

Conflict of Interest in Sponsored Programs and Research Bowling Green State University

1. STATEMENT OF GENERAL POLICY

Bowling Green State University actively encourages and participates in interaction with both the public and private sectors as an important component of its research, education, and public service activities. The University encourages the recruitment, retention, and recognition of individuals with creative abilities who can contribute to technology transfer and interactions with external entities (both private and public) consistent with their primary commitment to the University. For the purpose of this policy, external entity means any corporation, partnership, sole proprietorship, firm, franchise, association, organization, holding company, joint-stock company, receivership, business or real estate trust, or any other non-governmental legal entity organized for profit, not-for-profit, or charitable purposes. Employees¹ involved in such interactions may receive personal financial compensation in accordance with the principles and guidelines provided in this policy. Activities supported by grants and contracts from public and private entities provide a valuable source of funds and equipment for the University. Professional interactions, including consulting arrangements, between employees and public entities and private businesses advance the University's ability to provide a high quality research and educational experience for students and enhance employment opportunities for students. University licensing of technology, employee's consulting, assisting in new business start-ups, and other forms of technology transfer to both public and private entities are critical to meeting society's needs. The University is committed to fostering the welfare of the State of Ohio through interaction by the University with other public and private entities.

At the same time, the University and its employees are committed to conducting themselves and University activities in accordance with the highest standards of integrity and ethics. This includes the identification of the potential for conflicts of interest and the assurance that they do not improperly affect University activities. It is the purpose of this policy to set forth the principles for identifying such potential for conflicts and the procedures for reviewing and addressing potential conflicts that occur.

2. CONFLICT OF INTEREST and EXTERNAL RELATIONSHIPS

A conflict of interest occurs when an employee compromises his/her professional judgment in carrying out University teaching, research, outreach, or public service activities because of an external relationship that directly or indirectly affects the significant financial interest (see below) of the employee, an immediate family member², or any associated entity³. University employees are free to have financial interests in private companies and, as set down below. Modest holdings do not fall under the purview of this policy. Nevertheless, there is the potential for a conflict of interest when an employee, an immediate member, or an associated entity has a significant financial interest in a business. Thus, it is imperative that such interests be disclosed and, if necessary, appropriate steps taken to insure that the employee's professional judgment is not compromised.

¹ Employee means any person possessing a faculty, administrative staff or classified staff appointment at Bowling Green State University.

² Immediate family includes the employee's spouse or domestic partner and children who qualify as dependents for tax purposes

³ An associated entity of an employee means any trust, organization, or enterprise over which the employee, alone or together with his/her family, exercises a controlling interest.

A financial interest is an interest in an external entity consisting of: (1) any stock, stock option, or similar ownership interest in such business, but excluding any interest arising solely by reason of investment in such business by a mutual, pension, or other institutional investment fund over which the employee does not exercise control; or (2) receipt of, or the right or expectation to receive, any income from an external entity whether in the form of a fee (e.g., consulting), salary, allowance, forbearance, forgiveness, interest in real or personal property, dividend, royalty derived from the licensing of technology or other processes or products, rent, capital gain, real or personal property, or any other form of compensation, or any combination thereof. For the purposes of this policy, a financial interest is significant, and thus disclosure is required, when the interest in a business by an employee or by an immediate family member exceeds \$5,000 in annual income of all types, or when there is any equity or ownership. Disclosure is also required when an extended family member⁴ holds a financial interest valued at ten (10) percent or more in an external entity.

There is also the potential for a conflict of interest when an employee, or any family member, serves on the board of directors or the advisory board of a business, or holds an executive position⁵ in a business. This does not mean that direct involvement in a company is necessarily precluded. Indeed, such involvement can be of important benefit to the research/instructional mission of the University by providing students with experience at the academic/industrial interface. But service on boards or in executive positions does create the potential for a conflict of interest. Thus, it is imperative that service in these capacities be disclosed and, if necessary, appropriate steps taken to insure that the employee's professional judgment is not compromised.

The potential for conflicts arises because of the nature and scope of employee's activities and responsibilities. The University assumes that potential for conflicts may occur in the normal conduct of activities. However, it is essential that the potential for conflicts be disclosed and reviewed by the University. After disclosure, the University can then make an informed judgment about a particular case and require appropriate oversight, limitations, or prohibitions on the activity in accordance with this policy.

