The University of Memphis

RE7003 - Disclosure of Financial Interests Related to Sponsored Research

Issued: May 25, 2016

Responsible Official: Vice President for Research

Responsible Office: Sponsored Programs

Policy Statement

It is the policy of The University of Memphis (University) that any University employee responsible for the design, conduct, or reporting of a sponsored project at the University must disclose significant personal financial interests related to the Investigator's institutional responsibilities. When the University determines that such an interest might reasonably appear to be directly and significantly affected by the sponsored project, the University will take steps either to manage or to eliminate the conflict of interest.

Purpose

The purpose of this Policy is to establish a process of open disclosure and review, to identify conflicts of interest between an Investigator's sponsored project obligations and personal financial interests or obligations, and to establish a process to reduce, manage or eliminate such conflicts so that financial interests of Investigators do not compromise the objectivity with which projects are designed, conducted, or reported. This policy applies to all research supported through external and internal funds, and to all other activities supported under externally sponsored agreements. This policy will apply to all projects submitted for external support such as any Federal agency, private source, governmental and intramural programs. Project Directors and Principal Investigators of all externally funded projects are required to be aware of and comply with their own sponsor's policies as well as the policies of the University regarding possible conflicts of interest.

This policy is consistent with the Public Health Service (PHS) regulations, "Objectivity in Research," 42 CFR Part 50, Subpart F, 45 CFR Part 94 and the National Science Foundation (NSF)

POLICIES

regulations, "Investigator Financial Disclosure Policy," and any amendments thereto.

This Policy supplements, but does not replace other University policies on Conflicts of Interests (SEE UNIVERSITY CONFLICT OF INTEREST POLICY UM 1692). This policy on Disclosure of Financial Interests Related to Sponsored Research is directed toward disclosure of any financial interest that would reasonably appear to be affected by the work performed under a sponsored project.

Definitions

CONFLICT OF INTEREST Conflict of interest (COI): An actual or potential interest that could directly and substantially affect the design, conduct, or reporting of funded research, or of scholarly and/or educational activities funded under external grants, contracts or cooperative agreements. COIs can be financial (FCOI) or obligatory (OCOI) in nature.

> Financial conflict of interest (FCOI): A financial interest that could directly and substantially affect the design, conduct, or reporting of funded research or scholarly and/or educational activities funded under external grants, contracts or cooperative agreements.

Obligatory Conflict of Interest (OCOI): A relationship (regardless of compensation) that involves a responsibility or commitment to an external entity, including but not limited to being a founding member of that entity, or holding scientific advisory or governing board membership

DISCLOSURE OF INTERESTS (DISCLOSURE)

Form to be completed by the Investigator of all Significant SIGNFICANT FINANCIAL Financial Interest related to the Investigator's institutional responsibilities.

Significant financial interest means:

(1) A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

- (i) With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
- (ii) With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or (iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

The National Science Foundation (NSF), and other funding sources have higher de minimis thresholds for disclosure of significant financial interests. The University of Memphis disclosure requirements is the same as required by the Public Health Service (PHS) significant financial interest de minimis threshold of \$5,000.

(2) Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

SIGNIFICANT FINANCIAL INTEREST EXCLUSIONS The term significant financial interest does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the

Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for profit organization; 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; income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an 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; or income from service on advisory committees or review panels for a Federal, state, or local government agency, an 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. Small Business Innovation Research (SBIR) Program means the extramural research program for small businesses that is established by the Awarding Components of the Public Health Service and certain other Federal agencies under Public Law 97-219, the Small Business Innovation Development Act, as amended. For purposes of this subpart, the term SBIR Program also includes the Small Business Technology Transfer (STTR) Program, which was established by Public Law 102-564.

INVESTIGATOR

Any University employee responsible for the design, conduct, or reporting of the results of the work performed or to be performed under the sponsored project. This includes the Principal Investigator, Project Director, Investigator, Co-Investigators, and any other individual who has independent responsibility for accomplishing project objectives.

