

# Wayne State University Research Policy

## Individual and Institutional Financial Conflict of Interest and Commitment

### 1. Purpose

- 1.1. The purpose of this university policy is to promote objectivity in Sponsored Programs that support the research, scholarship and service mission of the University. It will do so by establishing standards to ensure there is no reasonable expectation that the design, conduct or reporting of funded research or cooperative agreements with Companies will be biased by any conflicting financial interest of WSU Employees, students or Immediate Family members. Complete disclosure and expeditious review of such conflicts or potential conflicts is in the best interest of the Employee, student, and administration.
- 1.2. It is critical to maintain the highest standards of quality in research, scholarship and service to support the mission of WSU, and therefore the University and its Employees are committed to conducting themselves with the highest standards of integrity and ethics as these relate to potential Conflicts of Interest and Commitment. This policy will guide WSU Employees in the identification, disclosure, management, and when necessary, elimination of conflicts of interest.
- 1.3. This policy is applicable to Employees interacting with Companies in research and Sponsored Programs. It addresses the specific combination of activities or Significant Financial Interest that may lead to potential Financial Conflict of Interest and/or Commitment. This policy is designed (a) to guide Employees in the identification of Financial Conflict of Interest and Commitment involving Companies, (b) to assist Employees in the management of or, when necessary, elimination of Financial Conflict of Interest and Commitment, and (c) to establish a mechanism for disclosure and review of all relevant relationships with Companies.

### 2. Policy Statement

- 2.1. Without administrative approval, WSU Employees are prohibited from engaging in activities from which they, their families or their businesses will gain financially because of the employee's position at WSU or because of the use or disclosure of WSU information. Employees are required to disclose such situations, manage, and if so directed, to eliminate or avoid situations which either create Financial Conflicts of Interest or which appear to be Financial Conflicts of Interest.
- 2.2. Faculty members and other employees who accept employment at WSU make a commitment to WSU that includes the appropriate and responsible use of WSU information and resources. Employees must ensure that both their use of WSU information and resources and their outside obligations, financial interests, and activities do not interfere with, nor appear to interfere with, their primary obligations to WSU. It is the responsibility of the Employee to disclose in writing any potential or actual Financial Conflict of Interest. The failure of an Employee to disclose a Financial Conflict of Interest or failure to eliminate a conflict when so directed may be grounds for disciplinary action up to, and including, discharge or termination for cause.
- 2.3. Wayne State University encourages external activities that enhance an employee's value to WSU; which enhance WSU's presence in local, national, or international

communities; or which provide public service. Such service to outside educational, professional, scientific, artistic, cultural, civic, business or other organizations is permissible under the terms of this policy as long as it does not pose a Financial Conflict of Interest.

### 3. Definitions<sup>1</sup>

- 3.1. **AIC.** The “AIC” refers to the Animal Investigation Committee at the University.
- 3.2. **Company.** “Company” means any corporation, partnership, sole proprietorship, firm, franchise, association, organization, holding company, joint stock company, receivership, business or real estate trust, or any nongovernmental legal entity organized for profit or nonprofit purposes.
- 3.3. **Company Position.** “Company Position” means holding any executive position or membership on a board regardless of compensation.
- 3.4. **Conflict of Commitment.** A “Conflict of Commitment” exists when the external activities of an Employee are so substantial or demanding of the staff member’s time and attention as to interfere with the individual’s responsibilities to the unit to which the individual is assigned, to students or to the University.
- 3.5. **Disclosure.** To inform the Financial Conflict of Interest committee of any significant financial interest, income, corporate or for profit leadership position, and/or named as an inventor on a patent, patent application or copyright involving technology/processes/products licensed or expected to be licensed to the company sponsor.
- 3.6. **Employee.** “Employee” means:
  - (1) any person possessing either a full-time or part-time appointment at the University. These include the faculty ranks of professor, associate professor, assistant professor (and all of the foregoing whose appointments contain such terms as “Research,” Adjunct,” “Visiting,” or “Clinical,”) instructor, and lecturer, as well as academic professionals and postdoctoral associates.
  - (2) employees, students, and other individuals identified as key personnel on grant applications, whether salaried or not salaried, who on behalf of the University are responsible for or in a position to influence, the design, conduct or reporting of the research or other scholarly activity.
- 3.7. **Equity.** An interest in a business consisting of any stock, stock option or similar ownership interest in such business
- 3.8. **FCOI.** The “FCOI” refers to Financial Conflict of Interest.
- 3.9. **Financial Conflict of Interest.** “Financial Conflict of Interest” refers to situations in which financial considerations may compromise or have the appearance of compromising, an investigator’s professional judgment in conducting or reporting research. The bias such conflict may conceivably impart not only affects collection, analysis, and interpretation of data, but also the hiring of staff, procurement of materials, sharing of results, choice of protocol, involvement of human participants, and the use of

