

Loyola University Maryland Conflict of Interest Policy Pertaining to Sponsored Projects

Policy Statement

Loyola University Maryland is committed to creating an environment that promotes the responsible conduct of research in order to protect the credibility and integrity of the University, its faculty, administrators, and staff, as well as to ensure continued public trust and confidence in its sponsored research activities. This commitment requires the University to ensure that there is no reasonable expectation that research results are biased by the external commitments and financial interests of those who are responsible for its design and execution.

To that end, Loyola has established this Conflict of Interest policy. This policy requires investigators to disclose any significant financial interest that may affect or appear to affect the design or conduct of any sponsored project at the University and establishes procedures by which any conflicts of interest may be appropriately avoided or managed. In so doing, the University will promote objectivity in research and protect the credibility of research conducted by Loyola personnel.

Scope

This policy pertains to all sponsored projects. However, in the event that an agency or organization should adopt a more restrictive policy, Loyola will implement these more restrictive requirements on an as-required basis.¹

Conflicts of interest can arise in sponsored projects when an investigator has one or more financial interests that could be affected by, or appear to be affected by, the results of the research project. Investigators have an obligation not to let outside financial interests interfere with the conduct of research.

A conflict of interest occurs when an independent observer might reasonably question whether an individual's professional actions or decisions are determined by considerations of personal gain, financial or otherwise. Conflicts of interest can arise naturally from an investigator's engagement with the world outside the campus community and the mere existence of a conflict of interest does not necessarily imply wrongdoing. However, conflicts of interest, both actual and potential, must be disclosed and evaluated to ensure that the conduct of research is not inappropriately biased.

Definitions

¹For example, the U.S. Department of Health and Human Services amended its regulations related to financial disclosure on August 25, 2011. To comply with regulations when applying for funding from the National Institutes of Health (NIH) and other entities of the Public Health Services (PHS), Loyola utilizes its Conflict of Interest Policy Pertaining to Sponsored Projects supported by the National Institutes of Health and other entities of the Public Health Services.

Investigator means a principal investigator/project director, co-principal investigator, or any other person at the University who is responsible for the design, conduct, or reporting of research or educational activities funded, or proposed for funding, by an external sponsor. In this context, the term "Investigator" includes the individual's spouse and dependent children.

Significant Financial Interest means anything of monetary value, including but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights, and royalties from such rights). The term does not include:

1. Salary, royalties, or other remuneration from Loyola University Maryland;
2. Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
3. Income from service on advisory committees or review panels for public or nonprofit entities;
4. An equity interest that when aggregated for the Investigator and the Investigator's spouse and dependent children, meets both of the following tests:
 - (a) does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value; and
 - (b) does not represent more than a five percent (5%) ownership interest in any single entity; or
5. Salary, royalties or other payments from an entity other than Loyola University Maryland that when aggregated for the Investigator and the Investigator's spouse and dependent children over the next twelve months, are not expected to exceed \$10,000.

Appropriate Dean means the Dean of the School or College overseeing the Investigator's department. If the Investigator is not from a School or College, Appropriate Dean means the Vice President overseeing the area or his or her designee.

Procedures

General Disclosure Requirements

Each Investigator who proposes to engage in sponsored research funded by any external organization is required to disclose the following financial interests:

1. Any Significant Financial Interest (over \$10,000) of the Investigator that would reasonably appear to be affected by the research or educational activities funded, or proposed for funding, by an external sponsor; or
2. Any Significant Financial Interest of the Investigator (over \$10,000) in an entity whose financial interest would reasonably appear to be affected by the research or educational activities funded, or proposed for funding by an external sponsor.

Regardless of the above minimum requirements, an Investigator or other faculty or staff member may choose to disclose any other financial or related interest that could present a conflict of interest.

All Significant Financial Interests must be disclosed prior to the time a proposal is submitted. Each Investigator who is submitting a proposal to a government agency shall complete a Significant Financial Interests Disclosure Form (“Disclosure Form”) and submit it along with the routing form to facilitate this process.

