



University: <input checked="" type="checkbox"/>	Division: Academic Affairs
Subject: NIH Financial Conflicts of Interest Policy (FCOI)	
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Effective Date: 3/1/2021	Previous Issued: Click here to enter text.
Responsible University Official: Executive Director of Research	
Responsible Office: Office of Research and Sponsored Programs	

Policy Owner – Office of Research and Sponsored Programs (ORSP)

Policy Title: National Institutes of Health (NIH) Promoting Objectivity in Research--Financial Conflicts of Interest in Research for Public Health Services (PHS) Investigators

1. Policy Summary

This policy seeks to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research performed under Public Health Services (PHS) grants or cooperative agreements will be free from bias resulting from an investigator’s financial conflicts of interest.

2. Policy Statement

Loyola Marymount University (LMU or “The University”) and its employees may be asked to assist in a broad range of economic development activities, to work on projects that involve support from the governmental and the commercial sectors, and to engage in consulting relationships and other outside economic activities related to the funded research. Generally, such outside activities enhance professional development, scholarship, and teaching and are strongly encouraged. Along with these benefits, the arrangements between external enterprises and LMU, its employees, or students, may also potentially create financial conflicts of interest.

A financial conflict of interest (FCOI) occurs when there is a divergence between an individual’s private interests and his or her professional obligations to the University, such that an independent observer might reasonably question whether the individual’s professional actions or decisions are determined by considerations of personal financial gain. A financial conflict of interest depends on actual situational conditions and the respective roles of the personnel who may be involved, but not on perceptions of the individual’s moral character.

3. Reason for Policy

This policy is intended to establish requirements to ensure that the University is in full compliance with all pertinent regulatory requirements in applying for or receiving Public Health

Services (PHS) funding from a grant or cooperative agreement and is applicable to any PHS proposals submitted and/or awards received on or after August 24, 2012. This policy provides a detailed explanation of the FCOI requirements for PHS-funded investigators in accordance with 42 CFR 50, Subpart F, and 45 CFR 94.

4. Responsibilities

For following the policy for all NIH PHS-funded Principal Investigators must comply with the following responsibilities:

- 4.1. Disclose Significant Financial Interests (SFI) (and those of the Investigator's spouse and dependent children) that reasonably appear to be related to the Investigator's institutional responsibilities, over the previous twelve-month period to the Executive Director of Research (the University's Research Integrity Officer (RIO)) no later than at the time of the application for PHS-funded research.
- 4.2. Submit an updated disclosure of SFIs via email to the RIO at least annually, but no later than January 15, during the period of award.
- 4.3. Submit an updated disclosure of SFIs within 30 days of discovering or acquiring a new SFI. (42 CFR 50.604 (e)(1)-(3))
- 4.4. Complete NIH FCOI training at <https://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm> prior to the expenditure of funds for any funded project. Thereafter training must be completed at least every four years and immediately when:
 - 4.4.1. Institutional Financial Conflict of Interest policies change in a manner that affects investigator requirements
 - 4.4.2. An investigator is new to LMU
 - 4.4.3. LMU finds that an investigator does not comply with this Financial Conflict of Interest policy or a management plan. (42 CFR 50.604 (b))
- 4.5. Comply with any FCOI management plan requirements and any monitoring of that management plan. The management plan will be created with the Principal Investigator (PI), ORSP, and other offices as needed, such as Post Award Accounting Administration to adhere to the FCOI requirements and mitigate risks for the PI and LMU.

Principal Investigator Responsibilities

The Principal Investigator is responsible for ensuring and certifying that each Investigator on the PHS proposal (as well as the investigator's spouse and dependent children) has disclosed his/her SFIs. PIs are also responsible for ensuring and certifying that each investigator has completed the mandatory LMU FCOI training and that all students, collaborators and sub-awardees submit required disclosures and complete training as required by relevant regulation.

Responsibility for enforcement of policy: The Executive Director of Research will serve as the Research Integrity Officer (RIO) responsible for compliance with Financial Conflict of Interest regulations. (42 CFR 50.604) (d)

Responsibility for oversight of policy: Provost

Responsibility for procedures implementing policy: The Research Integrity Officer (RIO)

5. Definitions (45 CFR 50.603)

“**Financial Conflict of Interest**” means a significant financial interest that is related to a NIH research program or project and could directly and significantly affect the design, conduct or reporting of that research.