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<sup>1</sup> Throughout the policy, the first letter of each word being capitalized indicates terms defined in this section.

statistical methods.<sup>2</sup>

Examples of potential financial considerations include salary; equity; stock options; stock warranties; consulting fees; royalty interest; income from seminars, lectures or teaching engagements; income from service on advisory committees or review panels; legal partnerships; gifts to their institutions; and other forms of payment to the investigators, key personnel, their spouses, domestic partners and dependent children.

Potential Financial Conflict of Interest may be classified in one categories as described in Section 5 of this report.

3.10. **HIC.** “HIC” refers to the Human Investigation Committee or one of the Institutional Review Boards at the University.

3.11. **Immediate Family.** “Immediate Family” means the employee’s spouse or domestic partner and dependent children.

3.12. **Institutional Financial Conflict of Interest.** “Institutional Financial Conflict of Interest” may occur when the institution, any of its senior management or trustees, or a department, school, or other sub-unit, or an affiliated foundation or organization, has an external relationship or financial interest in a company that itself has a financial interest in a faculty research project. Senior managers or trustees may also have conflicts when they serve on the boards of (or otherwise have an official relationship with) organizations that have significant commercial transactions with the University. The existence (or appearance) of such conflict can lead to actual bias, or suspicion about possible bias, in the review or conduct of research at the University. If they are not evaluated or managed, they may result in choices or actions that are incongruent with the missions, obligations or the values of the University.<sup>3</sup>

Note: The definition does not apply to affiliated foundations if the structure of the relationship between the University and the foundation effectively eliminates any potential Financial Conflict of Interest on the part of the foundation (e.g. if the foundation simply provides financial support for a particular project through the University and does not retain any direct financial interest in the project.)

3.13. **Significant Financial Interest.** “Significant Financial Interest” means anything of monetary value including but not limited to:

- (1) an interest in a business consisting of any stock, stock option or similar ownership interest in such business whether or not it is publicly traded on the stock exchange, 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) Ownership interest of any amount when the value would be affected by the outcome of the research. whether or not it is publicly traded on the stock exchange,
- (3) receipt of, or the right or expectation to receive, any income in one or more of the following forms: a consulting fee, honoraria, 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 or any other

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<sup>2</sup> Task Force on Research Accountability, Report on Individual and Institutional Financial Conflict of Interest, Report and Recommendations, Association of American Universities, October 2001, p. 2.

<sup>3</sup> Task Force on Research Accountability, Report on Individual and Institutional Financial Conflict of Interest, Report and Recommendations, Association of American Universities, October 2001, p. 10.

form of compensation when the value would be affected by the outcome of the research.

- (4) Proprietary interests including, but not limited to a patent, trademark, copyright or license agreement, and
- (5) Uncompensated board or executive relationships regardless of compensation.

3.14. **Sponsored Programs.** "Sponsored Programs" means research, training, and instructional projects involving funds, materials or other compensation from outside sources under agreements that contain any of the following: The agreement binds the University to a line of scholarly or scientific inquiry specified to a substantial level of detail; a line-item budget is involved; financial reports are required; the award is subject to external audit; unexpended funds must be returned to the sponsor at the conclusion of the project; or the agreement provides for the disposition of either tangible or intangible properties that may result from the activity.

