Loyola University Maryland
Conflict of Interest Policy Pertaining to Sponsored Projects Supported by the National Institutes of Health and other entities of the Public Health Services

Background

The Department of Health and Human Services amended its regulations related to financial disclosure on August 25, 2011. All institutions applying for funding by the National Institutes of Health (NIH) and other entities of the Public Health Services (PHS) are required to have a policy compliant with these news 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 1, subchapter D, part 50 and 45 CFR subtitle A, subchapter A, part 94.

This policy is adopted in addition to and as a supplement to the Loyola University Maryland Conflict of Interest Policy Pertaining to Sponsored Projects.

Policy Statement

Loyola 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 policy sets forth procedures and guidelines to be followed by all Investigators who are involved in PHS-funded research.

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 funded by the National Institutes of Health and other Public Health Services entities.

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

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, partner and dependent children.

Significant Financial Interest means one or more of the following interests, if it reasonably appears to be related to the Investigator's institutional responsibilities, including all research, teaching, and/or service to the University.

1. With regarded to any publicly traded entity, a Significant Financial Interest exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure and the value of any equity interest in the entity as of the date of the disclosure, exceeds $5,000. Remuneration includes any salary and/or any payment for services not otherwise identified as salary (e.g. consulting fees, paid authorship, honoraria); equity interest includes any stock, stock option, or other ownership interest as determined through reference to public prices of other reasonable measures of fair market value.
2. 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 12 months preceding the disclosure exceeds $5,000 or when the Investigator or the Investigator's spouse, partner, or dependent interest owns any equity interest regardless of dollar value.
3. With regard to intellectual property rights and interests (e.g. patents and copyrights), a Significant Financial Interest exists upon receipt of any income related to such rights.
4. Any occurrence of sponsored travel (i.e. that which is paid on behalf of the Investigator and not reimbursed by the Investigator) or any reimbursed travel related to the Investigator's institutional responsibilities with the exception of any travel reimbursed or sponsored by a federal, state or local government agency, an institution of higher education, an academic teaching hospital, or a research institute that is affiliated with an institution of higher education. The Investigator must disclose the purpose of the trip, the identity of the sponsor and/or organizer, the destination and the duration. Additional information, such as the estimated cost of travel, may be required.

Exclusions. The term Significant Financial Interest does not include:

1. salary, royalties, or other remuneration from Loyola University Maryland.
2. income from investment vehicles such as mutual funds or retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;
3. income from seminars, lectures or teaching engagements 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; or

4. 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.

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 for Disclosure

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 $5,000) 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 $5,000) 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 PHS/NIH Significant Financial Interests Disclosure Form ("Disclosure Form") and submit it along with the routing form to facilitate this process.

All Investigators must submit an updated NIH/PHS Disclosure Forms upon award and annually thereafter through the termination of the grant award. Additionally Investigators must report all new reportable Significant Financial Interests and/or any material change in an existing Significant Financial Interest 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.

Training

Each Investigator must complete training on this Policy preior 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 Dean in the event that this Policy is substantively amended in a manner that affects the requirements of the Investigators, or if it is determined that the Investigator has not complied with this policy or with a management plan related to their activities. The ORSP shall keep records of Investigators who are trained and the date of the training.

Subcontractors

Collaborators/subrecipients/subcontractors from other institutions must either comply with this policy or provide assurances that their institutions are in compliance with the policies of the PHS regarding conflict of interest and that their portion of the project is in compliance with their institutional policies.

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.