Employees are encouraged to participate in technology transfer activities and other interactions with external entities. Such activities, referred to in this document as external relationships, may have the potential for conflicts of interest. This policy is predicated on the belief that disclosure of potential conflicts of interest itself will effectively address the vast majority of cases. In those few cases in which measures need to be taken to effectively manage potential conflicts of interest, the goal is to insure that the employee's professional judgment is not compromised while maintaining the benefits that result from entrepreneurial activities and external relationships.

Significant Combinations of Activities and External Relationships

The potential for a conflict interest arises when certain behaviors on the part of the employee occur and are coupled to the existence of certain external relationships. Some combinations (Category I below) are assumed to not have potential for a conflict of interest. Other combinations represent sufficient potential

⁴ Extended family of an employee includes children who do not qualify as dependents for tax purposes, parents and siblings.

⁵ Executive position refers to any position that includes responsibilities for a significant segment of the operation or management of a business.

for conflict of interest. (Category II below) that they require review and prior approval by the University before the employee can engage in the activity.

The following is a representative, though not inclusive, list of activities and external relationships covered by this policy. The categories are general guidelines, and application of appropriate review and oversight will always be in accordance with maintaining the full integrity or reputation of the University and its employees within the context of academic freedom.

Any combination of activity and external relationship not specifically represented in Categories I and II that an employee reasonably believes constitutes a potential conflict of interest must be discussed with the Vice President for Research in order to determine whether or not it falls under the provisions of this policy.

CATEGORY I - Relationships that do not involve a conflict of interest

The following are not considered conflicts of interest and do not require disclosure. They are appropriate, if they are consistent with other policies of the University including the Patent Policy and Copyright Policy.

- a) An employee receiving royalties and honoraria for published scholarly works, occasional lectures, and other writings or creative works if less than \$5,000 aggregate over the previous 12 months from a single entity.
- b) An employee receiving honoraria for serving as a special reviewer or serving on review panels for academic or governmental entities.
- c) An employee receiving royalties under the University's royalty-sharing policies, or another academic institution's royalty-sharing policies if less than \$5,000 aggregate over the previous 12 months from a single entity.

CATEGORY II - Combinations of activities and external relationships that have the potential for conflict of interest

The following combinations range from those that are considered to have minimal to moderate potential for conflict of interest (Section A) to those that have a moderate to high potential for conflict of interest (Section B). The activities in Section A are ordinarily appropriate following disclosure and, where necessary, the implementation of oversight or other management procedures. The activities and external relationships listed in Section B require case-by-case review and only some of the specific relationships may be approved. Special oversight or management procedures are likely to be required.

SECTION A - Combinations of activities and external relationships in which there is a minimal to moderate potential for conflict of interest

- a) An employee participating in research on a technology, process, or product developed in whole or in part by that employee in which the employee, a member of his/her immediate family, or an associated entity is entitled to receive royalties from an existing agreement with an external entity under the University's or another academic institution's royalty-sharing policies, but has no other financial interests in the project.
- b) An employee assigning students, postdoctoral fellows, or other trainees to research projects in which the employee, a member of his/her immediate family, or an associated entity is entitled to receive royalties from an existing agreement with an external entity under the University's or

another academic institution's royalty-sharing policies, but has no other financial interests in the project.

- c) An employee assigning students or other trainees to instructional projects, for example, design projects, for an external entity in which the employee, a member of his/her immediate family, or an associated entity has a significant financial interest.
- d) An employee receiving reimbursed or sponsored travel related to their institutional responsibilities from an external entity. Excluded is travel that is reimbursed or sponsored by a federal, state, or local government agency, and 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.

SECTION B - Combinations of activities and external relationships in which there is a moderate to high potential for conflict of interest

- a) An employee participating in clinical trials or evaluation or development of a technology, process, or product owned or controlled by an external entity in which the employee, a member of his/her family, or an associated entity has a significant financial interest.
- b) An employee assigning students, postdoctoral fellows, or other trainees to projects supported by an external entity (through a sponsored project⁶) in which the employee, a member of his/her family, or an associated entity has a significant financial interest, other than royalty income or the entitlement to future royalty income under university royalty-sharing policies.
- c) An employee receiving University-supervised sponsored project support (whether in dollars or in kind) for research from an external entity in which he/she, a member of his/her family, or an associated entity has a significant financial interest, other than royalty income or the entitlement to future royalty income under university royalty-sharing policies.
- d) An employee receiving sponsored project support from an external entity in which the employee or a member of his/her family serves on the board of directors or advisory board.
- e) An employee holding an executive position in an external entity engaged in commercial or research activities directly related to his/her University responsibilities.
- f) An employee taking administrative action on behalf of the University with respect to the University or any University-affiliated organization that is beneficial to in which he/she, a member of his/her family, or an associated entity has a significant financial interest.
- g) An employee taking administrative action on behalf of the University with respect to any supported research activity (a sponsored project) for an external entity in which the employee, a member of his/her family, or an associated entity has a significant financial interest in the sponsor or donor.
- h) An employee while acting in the context of his/her University duties making professional referrals to an external entity in which he/she, a member of his/her family, or an associated entity has a significant financial interest of which the employee is aware or reasonably should be aware⁷.