“**HHS**” means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

“**Institutional Responsibilities**” means the Investigator’s professional responsibilities on behalf of the University including, but not limited to, activities such as research, consultation, teaching, professional practice, institutional committee membership, and service on panels such as Institutional Review Boards or Data and Safety Monitoring boards.

“**Investigator(s)**” means the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, analysis or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.

“**Research Integrity Officer (RIO)**” means the institutional official responsible for assessing allegations of research misconduct and determining when such allegations warrant inquiries and for overseeing inquiries and investigations. The Research Integrity Officer is also the institutional official who makes final determinations on allegations of research misconduct and any responsive institutional actions upon recommendation of the University Research Committee. The Executive Director of Research, or his or her designee, will serve as the Research Integrity Officer.

“**The U.S. Public Health Service (PHS)**” means the Public Health Service of the U.S. Department of Health and Human Services (HHS), and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH). Within the HHS, eight agencies are designated components of the U.S. Public Health Service (PHS): (1) the Agency for Healthcare Research and Quality (AHRQ), (2) the Agency for Toxic Substances and Disease Registry (ATSDR), (3) the Centers for Disease Control and Prevention (CDC), (4) the Food and Drug Administration (FDA), (5) the Health Resources and Services Administration (HRSA), (6) the Indian Health Service (IHS), (7) the National Institutes of Health (NIH), and (8) the Substance Abuse and Mental Health Services Administration (SAMHSA).

Public Health Service Act or PHS Act means the statute codified at 42 U.S.C. 201 et seq.

“**PHS Awarding Component**” means the organizational unit of the PHS that funds the research that is subject to 42 CFR 50 Subpart F.

“**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 42 CFR 50 Subpart F, 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.

“University Research Committee (URC)” refers to the university committee that advises the Provost on conflict of interest matters in research. Faculty appointments to committees are made by the President through the Provost on the recommendation of the Faculty Senate as advised by the Committee on Committees.”

The Provost appoints the following ex-officio, non-voting members an IRB Chairperson, as a liaison to/from the IRB; and External Relations.

The committee, should include a member external to the LMU community, non-voting, and at its discretion may add individuals with expertise in biomedical and behavioral research, if further faculty or non-faculty is desired. Appointments to committees are made by the President through the Provost on the recommendation of the Faculty Senate as advised by the Committee on Committees.

“Significant Financial Interest (SFI)” means, except as otherwise specified in this definition:

1. A financial interest consisting of one or more of the following interests of the Investigator (and/or those of the Investigator’s spouse and/or 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 the 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, travel reimbursement). Equity interests include: 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 the Investigator (or the Investigator’s spouse or dependent children) hold any equity interest.
 - c. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
2. For PHS-funded investigators, any reimbursed travel or sponsored travel (i.e., that which is paid on behalf of 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 excluded sources. It is provided in regulation 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.

3. The term significant financial interest does not include the following types of financial interests:

- a. Salary, royalties, or other remuneration paid to the Investigator if the investigator is currently employed or otherwise appointed by the university, including intellectual property rights assigned to the Institution 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;
- b. Income from seminars, lectures, or teaching engagements sponsored by a federal, state or local agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education;
- c. Income from service on advisory committees or review panels for a federal, state or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education;
- d. For PHS-funded investigators, travel that is reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

6. Procedures

6.1. Institutional Responsibilities for FCOI

- 6.1.1. Develop and implement policies and procedures that promote compliance with relevant regulations.
- 6.1.2. Provide adequate guidelines consistent with the regulation for the designated institutional official to determine whether an Investigator's SFI is related to PHS-funded research and, if so, whether the SFI is an FCOI. (42 CFR 50.604(f))
- 6.1.3. Provide information to Investigators, including:
 - 6.1.3.1. The existence of the relevant federal and state regulations (42 CFR 50.604) (b))
 - 6.1.3.2. LMU's FCOI policy that will be posted on the Research Compliance website (42 CFR 50.604) (b))