#### 4. Compliance with relevant Policies and Laws

##### 4.1. Applicable University Policies

4.1.1. WSU Code Annotated 2.41.03 CONFLICT OF INTEREST; CONTRACTS.

4.1.2. WSU Executive Order 89-3 Conflict of Interest Disclosure (Management), September 22, 1989.

4.1.3. WSU Executive Order 96-2 Investigator Disclosure, April 1, 1996.  
NOTE: This "Research Policy" further defines the procedures for disclosure and management of conflicts outlined in the Executive Order.

4.2. Institutional policies on Financial Conflict of Interest and Commitment were developed to encourage Employees to be in compliance with all applicable federal and state laws and regulations involving Financial Conflict of Interest and Commitment. These include, but are not limited to:

4.2.1. Public Health Service Regulation: "Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought," 42 CFR, pt. 50 Subpart F, effective October 1, 1999.

4.2.2. Public Health Service Regulation: "Managing Conflict of Interest," 45 CFR, pt. 94, October 1, 2001.

4.2.3. National Science Foundation: "Investigator Financial Disclosure Policy," 60 Federal Register 132 35809, effective July 11, 1995.

4.2.4. Food and Drug Administration Regulation: "Financial Disclosure by Clinical Investigators," 21 CFR pt 54 and applicable portions of part 312, 314, 320, 330, 601, 807, 812, 814, and 860, effective February 2, 1999.

4.2.5. State of Michigan Conflict of Interest Law: "Contracts of Public Servants with Public Entities" Public Act 317 of 1968, as amended by Public Act 81 of 1984.

#### 5. Classification of Potential Financial Conflict of Interest and Commitment

5.1. A potential Financial Conflict of Interest or Commitment may exist when an Employee has multiple relationships (consulting, conducting research, receiving royalty, having an equity position, maintaining an executive position, serving on the board, etc.) with a Company.

5.2. The following chart lists categories of activities and external relationships covered by this policy. For each level, depending on whether the Sponsored Program involves human participants, the requirements for disclosure and/or management are provided. Any combination of activity and external relationships not specifically identified in the chart, that an employee reasonably believes constitutes a potential conflict of interest, must be disclosed. A designated representative of the Financial Conflict of Interest (FCOI) Committee will determine whether the relationship represents an activity requiring additional review.

5.3.

HUMAN RESEARCH STUDY					
1	2	3	4	5	6
< \$10,000 or < 5% equity No company position or other commitment	< \$10,000 or <5% equity + company position or other commitment	\$10,000- \$25,000 or 5- 15% equity No company position or other commitment	\$10,000- \$25,000 or 5- 15% equity + company position or other commitment	>\$25,000 or >15% equity, with or without other commitments	More complex than Level 5
No management plan	Expedited management plan	Expedited management plan	Electronic review by full committee	Electronic review or full committee review	Full committee review
No consent language	Possible consent language	Possible consent language	Consent language required	Consent language required	Consent language required
NON-HUMAN RESEARCH PROGRAM					
1	2	3	4	5	6
< \$10,000 or < 5% equity No company position or other commitment	< \$10,000 or <5% equity + company position or other commitment	\$10,000- \$25,000 or 5- 15% equity No company position or other commitment	\$10,000- \$25,000 or 5- 15% equity + company position or other commitment	>\$25,000 or >15% equity, with or without other commitments	More complex than Level 5
No management plan	No management plan	Expedited management plan	Expedited management plan	Electronic review or full committee review	Full committee review

**Definitions:**

**Commitment:** Self, spouse, domestic partner, or dependent children (1) have a Company Position; (2) are listed as inventor on a patent, patent application, or copyright which relates to the company or research project; (3) have reporting relationship to other project investigator(s);

(4) have other relevant potential or actual financial conflicts of interest not covered under income, equity or categories 1-3 of "commitment"

**Consent Language:** language that discloses the investigator(s) financial conflict in the research informed consent document that requires approval by The Human Investigation Committee.

