement a management plan within 60 days when required for an Investigator who is a new participant of the research project or for an existing Investigator who discloses a new SFI.
- The Director and Committee will review disclosures of SFIs, make determinations of FCOIs, and implement a management plan, when required, within 60 days whenever an Institution identifies a SFI that was not disclosed by an Investigator or not previously reviewed.
- The Director will work with the Committee and additional administrative offices and institutions as necessary to manage FCOIs, including any financial conflicts of a subrecipient Investigator, if applicable, and to monitor Investigator compliance with management plans until completion of the project.

Training

- Through its staff and website, the Office of Grants and Sponsored Programs will convey this policy and the university-wide policy, and the federal regulation to each Principal Investigator, and will make each Principal Investigator aware of his or her disclosure responsibilities prior to the submission of any application for PHS funding. Generally, these policies and regulations will be discussed at the time that the office is notified of the application.
- It is the responsibility of each Principal Investigator to make every other Investigator associated with the project aware of this policy, the university-wide policy, and the federal regulation prior to the submission of any application for PHS funding.
- Each PHS-supported Investigator is required to complete FCOI training:
 - Prior to engaging in research related to any PHS-funded grant or contract;
 - At least every four (4) years; and
 - Immediately if (1) Loyola revises this policy or its university-wide policy in a manner that affects the requirements of the investigators, (2) an Investigator is new, or (3) an Investigator is determined to be incompliant with the policy or management plan.
- All Investigators are to be trained by the Office of Grants and Sponsored Programs and at the same time as the Principal Investigator. If simultaneous training is not feasible in a timely manner, the Principal Investigator will be responsible for training and obtaining a Certificate of Training for each additional Investigator.
- Upon the completion of training, each Investigator will submit to the Office of Grants and Sponsored Programs a signed Certificate of Training for office approval. Only after approving the Certificate of Training for each Investigator will the Office of Grants and Sponsored Programs notify Financial Affairs that the award funds may be

expended. In cases where an Investigator will not participate immediately in the PHS-funded research, the Office of Grants and Sponsored Programs may permit the project to proceed provided that the untrained Investigator is not involved. In this case, the Principal Investigator must submit to the Office of Grants and Sponsored Programs a signed written statement affirming that the untrained Investigator will not participate in the research until training and certification have occurred.

- Training must be repeated and a Certificate of Training completed and approved for each Investigator every four (4) years or upon determination of an Investigator's non-compliance with this policy or management plan. The certificate must be approved by the Office of Grants and Sponsored Programs within 30 days of the first day of the fourth grant year (including extensions) or of notification of noncompliance, respectively.

Recordkeeping

- The Office of Grants and Sponsored Programs will maintain all FCOI-related records for at least three (3) years from the date that the final expenditure report is submitted to the PHS. The only exceptions are the following:
 - If any litigation, claim, financial management review, or audit is started before the expiration of the three (3)-year period, the records shall be retained until all litigation, claims, or audit findings involving the records have been resolved and final action taken.
 - Records for real property and equipment acquired with Federal funds shall be retained for three (3) years after final disposition.
 - In cases in which the University must report income after the period of grant support, the retention period pertaining to the earning of the income will start from the end of the University's fiscal year in which the income is earned.

Subrecipients

- Prior to releasing any PHS funding to a subrecipient, the Office of Grants and Sponsored Programs will determine whether the subrecipient will be subject to this policy or the FCOI policy of the subrecipient institution. In making this determination, the Office of Grants and Sponsored Programs will consider whether the subrecipient is actively registered with grants.gov and receiving any PHS or other federal award funding.
- If the subrecipient will follow its own FCOI policy, then prior to the release of any PHS funds to that institution, the Office of Grants and Sponsored Programs will obtain (1) a certification from an authorized official of that institution that its policy complies with the PHS regulation and (2) a written agreement endorsed by the subrecipient's institution's authorized official that the subrecipient will report identified FCOIs in a time frame that allows the University to meet its reporting requirements under the PHS regulation.
- If the subrecipient will follow this policy, then the Office of Grants and Sponsored Programs will obtain a written agreement that the subrecipient will (1) provide disclosures on the specified University forms and within a timeframe that enables the University to meet its reporting requirements under the PHS

regulation, and (2) agree to enforce the management planned established by the University should an FCOI be identified.

Public Accessibility

- A current version policy will be made accessible to the public through the Grants and Sponsored Programs website.
- The Office of Grants and Sponsored Programs will post to its website the following information about each FCOI related to the PHS research that is identified for an Investigator who is serving as one of the senior/key personnel:
 - The Investigator's name;
 - The Investigator's title and role with respect to the research project;
 - The name of the entity in which the significant financial interest is held;
 - The nature of the SFI; and
 - The approximate dollar value of the SFI, or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.
- Whenever posted, the above-mentioned information will be updated annually, updated within 60 days of a newly identified FCOI, and remain posted for three years from the date that the information was most recently updated.

Enforcement and Retrospective Review

- Failure to comply with this policy may result in sanctions and administrative actions, including refusal on the part of the Office of Grants and Sponsored Programs to submit an application when pre-submission requirements are not met.
- Failure of an Investigator to disclose one or more SFIs as specified elsewhere in this policy or to comply with the development or implementation of a management plan within the timeframe specified by the Director will result in the following initial sanctions:
 - The Principal Investigator, the Investigator's chair or immediate supervisor, the Investigator's dean, and the Provost will be notified in writing of the lack of compliance.
 - The Director of Grants and Sponsored Programs will notify the Investigator, the Principal Investigator, the Investigator's chair or immediate supervisor, the Investigator's dean, the Provost, and the Office of Financial Affairs that the Investigator is not permitted to participate in the project, at least until compliance is achieved.
- Sanctions and administrative actions beyond the initial sanctions will be determined by the Director after review by the Conflict of Interest Committee and in accordance with applicable University policies and procedures. Possible sanctions include those listed in the university-wide policy.
- The Office of Grants and Sponsored Programs will complete and document respective reviews within 120 days of its determination of noncompliance due to an SFI not having been either disclosed or reviewed in a timely manner, or due to an FCOI not having been identified or managed in a timely manner.
- Whenever the Department of Health and Human Services determines that a PHS-funded research project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with an FCOI that was not properly managed or reported by the Institution, the Investigator will be required to:

- Disclose the FCOI for each public presentation of the results of the research, and
- Request addendum to previously published presentations in order to disclose the FCOI.

Appeals

The appeals process is identical to that described in the university-wide policy, except that each employee must submit a copy of his or her written appeal to the Director of Grants and Sponsored Programs on the same day that the original appeal is submitted to his or her Vice President.

History

This policy was developed after consultation with General Counsel and the amendment of the university-wide policy dated August 15, 2012. Dated November 28, 2012, Version 1.1 introduced revisions including a shortening of the Investigator's timeline for reporting a newly discovered or acquired SFI. Dated October 2017, Version 1.2 included flexibilities on pre-submission requirements.

Contact Information

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