

POLICY NO. 306**Area: General Administration**

Date Adopted: August 2012

Certified by _____
Daarel Burnette, Vice President of
Administration and Chief Financial OfficerRevisions Approved:
-----**Subject: SPONSORED PROJECTS AND RESEARCH CONFLICT OF INTEREST**
-----**1. Purpose**

The policy promotes objectivity in research and other sponsored activities by defining special standards of conduct appropriate for each faculty/staff member participating in a sponsored project. The intent is to ensure that the design, conduct, and reporting of the project are neither compromised nor appear to be compromised by any significant financial interest of the responsible faculty/staff members.

2. Applicability

This policy applies to all faculty/staff members who apply for, receive, or who are currently working on a grant, contract, cooperative agreement, subgrant, subcontract, or sub-cooperative agreement which is funded in whole or in part by external funds.

Specific guidance and requirements regarding Public Health Service (PHS)-funded research are noted in this document (or provided in Appendix A).

3. Definitions

Project means any externally funded scholarly activity such as basic, applied, or developmental research; instructional or curricular activities; student aid; career development; or other activity conducted by faculty or staff members on behalf of the University.

Investigator means the project director/principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research, or proposal for funding, including persons who are subcontractors, collaborators, or consultants.

Family means spouse, domestic partner, relatives, and any member of the household.

Management Plan means a written plan developed to manage conflicts by eliminating or reducing the Financial Conflict of Interest so that the design, conduct or reporting of research is free from bias or the appearance of bias.

Financial interest means anything of monetary value including, but not limited to, salary or other payments for service such as consulting fees or honoraria; equity interests such as stocks, stock options, or other ownership interests; and intellectual property rights such as patents, copyrights, and royalties from such rights.

Significant financial interest means, except as otherwise specified in this definition:

1. A financial interest consisting of one or more of the following interests of the Investigator (and/or those of the Investigator's spouse and/or dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:
 - a. 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 the 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, travel reimbursement). Equity Interests includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.
 - b. 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 the Investigator (or the Investigator's spouse or dependent children) holds **any** equity interest.
 - c. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
2. For PHS-funded investigators, any reimbursed or sponsored travel (i.e., that which is paid on behalf of the investigator so that the exact monetary value may not be readily available) related to their institutional responsibilities.
3. The term *significant financial interest* **does not** include the following types of financial interests:

- a. Salary, royalties, or other remuneration paid by the University to the investigator if the investigator is 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 the investigator does not directly control the investment decisions made in these vehicles;
- b. Income from seminars, lectures, or teaching engagements sponsored by a Federal, state or local 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;
- c. 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.
- d. For PHS-funded investigators, 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

Conflict of Interest exists if financial interests or other opportunities for tangible personal benefit may exert a substantial and improper influence on an employee's professional judgment in exercising any University duty or responsibility, including designing, conducting, or reporting on a project. A conflict of interest is not an accusation and does not imply that an employee's judgment has been compromised.

Institutional Responsibilities means an investigator's professional responsibilities on behalf of the University including, research, consultation, teaching, professional practice, and service.

Research means a systematic investigation designed to develop or contribute to generalizable knowledge. It includes basic and applied research and product development. It includes activities sponsored through a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project or research resources award.

4. INVESTIGATOR RESPONSIBILITIES

Investigators are responsible for the following:

- Reading and understanding this policy;
- Disclosing significant financial interests to the University by completing

appropriate forms on or before a specified date or before submission of the grant/contract application;

- Completing any training in a timely manner as required by the sponsor or University;
- Updating disclosure statements as changes occur, so that the statement on file is current and accurate at all times when an award is pending or in force; and
- Complying with any and all Management Plan provisions and monitoring requirements, as applicable.

5. Conflict and Non-Conflict Situations

A conflict of interest occurs when an investigator compromises or appears to compromise the conduct of a project because of an outside relationship that directly or indirectly affects the financial interests of the investigator or the investigator's family. Situations in which conflicts of interest for investigators or their families may arise or may be perceived to arise include:

1. Failing to perform University responsibilities adequately due to involvement in external activities.
2. Possessing a significant financial interest, including a significant consulting relationship, in a business that competes with services provided by the University.
3. Accepting other than nominal gratuities or favors from an individual or entity that does business with the University or is proposing to do business with the University.
4. Associating one's name or one's work with an external activity (such as consulting) in a way that implies endorsement or sponsorship by the University.
5. Using, without authority, confidential information obtained through one's University position.
6. Publishing or presenting results of sponsored research conducted at the University without simultaneously disclosing any significant financial interest relating to the results or the subject.
7. Taking an administrative action or negotiating an agreement in a manner that benefits a business in which the employee or his/her family members have a significant financial interest.
8. Serving in an executive, management or directorship role or having a significant financial interest in an entity that does business with the University.
9. Conducting research, testing, or clinical trials sponsored by a company in which the

University employee or his/her family members have a significant financial interest.

10. Diverting research or business opportunities away from the University to another entity.

11. Making referrals or directing purchasing opportunities to a business in which the University employee, his/her family members, or his/her business associates has a significant financial interest.