**Electronic review:** FCOI-ER Subcommittee appoints two FCOI Committee reviewers; recommendation is sent to full committee by e-mail and objections are requested within a specified time period.

**Expedited management plan:** The Financial Conflict of Interest Expedited Review (FCOI-ER) Subcommittee (AVP or VP or Chair, and Conflict of Interest Coordinator); details of expedited management plans will be read into the minutes of the full committee meeting.

**Full committee review:** Full FCOI Committee develops management plan or disapproves proposal, discussion and voting by teleconference or at regularly scheduled meeting.

## 6. Students

6.1. The following applies to Employees assigning students, postdoctoral fellows or other trainees to a Sponsored Program with a Company in which the Employee or the Immediate Family may be entitled to receive Significant Financial Interest or Company Position from a consulting services or Company Position: the multiple relationships must be disclosed to the trainee, to the thesis advisory committee and/or to the chair of the department, as appropriate.

## 7. Appointment of and Responsibilities for a Financial Conflict of Interest Committee

7.1. The Vice President for Research shall appoint members of a Financial Conflict of Interest (FCOI) Committee. While membership should come from the faculty and administration, a majority of the voting members of the Committee shall represent the faculty.

7.2. The responsibilities of the FCOI Committee are to:

7.2.1. Formulate guidelines, applicable to Employees, that identify the types of potential Financial Conflict of Interest and Commitment in academic-industrial relationships;

7.2.2. Develop procedures to obtain and review information supplied by Employees;

7.2.3. Conduct the review of all disclosures via an expedited or full committee review process, recommend an appropriate management plan and, when appropriate, recommend the elimination of Financial Conflict of Interest. The Employee and/or WSU administration will not implement a Sponsored Program, human participant protocol or animal protocol until a management plan, approved by the FCOI Committee, has been implemented or the FCOI has been eliminated,

7.2.4. Communicate with the HIC, the AIC, and other administrative units about multiple relationships that an Employee has with a Company.

7.3. The Office of the Vice President for Research shall provide administrative support for the Financial Conflict of Interest Committee. A representative from that Office shall staff

the Committee and provide education and advice to Employees concerning their responsibilities under this policy. That representative shall also oversee and coordinate compliance with the recommendations of the Committee.

## 8. Disclosure and Review Process

### 8.1. Disclosure to the Financial Conflict of Interest Committee

8.1.1. **Sponsored Program with Human Participants:** At the time that a proposal for Company support of a Sponsored Program is being submitted, an Employee must disclose to the FCOI Committee multiple relationships with the Company in which the Employee or Immediate Family member has a Significant Financial Interest as determined through reference to public prices or other reasonable measures of fair market value or Company Position. Refer to chart above  
Funding for the Sponsored Program will not be available to the Employee until the disclosure of financial interest is reviewed and approved by the FCOI Committee. In addition, funding for the Sponsored Program will not be available to the Employee until an appropriate management plan, approved by the FCOI Committee, has been implemented.

8.1.2. **No human participants in Sponsored Program:** Disclosure is required when an Employee has a Significant Financial Interest or Company Position equal to or greater than \$10,000 annually or five percent of the Company as determined through reference to public prices or other reasonable measures of fair market value.

Until a management plan for managing the potential Financial Conflict of Interest has been approved by the FCOI Committee and implemented, Employees may not participate in activities involving multiple relationships.

8.1.3. **Potential Financial Conflict of Interest involving University royalty entitlements** shall be disclosed by the Employee to the FCOI Committee at the time that a Sponsored Program, HIC protocol or AIC protocol is being submitted.

8.1.4. The Employee is required to update their disclosure to the FCOI on an annual basis or within 30 days when there is a proposed significant change to an existing relationship.

8.1.5. When there is no potential for Financial Conflict of Interest and/or Commitment for any member of the research team, the Principal Investigator may certify no Financial Conflict of Interest on the Sponsored Program Administration Form for External Support (FES).