⁶ Sponsored project means research, training, and instructional projects involving funds, materials, or other compensation from outside sources which in accordance with university policy requires the signature of the Vice President for Research.

⁷ Only in special situations should employees be permitted to engage in this type of activity, for example, when the function is not generally available from other sources and the employee fully discloses his/her financial interest to prospective clients.

3. DISCLOSURE REQUIREMENTS & RESPONSIBILITIES

Disclosure of significant financial interests and other external relationships falling under this policy is intended to protect the integrity of the design, conduct, and reporting of project activities by effectively managing, reducing, or eliminating those significant financial interests which cause or appear to cause a conflict of interest on the part of an investigator. Disclosure is accomplished by submitting a Conflict of Interest (COI) Disclosure Form. This form indicates either that the employee is not involved in any activities that have the potential for conflict of interest as defined by category II of this policy or that such potential does in fact exist. In the latter case, a description of the potential conflict of interest must also be provided. *For the purposes of this policy, disclosure is required (1) when the interest in a business by an employee or by an immediate family member exceeds \$5,000 in annual income of all types, or when there is any equity or ownership interest; (2) when an employee or a member of his/her family has an executive position in a business or serves on a board of directors or advisory board; (3) when an extended family member holds an executive position in a business, or holds equity or ownership interest valued at ten (10) percent or more in a business.*

Disclosure at the time of submitting a proposal for a sponsored project

All principal investigators (PIs) and co-PIs must disclose significant financial interests and other external relationships falling under this policy at the time of their application for external sponsored project support or technology transfer. It is also the responsibility of all PIs and co-PIs to inform and explain the provisions of this policy to all persons employed on a sponsored project, and to report any potential conflicts (relationships falling under category II of this policy) to the Director of Sponsored Programs and Research. Funding for the project will not be accessible to the employee until the disclosure of financial interests is reviewed and approval is given, and other appropriate measures have been implemented in accordance with this policy. In the case of multi-year applications that receive funding, employees must update the disclosure annually.

Disclosure when involved with technology transfer

When employees are involved with transferring technology through patents or copyrights covered by the Copyright Policy, or licensing to a business in which the employee has a significant financial interest, or other external relationships covered by this policy, the employee must disclose the financial interest to the Vice President for Research. For disclosure when an employee is involved with review or advisory activities: All employees must temporarily excuse themselves from any University committee or review process that is considering an activity in which they have a significant financial interest or other external relationships covered by this policy.

Disclosure to external entities

Employees must disclose relevant significant financial interests or other external relationships covered by this policy to sponsors of projects and in reporting by either written or oral communication project results.⁸ Disclosure must also be made by any employee who makes an appearance, either in person or by way of a written communication, before any public body, commission, group, or individual, to present facts or to give an opinion respecting any issue or matter under consideration, discussion, or action.

⁸ When submitting a paper for publication, an employee must disclose to the editor any significant financial interest that may be affected by publication. This provision also applies to release of information to news media.

Disclosure Responsibilities

It is the responsibility of all PIs, co-PIs, and any individuals (paid or unpaid) involved in the design, conduct, or reporting of research to complete training regarding financial conflict of interest regulations and to report any potential conflicts (relationships falling under category II of this policy) to the Director of Sponsored Programs and Research. Training is required to be completed:

- Prior to engaging in sponsored research and at least every four (4) years, and immediately under the following circumstances:
 - University Financial Conflict of Interest policies change in a manner that affects Investigator requirements
 - An Investigator is new to the University
 - The University finds that an Investigator is not in compliance with the University's Financial Conflict of Interest policy or management plan.

4. REVIEW OF POTENTIAL CONFLICT OF INTEREST

The general purpose of the review process is to assist employees and the University in avoiding or controlling risks to integrity and reputation engendered by external relationships, while at the same time protecting and furthering the interests of employees, the University, and society in the activities supported by consulting, technology transfer and sponsored projects.