12. Assigning students or other University employees to work on projects from which the University researcher stands to gain financially (beyond ordinary University compensation mechanisms) or which are funded by an outside sponsor or donor in which the researcher has a significant financial interest.

What financial gains do not involve a conflict of interest situation?

A conflict of interest situation generally does not exist when a University employee's personal financial gains result from:

1. Properly approved remuneration from the University such as salary, royalties, or other interests of value.
2. Income from activities unrelated in any way to his/her position at the University.
3. Income from seminars or lectures sponsored by public non-profit entities.
4. Income from service on advisory committees or review panels for public or non-profit entities or from service as a reviewer of manuscripts for possible publication by journals and other publishers.
5. An interest arising solely by reason of investment in a business by a mutual, pension, or other institutional investment fund over which the researcher exercises no control.
6. Income from royalties from intellectual property unrelated to his/her University duties and in which the University has no interest.
7. Income from routine consulting, consistent with the University's policy on consulting, and which does not pose any potential conflict with University interests.
8. Royalties, stipends, and/or honoraria received for published scholarly works and other writings, creative works, lectures, and/or presentations.

6. Disclosure of Potential Conflict of Interest

a. Disclosure of potential conflict of interest is intended to protect the integrity of the design, conduct, and reporting of project activities by effectively permitting the management, reduction, or elimination of those factors which cause or appear to cause a conflict of interest on the part of an investigator. Successful implementation of this policy assumes a shared responsibility by all investigators and the administration of the University. Investigators are expected to comply with all the disclosure requirements described below. Once proposed activities have been administratively approved and a plan of action addressing potential conflicts has been determined, University officers will permit the activity as long as the investigator complies with the plan of action, the disclosure requirements, other University policies, and the law.

b. Any investigator applying for or conducting any project shall make prompt, written disclosure of any potential conflict of interest to the Director, Office of Sponsored Programs and Research (Director).

c. Faculty/staff applying for an externally funded project shall complete a Financial Conflict of Interest Screening/Disclosure form indicating that either no conflict of interest exists or that the investigator has filed a written disclosure with the Director. The conflict of interest box must also be marked on the proposal transmittal form.

d. The Director shall review the Conflict of Interest Form and make an initial determination as to whether or not a potential conflict of interest exists as defined above. If no evidence of a potential conflict of interest is disclosed, then the Director shall provide written documentation of this determination, which shall be retained with the other project records and shall so advise the investigator, the chair, the dean, and the Vice President for Academic Affairs or other appropriate Vice President. If a faculty/staff member fails to complete this form, fails to return it, or fails to disclose a potential conflict of interest to the Director, or if a conflict of interest is not resolved the Director and the appropriate Vice President shall not submit the proposal, withdraw the proposal if already submitted, or decline an award.

e. If the Director determines that a potential conflict of interest as defined above may exist, the Director will promptly convene a meeting of the Conflict of Interest Review Committee within ten working days. This committee will consist of:

- Director, Office of Sponsored Programs and Research;
- University Legal Counsel;
- University Controller; and
- Two members of the Faculty Senate Committee on Research and Library- Information Centers

7. Management Plan

a. If the Conflict of Interest Review Committee determines a conflict of interest does exist, the

committee will then notify the faculty/staff. The committee shall consult with the dean of the college or department head and together they shall review the disclosure, consult with the faculty/staff concerned, and seek any additional information to determine whether a possible conflict of interest exists. If they determine that a potential conflict of interest exists, they shall determine a plan of action consisting of the conditions or restrictions that shall be required by the University to manage, reduce, or eliminate such actual or apparent conflict of interest. If they are unable to agree on a mutually acceptable method for managing, reducing, or eliminating the potential conflict of interest, then the Conflict of Interest Review Committee shall refer the disclosure to the appropriate Vice President for a final determination.

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

1. Public disclosure of the significant financial interest;
2. Monitoring of the project by independent reviewers;
3. Modification of the project plan;
4. Disqualification of the investigator from participation in all or a portion of the project;
5. Withdrawal of the proposal or declination of an award;
6. Divestiture of the significant financial interest;
7. Severance of the relationship(s) that create actual or potential conflicts; or
8. Notifying the sponsor that a significant financial interest exists.

b. The appropriate Vice President shall notify the faculty or staff member, the appropriate chair and dean, faculty/staff director, and the President of the final determination.

c. Investigators shall update the Financial Conflict of Interest Screening/Disclosure Form in each September of each year. If an investigator acquires a new reportable significant financial interest, the investigator shall submit a revised or new Financial Conflict of Interest Screening/Disclosure Form to the Director within five (5) working days after acquisition.

d. Prior to accepting an award, the Director shall ensure that any potential conflicts of interest have been satisfactorily managed, reduced, or eliminated in accordance with this policy. If it is determined that a conflict cannot be satisfactorily managed, reduced, or eliminated, the appropriate Vice President shall disclose the existence of a conflict to the sponsoring agency before accepting the award.

e. If a sponsor requires disclosure of a significant financial interest or any potential or actual conflict of interest, the appropriate Vice President shall make such disclosures as required by the sponsor.