8.1.6. When Employees participate in Sponsored Programs with collaborators outside the University, the University, to the extent required by the sponsor, will take reasonable steps to ensure that external collaborators comply with appropriate Conflict of Interest disclosure and review requirements.

### 8.2. Disclosure to other Committees, Offices, and Outside Organizations

8.2.1. Employees must disclose their relationships with Company or temporarily excuse themselves from any University Committee or review process that is considering an Position.

- 8.2.2. If a Company is proposing to sponsor research, an Employee must disclose Significant Financial Interest or Company Position to that Company.
- 8.2.3. Employees proposing a Material Transfer Agreement under which the University will provide materials to or receive materials from a Company in which the Employee or their Immediate Family has a Significant Financial Interest, consulting relationship or Company Position must first disclose the proposed arrangement to the University's Technology Transfer Office.
- 8.2.4. Employees must disclose their relationships with Companies in all written or oral communications about the results of the Sponsored Program. The disclosure includes communication with professional groups and information to news media.
- 8.3. Correspondence with Financial Conflict of Interest Committee
  - 8.3.1. Employees may choose to sign and return the management plan received from the Committee, or may communicate questions, concerns, or disagreements about the management plan directly to the Committee. All correspondence must be in writing.
  - 8.3.2. Employees must respond to the Committee in writing within 30 days of receipt of a management plan. After that time, a new disclosure form may have to be submitted for consideration by the Committee.

## 9. Institutional Financial Conflict of Interest

- 9.1. Institutional Financial Conflict of Interest consists of two major types:
  - 9.1.1. Potential Conflict of Interest involving University equity holdings or a royalty arrangement related to Sponsored Programs, and
  - 9.1.2. Potential Conflict of Interest involving University officials who make decisions with institutional-wide implications, which can include department heads and centers and institutes directors, in addition to senior management.
- 9.2. Institutional Financial Conflict of Interest involving equity holding or royalty arrangements shall be covered by this policy and Institutional Financial Conflict of Interest involving University officials shall be covered by a separate Board of Governors policy (Currently Executive Order 89-3).
- 9.3. Department Chairs, Deans, Directors, and employees within the Office of the Vice President for Research who review, approve, and/or manage Sponsored Programs with Companies shall disclose to the FCOI Committee all relationships with those Companies in which they are involved.
- 9.4. The Assistant Vice President for Technology Transfer shall disclose to the COI Committee all technology transfer agreements in which the University is proposing an equity position in the Company.
- 9.5. All affiliated organizations, affiliated practice plans and investment subsidies must disclose equity holding in technology resulting from Sponsored Programs conducted at

the University.

## 10. Enforcement

10.1. Breaches of this policy include, but are not limited to failure to file, intentionally filing an incomplete, erroneous, or misleading disclosure form or failure to provide additional information as required by the FCOI Committee. Violation of this policy may be the basis for discipline of the Employee in accordance with other applicable Board of Governors and administrative policies and procedures. The potential sanctions may include, but are not limited to,

- 10.1.1. Letter of admonition;
- 10.1.2. Ineligibility of the Employee to participate in Sponsored Program;
- 10.1.3. Ineligibility of the Employee to participate in HIC or AIC protocols;
- 10.1.4. Ineligibility of the Employee to supervise graduate students;
- 10.1.5. Suspension
- 10.1.6. Nonrenewal of appointment; or
- 10.1.7. Dismissal.

10.2. While the FCOI Committee will have the authority to send letters of admonition to the Employee, all other forms of disciplinary action are advisory to the Vice President for Research who will coordinate and implement the recommendation with the appropriate administrative unit.

10.3. If an Employee who is involved with Sponsored Programs fails to comply with this policy, then the Dean of the academic unit or other individual who may become aware of the failure to comply must promptly inform the Office of the Vice President for Research of the violation.

10.4. To the extent required by sponsor or government agencies requirements, the Office of the Vice President for Research will notify the sponsoring or government agency of the violation and any corrective action taken or scheduled to be taken.