- 6.1.3.3. The Investigator's responsibility to disclose financial interests via the Significant Financial Interests Form (SFI) when scheduling an Award Set Up meeting; the form will be posted on the Research Compliance website (42 CFR 50.604) (b))
- 6.1.3.4. The Investigator's responsibility to complete NIH FCOI training video prior to the expenditure of funds. (42 CFR 50.604) (b))
- 6.1.4. Evaluate Significant Financial Interests and identify any that qualify as a Financial Conflict of Interest on the SFI Form. (42 CFR 50.604) (d))
- 6.1.5. Work collaboratively with investigator(s) to develop a management plan, if required.
- 6.1.6. Report SFI disclosure to the funding agency via NIH's FCOI report portal, if required.
- 6.1.7. For PHS funded work, make disclosure/management plan information available within 5 days of request as required.
- 6.1.8. Make the Financial Conflict of Interest policy available on LMU's website via its Research Compliance website. (42 CFR 50.604) (a))

6.2. Designation of Institutional Official

The Executive Director of Research will serve as the Research Integrity Officer (RIO) responsible for compliance with Financial Conflict of Interest regulations. (42 CFR 50.604) (d))

The Research Integrity Officer will collect and perform an initial review of all disclosed SFIs from 1) Investigators who are planning to participate in, or are participating in, the PHS-funded research 2) Investigators who are newly participating in the research project, and 3) for existing Investigators who disclose a new SFI to determine if a FCOI exists. The signed original SFI disclosure form will be retained in the RIO office, and a copy will be shared at the Award Set Up meeting with (Post Award Accounting Administration (PAAA)) and be filed in the associated grant file with PAAA. The RIO will develop and implement management plans, as needed to manage FCOIs. The RIO may submit an FCOI to the University Research Committee for review in complex cases. (42 CFR 50.605) (a) (1))

6.3. Management Plan

After a determination is made by the RIO that there may be a potential or actual FCOI, the RIO, in consultation with the University Research Committee, will develop and implement a management plan (see below) that shall specify the actions that have been, and shall be, taken to manage such FCOI until completion of the project. (42 CFR 50.604 (g) and 50.605(a)(4))

These plans will be developed collaboratively with the PI and all other parties that are part of the management plan and examples of conditions or restrictions that may be employed to manage conflicts include:

- Public disclosure of significant financial interests (e.g., when presenting or publishing the NIH funded research),

- For research projects involving human subjects research, disclosure of significant financial interests directly to participants,
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of research against bias resulting from the financial conflict of interest;
- Modification of research plan;
- Change of personnel, such as undergraduate students, lab coordinator, or a post doc, or personnel responsibilities or disqualification from participation in all or a portion of the research;
- Reduction or elimination of the financial interest (e.g., sale of an equity interest);
- Severance of relationships that creates financial conflicts.

If it proves impossible to reach an acceptable FCOI Management Plan, funds will be returned to the sponsor.

The IRB must be notified of any management plan, if an investigator has, a FCOI and is working on research involving human subjects.

6.4. Appeals

An investigator may appeal the RIO's recommendation to the University Research Committee. In the event the committee created the management plan, an investigator can submit a request for re-consideration. An investigator dissatisfied with his/her appeal may submit his/her disagreement in writing to the Provost for final resolution.

6.5. Reporting

Prior to expenditure of any funds or within 60 calendar days for any interest that LMU identifies as conflicting subsequent to LMU's initial report under a PHS-funded research project, LMU must provide the PHS Awarding Component with a Financial Conflict of Interest (FCOI) report regarding the related FCOI and implemented Management Plan. This report must include the following information:

- Grant/Contract Number
- Project Director/Principal Investigator (PD/PI) or contact PD/PI
- Name of investigator with FCOI
- Nature of the FCOI (e.g., equity, consulting fees, or honoraria)
- Whether the financial interest was managed, reduced or eliminated
- Value of the financial interest

- Description of how FCOI relates to PHS-funded research and the basis for LMU's determination that the financial interest conflicts with such research.
- Key elements of the Management Plan

Annual updates are also required for the duration of the research project and must include:

- Status of the FCOI
- Changes to the management plan

Initial, annual, and revised FCOI reports will also be sent to the PHS component following a retrospective review to update a previously submitted report, if appropriate. (42 CFR 50.604 (h)); (50.605 (b))

6.6. Retrospective Review

Identification of untimely or any delayed disclosure of an SFI by an investigator requires LMU's University Research Committee review within 60 days of determination: if it is related to PHS-funded research and if an FCOI exists. Determination that there is an unmanaged FCOI requires:

