Research Financial Conflict of Interest

UNIVERSITY POLICY #235

Authority:
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SECTION 1: Purpose

1.1 To establish guidelines for managing and avoiding financial conflicts of interest in approved research. This policy relates to all faculty and staff engaged in research to ensure that financial or other incentives do not negatively impact the collection, analysis and interpretation of data, scientific objectivity and integrity.

SECTION 2: Definitions

2.1 **Externally Funded Research**. Research funded by a public or private entity separate from the university through a gift, grant, award, contract, cooperative agreement or similar arrangement.

2.2 **Financial Conflict of Interest**. A financial conflict of interest exists when the university, through its designated officials reasonably determines that an investigator's significant financial interest is related to an externally funded research project and could directly and significantly affect the design, conduct or reporting of the research.

2.3 **Institutional Responsibilities**. An investigator's institutional responsibilities refers to professional responsibilities on behalf of the institution including, but not limited to, research, research consultation, teaching, extension/outreach, professional practice, and institutional committee memberships.

2.4 **Investigator.** Project director, principal investigator, and any other person, regardless of title or position, who is responsible for the design, conduct or reporting of university research, which may include, for example, collaborators or consultants. This does not include individuals who perform only incidental or isolated tasks related to a university research project.

2.5 **Significant Financial Interest**.

2.5.1 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:

2.5.1.1 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;

2.5.1.2 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 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

2.5.1.3 Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

2.5.2 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, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education. The disclosure must include the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

2.5.3 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; income from investments, such as mutual funds and retirement accounts, as long as the investigator does not directly control the investment decisions made; income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, and Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

SECTION 3: Procedure

3.1 **Conflict of interest disclosure.**

3.1.1 All individuals who meet the definition of investigator and all staff involved in the design, conduct, or reporting of research must complete a Financial Conflict of Interest Disclosure Form annually. Updates to the disclosure must be made within thirty days if the individual acquires any new financial interests, external professional activities, or business or financials transactions that were previously unreported, or if changes occur in the circumstances of a previously reported transaction or activity.

3.1.2 In addition to financial disclosures, faculty, staff and students who have participated as project directors, principal investigators, or senior/key personnel on Public Health Service-funded research projects in the past twelve months or who reasonably expect to receive new PHS funding during the current year must disclose the occurrence of any reimbursed or sponsored travel related to their institutional responsibilities. Public Health Service agencies include the National Institutes of Health, Food and Drug Administration, Centers for Disease Control and Prevention, Indian Health Service, Health Resources and Services Administration, Substance Abuse and Mental Health Services Administration, Agency for Healthcare Research and Quality, Centers for Medicare & Medicaid Services, Administration for Children and Families, or Administration on Aging.

3.2 **Review of financial disclosures for possible conflicts of interest.**

3.2.1 Conflict of Interest Disclosure Forms will be reviewed by the Conflict of Interest Advisory Committee, which will consist of the Vice President of Finance and Administration, General Counsel, Director of Grants and Revenue, two college deans, and the Provost. The committee will review the forms within two weeks of submission. The committee will determine whether a financial conflict of interest with an external entity is related to a particular research project on a case-by-case basis using the following general considerations:

3.2.1.1 Is the financial interest with a sponsor, subcontractor, supplier or lessor of goods, materials, proprietary information, services, or facilities of the investigator's current or proposed research?

3.2.1.2 Will the entity likely make use of the research or scholarly work – either directly or indirectly?

3.2.1.3 Is the financial interest with a member of an industry, trade, or advocacy group that funds the involved research or scholarly work?

3.2.1.4 Is the entity manufacturing, commercializing or developing a product that is being used, evaluated, or further developed by the research or scholarly work at issue?

3.2.1.5 Will the entity receive materials, data, or other information from the investigator?

3.2.1.6 Is the entity a competitor of the investigator's sponsor?

3.2.1.7 Does the entity have some other relationship not described above that could be related to or could be affected by the investigator's university responsibilities?

3.2.2 If the committee determines that a financial interest is reasonably related to an investigator's institutional responsibilities, the committee will then review the potential impact of the financial interest on the following:

3.2.2.1 The integrity of the research;

3.2.2.2 Risks to the rights and safety of human research subjects;

3.2.2.3 Risks to the rights and obligations of students and trainees participating in research;

3.2.2.4 The availability of research results to the scientific community for use in the public interest; and

3.2.2.5 The appearance of a conflict of interest.

3.3 **Conflict of Interest Management.** After the Conflict of Interest Advisory Committee has completed its review, it will determine the appropriate management plan and will communicate that plan in writing. Conflict of interest management plans may include one or more of the following:

3.3.1 Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research; to staff members working on the project; etc.);

3.3.2 For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;

3.3.3 Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the Financial Conflict of Interest;

3.3.4 Modification of the research plan;

3.3.5 "Change of personnel or personnel responsibilities, or disqualifications of personnel from participation in all or a portion of the research;

3.3.6 Reduction or elimination of the financial interest (e.g., sale of an equity interest); or

3.3.7 Severance of relationships that create financial conflicts.

3.4 Management plans will include a description of the key elements including the following:

3.4.1 The role and principal duties of the conflicted investigator in the research project;

3.4.2 Conditions of the management plan;

3.4.3 How the management plan is designed to safeguard objectivity in the research project;

3.4.4 Confirmation of the Investigator's agreement to the management plan;

3.4.5 How the management plan will be monitored to ensure Investigator compliance; and

3.4.6 Other information as needed.

3.5 As required by Public Health Service rules, the university must report potential financial conflicts of interest involving federally-sponsored research to the sponsor prior to the expenditure of federal research funding, or within sixty days of the university identifying the potential financial conflicts of interest after a project has begun. In addition, the university must also submit an annual financial conflict of interest update to the agency specifying whether the financial conflict of interest is still being managed or explaining why the financial conflict of interest no longer exists. Annual reports must be submitted for the duration of the project period at the time the university is required to submit an annual progress report.

3.6 If an investigator fails to disclose a significant federal interest that the Conflict of Interest Advisory Committee determines to be a financial conflict of interest related to a particular research project, if the university fails to review or manage a financial conflict of interest, or if an investigator fails to comply with the terms of a conflict of interest management plan, the university will within 120 days complete a retrospective review of the investigator's research to determine whether there was any bias in the design, conduct or reporting of the research.

SECTION 4: Record Retention

4.1 Per federal regulations, all records of investigator disclosures of financial interests and the university's review of, and/or response to such disclosure, and all actions taken under this policy will be maintained for at least three years from the date of the Financial Conflict of Interest Form submission.

SECTION 5: Investigator Training

5.1 The federal financial conflict of interest regulations require the university to provide formal conflict of interest training to investigators. Training must be completed prior to engaging in PHS-funded research and at least every four years. Training must also be completed immediately under the following circumstances:

5.1.1 Institutional financial conflict of interest policies change in a way that affects investigator requirements;

5.1.2 An investigator is new to the institution;

5.1.3 The institution finds that an investigator is not in compliance with the institution's financial conflict of interest policy or management plan.