

POLICY IMPLEMENTATION-
MANAGING CONFLICTS OF INTEREST IN SPONSORED PROJECTS

The **Senior Associate Vice Provost for Research Administration (SAVPRA)** is responsible for maintaining the University’s Policy on Managing Conflicts of Interest in Sponsored Projects (“Policy”) and for ensuring that it remains compliant with federal regulations. The SAVPRA is also responsible for ensuring University Personnel engaged in or managing sponsored projects, as well as sponsored project sub-recipient personnel engaged in or managing sponsored projects, are in compliance with this Policy.

The **Office of Research Administration (ORA)** maintains records of all conflicts of interest disclosures pertaining to sponsored projects and provides reports of such to federal regulators as required. Also, the ORA provides training and advice/guidance to University Personnel, including the Outside Interest Committee, regarding implementation of and compliance with this Policy.

The **Outside Interest Committee (OIC)** helps mitigate conflicts of interest in sponsored projects referred to it for consideration to protect the interests of the University Personnel, including investigators, scholars, and students, research subjects and the University community at large. Members of the OIC are appointed by the Senior Vice Provost for Research and include faculty, non-faculty employees, and administrators. Members of the OIC recuse themselves from consideration of individual or institutional conflicts of interest that relate to their own conflicts of interest.

The **Senior Vice Provost for Research (SVPR)** is responsible for working with the OIC and other University Personnel to develop and implement management plans necessary to mitigate conflicts of interest in sponsored projects as necessary.

The **Provost** has ultimate responsibility for this Policy. The Provost may, at his/her discretion, refer selected issues or matters to the Audit Committee of the Board of Trustees.

A. Disclosure of Significant Financial Interests

1. Individual Significant Financial Interests

At the time a proposal is developed for submission to a potential sponsor, or when a project is submitted to a relevant review body (such as the Institutional Review Board (IRB), the Institutional Animal Care and Use Committee (IACUC), and affiliated IRBs), University Personnel must disclose significant financial interests to the ORA.

For sponsored projects funded by the Public Health Service (PHS), which includes but is not limited to the NIH, all University Personnel must complete and submit disclosure forms; however, for non-PHS funded sponsored projects, only Senior/Key Personnel must submit disclosure forms.

Disclosure requirements are broad, in order to provide adequate protection for University Personnel, the University and affiliated institutions, and for members of the public. It is important to recognize that a disclosure requirement does not indicate that the activity in question is objectionable; indeed, disclosure is required in connection with many activities in which members of the University are expected to engage, such as technology commercialization, or are otherwise praiseworthy, such as the receipt of honorary awards.

On a sponsored project-by-sponsored project basis, University Personnel must disclose certain significant financial interests to the University that they, their spouses, and/or dependent children possess. The scope of the term “actual or potential” used below encompasses the 12-month period prior to and/or after the disclosure.

Specifically, University Personnel must disclose the following significant financial interests:

- Actual or potential income (e. g. gifts, favors, loans, services, salary, consulting fees) and/or equity interest(s), exceeding \$5000 when aggregated, from/in a publicly traded entity that sponsors or supports the project, creates a financial position that reasonably relates to their institutional responsibilities, or could reasonably appear to be affected by the outcome of their sponsored project activities or proposed sponsored project activities.
- Actual or potential income (e. g. gifts, favors, loans, services, salary, consulting fees) exceeding \$5000 when aggregated from a non-publicly traded entity that sponsors or supports the project, reasonably relates to their institutional responsibilities, or could reasonably appear to affect the outcome of their institutional responsibilities.
- Any actual or potential equity interests in a non-publicly traded entity that sponsors or supports the project, creates a financial position that reasonably relates to their institutional responsibilities, or could reasonably appear to be affected by the outcome of their sponsored project activities or proposed sponsored project activities.
- Intellectual property rights and interests that reasonably relate to their institutional responsibilities, upon the receipt of income related to such rights and interests, exceeding \$5000 when aggregated.
- Reimbursed or sponsored travel for University Personnel, their spouses, and/or dependent children reasonably related to University Personnel’s institutional responsibilities, exceeding \$5000 when aggregated.
- Any managerial interest (paid or unpaid).

The following exclusions apply to the above-mentioned disclosures:

- Salary, royalties, or other remuneration paid by the University to University Personnel if University Personnel are currently employed or otherwise appointed by the University, including intellectual property rights assigned to the University and agreements to share in royalties related to such rights.
- Income from investment vehicles, such as mutual funds and retirement accounts, as long as University Personnel do 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 in 20 U.S.C.

1001(a) (Institution of Higher Education), an academic teaching hospital, a medical center, or a research institute with an Institution of Higher Education affiliation.

- Income from service on advisory committees or review panels for a Federal, state, or local government agency, or 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.
- Travel reimbursed or sponsored by Federal, state, or local government agency, or 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.
- Grants and contracts administered through the University.