1. Implementation – at least in the interim – of a management plan that specifies the actions that have been and will be taken to manage the FCOI moving forward; and
2. Completion of a retrospective review of the Investigator's activities and the PHS-funded research to determine whether any PHS-funded research or a portion of it, conducted during the noncompliance period was biased in the design, conduct or reporting of such research within 120 days of the Investigator's noncompliance. Such noncompliance may have occurred due to the Investigator's failure to disclose an SFI, which is deemed an FCOI, LMU's failure to review or manage said FCOI, or the Investigator's failure to comply with a management plan. (42 CFR 50.605 (a)(3))

6.7. Mitigation Report (42 CFR 50.605 (a)(3)(iii))

As appropriate, LMU shall update the previously submitted FCOI report specifying the actions taken to manage the FCOI moving forward. If the institution determines there was bias it must notify the PHS awarding component (NIH Department) promptly and submit a mitigation report to that component.

The mitigation report and process must include:

1. The key elements documented in the retrospective review and a description of the impact of the bias on the research project and the institution's actions/action plan to eliminate or mitigate the effect of the bias in support of PI in eliminating or mitigating bias.
2. Subsequently the institution will submit annual reports, as per the regulation.

Depending on the nature of the FCOI, the institution may decide that additional interim measures are necessary regarding the Investigator's participation in the PHS-funded research project between the date of the FCOI or the Investigator's noncompliance is determined and the completion of the institution's retrospective review.

If a FCOI is not identified or managed in a timely manner (i.e. non-compliance to the disclosure requirements or management plan), LMU's University Research Committee will complete a retrospective review of the Investigator's activities and research project to determine whether the research was biased. If bias is found, LMU will notify PHS and submit a Mitigation Report. (42 CFR 50.605 (a)(3) and (i)-(iii))

6.8. Records

Records of the Investigator's significant financial interests and LMU's review and management of the SFI, will be retained by the University for (i) three years from the date of submission of the final expenditures report (in the case of grants and cooperative agreements); or (ii) three years from the final payment (in the case of research contracts), or (iii) resolution of any government action involving the records, or (iv) as otherwise required by law. (50.604 (i))

6.9. Public Accessibility

In accordance with PHS regulations, LMU will respond to requests to make available information concerning identified FCOI's held by senior/key personnel publically accessible prior to the expenditure of funds by written response within five business days of a request. The response shall include the Investigator's name, position relative to the research project, the name of the entity in which the SFI is held, nature of the SFI, approximate dollar value of SFI, or a statement that the value cannot be readily determined. This information will be updated at least annually. Newly identified FCOIs will be updated within 60 days of being identified. All information will remain available for three years from the date it was most recently updated. (42 CFR 50.604 (a) (5) (i)-(IV))

6.10. Sub Recipients

For PHS research that involves subcontractors, sub grantees or sub awardees (collectively "sub recipients") at other institutions, LMU requires written agreement terms from sub recipients that they have a conflict of interest policy that conforms to the requirements of all applicable regulations, including time periods to meet disclosure and/or financial conflict of interest (FCOI) reporting requirements.

If any sub recipient does not have such a conflict of interest policy, then LMU shall require that the sub recipient follow the university's policy, and sub recipient's failure to do so upon request from LMU shall be considered grounds for immediate termination by LMU of any applicable subcontract or sub award. Any written agreement terms required by the university shall contain the provision that sub recipients will report to LMU as the awardee institution any identified FCOI in sufficient time to allow LMU to report the FCOI to meet its reporting obligations. (42 CFR 50.604 (c) and (1) (i) – (iii))

6.11. Consequences of Non-Compliance

When an investigator is found to have violated this policy or the terms of the management plan, the RIO with guidance from the University Research Committee will make recommendations to the Provost who may impose sanctions consistent with policy. Disciplinary action may vary from a warning to termination of employment, in line with LMU's employment policy and appeal process. In cases of violation, the RIO (or designee) will notify the appropriate funding agency. (42 CFR 50.604 (j)) (50.606(a))

7. RELATED DOCUMENTS

<u>Policy or Document</u>	<u>Web Address</u>
<u>NIH FCOI Regulation</u>	https://grants.nih.gov/grants/policy/coi/index.htm
<u>SFI Form</u>	https://academics.lmu.edu/orsp/services/policiesandforms/
Click here to enter text.	Click here to enter text.