All Investigators must submit updated Disclosure Forms if at any time from the date the proposal is submitted through the termination of the grant award, new reportable Significant Financial Interests are obtained or if there is a material change in an existing Significant Financial Interest. The updated Disclosure Form should be submitted to ORSP within 30 days of the change.

Review of Disclosure Forms and Management of Conflicts of Interest

The Office of Research and Sponsored Programs (ORSP) will be responsible for the preliminary review of the Disclosure Form. In the event that the faculty member has indicated “no” for all responses on the form, the ORSP will maintain the form on file with the proposal. If the faculty member or applicant has indicated “yes” the ORSP will request that the Principal Investigator(s) provide supporting documentation describing in detail on a separate sheet the nature and extent of the affiliation, ownership interest or income as appropriate. The supporting documentation along with a copy of the Disclosure Form should be placed in a sealed envelope marked “Confidential”. The Appropriate Dean (“the Dean”) will be responsible for the initial review of all Disclosure Forms to determine if any disclosed Significant Financial Interest poses an actual or potential conflict of interest that could directly and significantly affect the design, conduct, or reporting of the proposed sponsored project.

If the Dean finds that no further action is warranted, the Dean will notify the ORSP in writing. The ORSP will keep this notification on file with the proposal.

If it is determined that further review is necessary, the Dean will convene a meeting with the Investigator and any other appropriate University officials to discuss the disclosure. If, after discussion, the Dean determines that appropriate conditions and/or restrictions are necessary to manage, reduce, or eliminate an actual or potential conflict of interest, such conditions will be imposed. The management plan may include restrictions such as:

- Public disclosure of Significant Financial Interests;
- Review of research protocol by independent reviewers;
- Monitoring of research by independent reviewers;
- Modification of the research plan;
- Disqualification from participation in all or a portion of the research funded;
- Divestiture of Significant Financial Interests; or
- Severance of relationships that create actual or potential conflicts of interest.

The management plan will be detailed in writing and signed by the Investigator, the Dean, and the Vice President for Academic Affairs. A copy of the management plan will be kept on file by the ORSP.

No grant funds may be expended from an award until all parties have signed the management plan. Further, if the sponsor requires reports regarding the management of the conflict of interest these must be submitted to the sponsor *prior to the expenditure of any funds under an award*.

Whenever an Investigator has violated this policy or the terms of the management plan, sanctions may be taken by the Vice President for Academic Affairs that could include actions up to and including dismissal and termination of employment. Sanctions imposed upon faculty members will be consistent with the policies and procedures set forth in the Rank and Tenure Policy Statement and the Faculty Handbook.

An Investigator may appeal the sanction to the President, who will review the file maintained by ORSP and may meet with the Investigator, the Dean, or other appropriate University personnel in order to evaluate whether the sanction is appropriate. The President may approve the sanction or disapprove the sanction and direct the Vice President for Academic Affairs to revise it. The decision of the President shall be final.

If the violation results in a proceeding under the University's policies regarding misconduct in scholarship, then a decision on sanctions will be deferred until a determination is made regarding the alleged misconduct.

Reporting

The ORSP will be responsible for overseeing any required reporting of violations of this policy to Federal agencies and or sponsors. The sponsor may take its own action as it deems appropriate, including the suspension of funding for the Investigator until the matter is resolved.

Recordkeeping

Records of investigator financial disclosures and actions taken to manage potential conflicts of interest shall be retained by the ORSP, in locked storage, until 3 years after the later of the termination or completion of the award to which they relate, or the resolution of any government action involving those records.

Subcontractors

Collaborators/subrecipients/subcontractors from other institutions must either affirm that they are in full compliance with federal conflict of interest regulations or abide by the terms of this policy. .

Investigators also must comply with the Financial Services Department's Conflict of Interest policy when purchasing goods and/or services for use in any sponsored project. This policy may be obtained from the Financial Services Department or obtained from their website.