University Personnel must also disclose for themselves and on behalf of their spouses and/or dependent children, on an ad hoc basis, when any new significant financial interests are discovered or acquired during the period in which a sponsored project agreement is active. Specifically, University Personnel have 30 calendar days to disclose the new significant financial interest or eliminated significant financial interest.

Whenever University Personnel have any doubts as to whether a financial interest must be disclosed, University Personnel should err on the side of disclosing the interest.

2. Institutional Significant Financial Interests

In order to manage institutional conflicts of interest in sponsored projects, the following University organizations must provide an annual report to the ORA as follows:

- The Senior Vice President of Finance and Chief Financial Officer must provide a list of the entities in which the University has any significant financial interest.
- The Board of Trustees Audit Committee must provide a list of the entities in which members of the Board of Trustees and senior officials of the University, their spouses, and/or dependent children, have any significant financial interests. The list of entities provided need not contain the identities of the University Personnel who have a significant financial interest in those entities.
- The Senior Associate Vice Provost for Technology Commercialization must provide a list of the University's equity holdings and technology licenses.

Also:

- Reports of potential institutional conflicts relating to research through the annual process are forwarded to the Senior Associate Vice Provost for Research Administration for evaluation.
- Potential Institutional conflicts of interest disclosed through the event driven and annual research disclosure are evaluated by the Office of Research Administration and referred to the OIC according to established guidelines.

B. Review of Disclosures

The ORA conducts an initial review of all significant financial interest disclosures it receives. If necessary, the ORA obtains additional information from relevant University Personnel. The ORA then identifies those determinations that must be referred to the OIC and those determinations that may proceed without the engagement of the OIC. When the ORA refers a determination to the OIC, the relevant University Personnel and principal investigator are notified of the referral. When the ORA determines that a conflict does not exist but should be managed to mitigate any potential risk, the ORA notifies the relevant University Personnel and principal investigator of this decision and provides an explanation thereof.

In determining whether to refer a matter to the OIC, the ORA considers the significance of University Personnel's disclosed financial interest and whether the disclosed financial interest could significantly and directly impact the design, conduct, and reporting of research. Some factors that are considered when reaching a determination are as follows:

- Relatedness between disclosed financial interest and sponsored project
- Project Role of the University Personnel
- Likelihood of actual or perceived bias
- Type of significant financial interest disclosed
- Value and/or magnitude of the significant financial interest
- Type and level of influence or impact to or from the significant financial interest
- Compliance History of University Personnel
- Nature of research
- Transparency
- Likelihood to influence professional judgment
- Type and depth of relationship between University Personnel and financial entity
 - Number of relationships
 - Nature of relationships
- Goal of the sponsored project
- University Personnel's suggestions/thoughts disclosed on the significant financial interest disclosure forms

Materials or information that may be used in the determination process

- Statement of Work
- Interview with PI and/or University Personnel
- Significant Financial Interest Disclosure Forms 1 & 2
- For OIC, COI Memo drafted by ORA
- Website of financial entity, if applicable
- Information on the web regarding University Personnel and financial entity

For each sponsored project, the ORA also reviews potential institutional conflicts of interest that may or may not have been disclosed, such as potential conflicts identified on review of the annual reports submitted by the Senior Vice President of Finance, Chief Financial Officer, the

Board of Trustees, the Office of Development, and the Office of Technology Commercialization. The ORA then identifies those activities that must be reviewed by the OIC and notifies the OIC of those activities as appropriate.

C. Development of Management Plans for Conflicts of Interest

In reviewing referrals forwarded by the ORA, the OIC assumes that the project cannot be undertaken without a suitable management plan. In some cases, the OIC may find that the conflict is unmanageable and may recommend that the sponsored project be terminated.

If a conflict of interest can be managed, the OIC is responsible for preparing a management plan for each project to mitigate the conflict of interest. Management plans are developed according to the nature of the conflict of interest and the sponsored project, e.g., whether there is an institutional as well as an individual conflict of interest and whether the investigator is conducting bench, animal, or human subjects research.

A management plan developed to manage a conflict of interest in a sponsored project may include but is not limited to the following actions:

- Require University Personnel to recuse him/herself from particular business decisions.
- Require University Personnel to reduce, modify, defer, waive, or eliminate the significant financial interest that is the source of the conflict, such as equity holdings, royalty income, stock options, and milestone payments.
- Require University Personnel to inform certain persons or institutions about the conflict of interest and the management plan (such as the ORA, IRBs, IACUCs, subjects, state and federal officials, project sponsors, co-investigators, colleagues, junior colleagues, students, trainees, members and prospective members of University Personnel's laboratory, journals to which manuscripts about the project are submitted, and media, lay, and professional audiences with whom the research or other activity is discussed orally or in writing).
- Prevent University Personnel from serving as the principal investigator, co-principal investigator, or investigator on the research project.
- Require University Personnel to refrain from participating in certain activities or aspects of the activities related to the sponsored project (such as requiring IRB members with conflicts of interest in connection with research protocols to recuse themselves from deliberations on those protocols, or, where compelling circumstances exist to allow certain research stages or activities to proceed despite a conflict of interest, restricting University Personnel's roles to those stages and activities, including establishing a point in time for stopping participation and strategies to keep University Personnel's involvement at a minimum).
- Require University Personnel's activities to be approved by additional individuals or entities (such as Deans, Department Chairs, or Program Chairs).
- Prohibit the University from accepting sponsor support from companies founded by University Personnel.
- Require the University to reduce or modify its financial stake in an outside entity or sponsored project.