Technology transfer

All patent disclosures, copyright requests covered by the Copyright Policy, or efforts to license a product owned by the University to an external entity in which the employee has a financial interest, must be accompanied by a completed Conflict of Interest (COI) Disclosure Form when submitted to the Vice President for Research. This form indicates either that the employee is not involved in any activities that have the potential for conflict of interest as defined by category II of this policy or that such potential exists. In the latter case, a description of the potential conflict of interest must also be provided. If the Vice President for Research determines that a potential for conflict exists, the matter shall be handled in accordance for the provisions for the review of sponsored projects presented below.

Sponsored projects

All proposals for external support must be accompanied by a completed Conflict of Interest (COI) Disclosure Form. The Director of the Office of Sponsored Programs and Research shall review the COI Disclosure Form. If the form does not indicate any potential for conflict of interest as defined by category II of this policy, and there is no other evidence of a potential conflict of interest, then the Director shall process the proposal in accordance with University procedures. If the Director determines that a potential for conflict of interest as defined by category II of this policy exists, the Vice President for Research shall be notified immediately.

Review Process

The Vice President for Research (or his/her designee) shall consult with the employee's contracting officer (in most cases this will be the dean of the college). Together they shall review the disclosure, consult with the employee, and seek any additional information needed to determine whether the potential conflict of interest is of such a nature that it warrants institutional restrictions designed to manage, reduce, or eliminate the potential for conflict of interest. Either of their own accord, or upon the request of the employee, the Vice President for Research and the contracting officer may establish an ad hoc committee to review the situation and recommend a course of action.

Examples of the conditions or restrictions that might be imposed include:

- public disclosure of the financial interest;
- monitoring of the project by independent reviewers;
- modification of the project plan;
- disqualification of the investigator from participation in all or a portion of the project;
- withdrawal of the proposal or declination of an award;
- divestiture of the financial interest;
- severance of the relationship(s) that create actual or potential conflicts; or
- notification to the sponsor that the financial interest exists.

If the employee, contracting officer and Vice President for Research are unable to agree on a mutually acceptable method for managing, reducing, or eliminating the potential conflict of interest, then the Vice President for Research shall refer the case to the Vice President for Academic Affairs for a final determination.

Employees engaged in multi-year sponsored projects shall update the COI Disclosure Form at least annually to the Director of the Office Sponsored Programs and Research. If an employee acquires a new potential for conflict of interest as defined by category II of this policy, the employee shall submit a revised or new COI Disclosure Form to the Director of the Office Sponsored Programs and Research within thirty (30) working days after acquisition.

When a conflict of interest is disclosed by an employee at the time of an application, the Vice President for Research shall review, consult with the employee, seek any additional information needed, document the result in writing, and disclose the existence of the conflict and the plan for mitigating the conflict to the sponsoring entity as may be required, before accepting an award or the expenditure of funds.

When a conflict of interest is discovered or disclosed post-award, and for identification for an Investigator who is newly participating in a project, within 60 days of discovery/disclosure the Vice President for Research shall review, consult with the employee, seek any additional information needed, document the result in writing, and disclose the existence of the conflict and the plan for mitigating the conflict to the sponsoring entity.

Additionally for conflicts of interest discovered, not previously disclosed, or not reviewed post-award, with the exception of an Investigator who is newly participating in a project, a retrospective review shall occur within 120 days of the discovery or disclosure for non-compliance, and documentation required by 42 CFR Section 50.605 shall be gathered and reported as applicable.

All records pertaining to conflicts of interest for sponsored projects shall be retained by the Office of Sponsored Programs and Research and the Vice President for Research for a minimum of three (3) years after the submission of a Final Expenditure Report (FER). Records for proposals which are not funded by sponsoring agencies will be retained for a period of at least one (1) year after the decision of the sponsoring agency. All records shall be retained in a manner to protect confidentiality as allowed by law.

5. COMPLIANCE

The University expects employees to comply fully and promptly with all the requirements of this policy. Breaches of this policy are considered forms of research misconduct and will be handled in accordance with the provisions of the Research Misconduct Policy. Breaches include, but are not limited to, failure to file, intentionally filing an incomplete, erroneous, or misleading disclosure form, or failing to provide additional information as required by the approving authority. The potential sanctions may include, but are not limited to, the following:

- letter of admonition;
- ineligibility of the employee for grant applications, Institutional Review Board (IRB) approval, or supervision of graduate students;
- suspension;
- nonrenewal of appointment; and
- dismissal.