8. Reporting Requirements

The Director of the Office of Sponsored Programs and Research shall submit a written report to the appropriate Vice President detailing the number, nature, and resolution of significant financial

interest and/or conflict of interest disclosures annually, within 60 days.

9. Related Sections of the Ohio Revised Code and Federal Statutes and Regulations

Among others, federal regulations and statutes of the Ohio Revised Code govern conduct related to a staff member's carrying out of his or her assigned duties for the University.

State

- Ohio Revised Code (Sections 102.03, 2921.42 and 2921.43)

Federal

- Public Health Service (PHS) 42 CFR, part 50, subpart F and 45 CFR Part 94
- National Science Foundation (NSF) Grantee Conflict of Interest Policies
- U.S. Food and Drug Administration (FDA) 21 CFR 54
- PART 220--Cost Principles For Educational Institutions (OMB CIRCULAR A-21)
- Securities and Exchange Commission (SEC)

10. Possible Disciplinary Actions for Violations of this Policy

a. The University expects investigators to comply fully and promptly with all the requirements of this policy. Examples of breaches of this policy include failure to file; intentionally filing an incomplete, erroneous, or misleading disclosure form; or failing to provide additional information as required by the Director or appropriate Vice President.

b. In addition to any potential legal penalty(ies), the University may take appropriate disciplinary action against individuals who violate this policy. This disciplinary action may include, but not be limited to, oral admonishment, written reprimand, reassignment, suspension, or termination of the individual's employment. Disciplinary action under this policy shall be consistent with and subject to applicable provisions of the University's human resources policies or applicable sections of the Collective Bargaining Agreement between the University and the AAUP, CSUSA and AFSCME. If the sponsor requires disclosure of any disciplinary actions taken for violations of this policy, the appropriate Vice President shall make such disclosure in a timely manner.

11. Records Retention

All records pertaining to conflict of interest for sponsored projects shall be retained for a minimum of three years after the completion of all project activity by the Office of Sponsored Programs. Records for proposals that are not funded by sponsoring agencies will be retained for a period of at least one year after the decision of the sponsoring agency. All records shall be retained in a manner to protect confidentiality as allowed by law.

APPENDIX A

Public Health Service (PHS) Funded Research Reporting Requirements

This Appendix details the requirements for all Investigators engaged in PHS- funded research.

Prior to expenditure of any funds or within 60 calendar days for any interest that the University identifies as conflicting subsequent to the University's initial report under a PHS-funded research project, the University must provide the PHS Awarding Component with a Financial Conflict of Interest (FCOI) report regarding the related FCOI and implemented Management Plan. This report must include the following information:

- Grant/Contract Number
- Project Director/Principal Investigator (PD/PI) or contact PD/PI
- Name of investigator with FCOI
- Nature of the FCOI (e.g., equity, consulting fees, or honoraria)
- Whether the financial interest was managed, reduced or eliminated
- Value of the financial interest
- Description of how FCOI relates to PHS-funded research and the basis for the University's determination that the financial interest conflicts with such research.
- Key elements of the Management Plan

Annual updates are also required for the duration of the research project and must include:

- Status of the FCOI
- Changes to the management plan

If a significant financial interest (SFI) is not disclosed or reviewed in a timely manner, the University must review the SFI, determine if it is related to PHS-funded research; determine whether a financial conflict of interest exists, and, if so:

- Implement a Management Plan for ongoing research;
- Complete a retrospective review of investigator's activities and the PHS-funded research project within 120 days of a non-compliance finding to determine if there was bias in the design, conduct, or reporting of such research; and
- If bias is found, notify the PHS Awarding Component promptly by submitting a mitigation report.

Public Disclosure

In accordance with PHS regulations, the University will respond to requests regarding financial conflicts of interest by written response within five business days of a request. The response shall include the investigator's name, position relative to the research project, the name of the entity in which the SFI is held, nature of the SFI, approximate dollar value of SFI, or a statement that the value cannot be readily determined.

Subrecipients

For PHS research that involves subcontractors, subgrantees or subawardees (collectively "subrecipients") at other institutions, the University requires written agreement terms from subrecipients that they have a conflict of interest policy that conforms to the requirements of all applicable regulations, including time periods to meet disclosure and/or financial conflict of interest (FCOI) reporting requirements.

If any subrecipient does not have such a conflict of interest policy, then the University shall require that Subrecipient follow the University's (CSU's) policy, and Subrecipient's failure to promptly do so upon request from the University shall be considered to be grounds for immediate termination by the University of any applicable subcontract or subaward. Any written agreement terms required by the University shall contain the provision that subrecipients will report to the University as the awardee Institution, any identified FCOI in sufficient time to allow the University to report the FCOI to meet reporting obligations described above.

Required Training for Investigators

Investigators must complete the University's FCOI training requirements prior to engaging in research related to any PHS-funded grant or contract and at least every four years, and immediately under the designated circumstances:

- This policy changes in a manner that affects Investigator requirements
- An Investigator is new to the University
- The University finds that an Investigator is noncompliant with this policy or their University- approved management plan.