- Require others to review academic decisions in which University Personnel participate.
- Require independent involvement in the project (such as in recruiting and selecting subjects, participating in or designing the consent process, providing clinical treatment to subjects apart from the research intervention or procedures, monitoring data, reviewing study design, collecting data, and determining authorship status or order).
- Require University Personnel to vacate a position.
- Prohibit University Personnel from disclosing confidential institutional information or channeling discoveries to an outside entity.
- Prohibit University Personnel from serving on the board of directors of the outside entity, or as an officer, member of the scientific advisory board, member of a speakers' bureau, or consultant.
- Prohibit the project from taking place on the University campus.
- Enhance or create firewalls or other conflict-management approaches to separate financial and sponsored project decision-making.
- Require continued oversight of the activity by the OIC.

Before finalizing a management plan, the OIC must review it with the appropriate Dean or Director; in the case of University officers, with the appropriate senior official; and in the case of non-University-based, non-faculty employees, with the senior University official who has oversight over them.

If the Dean, Director, or senior official and the OIC are unable to agree on the terms of the management plan, the matter is referred to the SVPR for appeal.

D. Appeals

If University Personnel are dissatisfied with a determination of the OIC, University Personnel may submit a written appeal to the SVPR within 15 days of receipt of the decision. If the SVPR upholds the OIC's determination, the SVPR's decision is final.

If the appealing party is the SVPR, the SVPR may submit a written appeal to the Provost within 15 days of receipt of the decision.

E. Ensuring Management Plan Compliance

Whenever a management plan is implemented, the ORA will monitor University Personnel's compliance with the management plan on an ongoing basis until the completion of the sponsored project.

F. University Reporting and Management Requirement under 42 CFR Part 50, Subpart F

Per 42 CFR Part 50, Subpart F, the ORA will review all significant financial interest disclosures and will determine how to effectively manage any resulting conflicts in accordance with the implementation procedures described herein. The ORA will report a conflict of interest related to Public Health Service (PHS)-funded sponsored projects to the PHS awarding component prior to the expenditure of funds and within 60 days of identifying a new conflict of interest.

The report to the PHS Awarding component will include information sufficient to enable the PHS Awarding Component to understand the nature and extent of the conflict and will specify how the conflict of interest is being managed and monitored. If the failure of University Personnel to comply with 42 CFR Part 50, Subpart F has biased the design, conduct, or reporting of a PHS-funded sponsored project, the ORA will promptly notify the PHS Awarding component of the corrective action taken or to be taken. The PHS Awarding Component will consider the situation and take, as necessary, appropriate actions, which may include directions on how to maintain appropriate objectivity in the sponsored project.

In accordance with 42 CFR 50.604(e), the University will maintain records of all significant financial interest disclosures and all actions taken by the University with respect to each conflicting interest for at least three years, and in the case of PHS-funded research, from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR 74.53(b) for different situations (e.g., transferred records, instances of litigation, etc.)

G. Sanctions

Failure to comply with the Policy includes but is not limited to the following types of conduct: University Personnel providing false information, omitting required information, failing to submit a required report, failing to follow a management plan adopted in accordance with this Policy, and failing to carry out duties prescribed by this Policy.

University Personnel's failure to comply with this Policy may result in a decision by the SVPR to suspend the project or refuse to approve a new sponsored project and is also subject to the full range of University disciplinary procedures, including:

- Formal admonition.
- A letter in University Personnel's file indicating that University Personnel's good standing as a member of the University has been called into question.
- Ineligibility of University Personnel to apply for grants, IRB approval, or supervision of graduate or professional students or trainees.
- Non-renewal of appointment.
- Termination of employment.

If University Personnel fail to comply with this Policy, the OIC determines whether the matter can be handled by requiring University Personnel to comply with a corrective action plan devised by the OIC. If so, the OIC devises the plan and advises University Personnel of its requirements. If the OIC determines that the matter cannot be handled by requiring University Personnel to comply with a corrective action plan, or University Personnel refuse to comply, the OIC refers the matter, along with its recommendations about how the matter should be handled, to the SVPR.

If University Personnel other than a non-faculty employee is dissatisfied with a determination of the OIC to impose a corrective action plan, University Personnel may submit a written appeal to the Provost within 15 days of receipt of the determination.

Grievance proceedings are conducted in accordance with the procedures provided in University Faculty Handbook.