RELATED FINANCIAL INTEREST

When the work to be performed under the sponsored project and the results of the undertaking would reasonably appear to affect the financial interest, the financial interest is "related" to the sponsored project and must be disclosed. The following are examples of financial interests that are "related" to a sponsored project:

1. The Investigator is carrying out a project whose results would be relevant to the development, manufacturing, or improvement of the products or services of the entity in which there is a financial interest;

- 2. The Investigator has a financial interest in an entity which might manufacture or commercialize a drug, device, procedure, or any other product used in the project or that will predictably result from the project;
- 3. The Investigator has consulting income in his/her professional field (Consulting activities in the professional field of the Investigator are considered "related" interests and all income must be disclosed if it meets the threshold for a financial interest);
- 4. The Investigator has a financial interest in an entity and the sponsored project proposes to subcontract a portion of the work, or lease property, or make referral of participants to, or make purchases from the entity;
- 5. The Investigator has a financial interest in an entity that is part of a consortium or that will otherwise participate in the sponsored project.

Financial interests which are not "related" to the sponsored project do not need to be disclosed.

INSTITUTIONAL RESPONSIBILITIES

An Investigator's professional responsibilities on behalf of the Institution which may include for example: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

INDEPENDENT SUBSTANTIVE REVIEW COMMITTEE (ISRC)

An advisory committee comprised of research deans is appointed by the Vice President for Research to review disclosures, relevant features of the sponsored projects and, on the basis of their review, recommend to the Vice President for Research whether funding for the project should be accepted, and if so, whether any modifications or conditions are needed.

DESIGNATED REVIEWING OFFICIAL

The Financial Conflict of Interest Officer or officials designated by the Vice President for Research to review completed Disclosures of Financial Interests forms and to determine whether any reported financial interest would reasonably appear to be directly and significantly affected by the sponsored project.

Procedures

DISCLOSURE REQUIREMENT

For each sponsored project application, the Principal Investigator must fully disclose all related financial interests and must ensure that all other Investigators on the project have also completed such Disclosures prior to the University's acceptance of the award. All Investigators must also file an Update of Disclosure of Financial Interest either when they acquire new financial interests related to active projects, and on an annual basis, as determined by Vice President for Research.

SUB-RECIPIENTS

The Investigator is responsible for ensuring that sub-recipients to a sponsored program certify to the University any conflicts of interest related to the sponsored program. Sub-recipients are required to identify on the Sub-recipient Commitment Form whether they will follow this University of Memphis policy, or if they have their own in place. If they are following their own financial conflict of interest policy, they must verify on the Sub-recipient Commitment Form that their policy complies with all appropriate regulations.

The Office of Sponsored Programs may accept a single, annual Disclosure from an Investigator in lieu of a separate Disclosure with each award, provided that a Designated University Official and, if necessary, an Independent Substantive Review Committee (ISRC), can assure that each specific sponsored project and the related financial interests were examined in the scope of the annual review.

Under the Tennessee Open Records Act, T.C.A. 10-7-503, Disclosures and Updates are open to the public inspection upon request.

UPDATE OF DISCLOSURE OF FINANCIAL INTERESTS (UPDATE) Form to be completed by Investigators annually and within 30 days of acquiring new financial interests that were not listed in the original Disclosure of Financial Interests and that are related to their institutional responsibilities.

REVIEW OF DISCLOSURES

The Disclosures shall be reviewed by the Designated Reviewing Official to determine whether any related financial interest is

one which would reasonably appear to be directly and significantly affected by the proposed sponsored project.

A direct impact occurs when the project results would be directly relevant to the development, manufacturing, or improvement of the products or services of the organization in which the employee has a financial interest, or when the organization is a proposed subcontractor or participant in the project.

A significant impact on the financial interest is one which will materially affect the value of the organization, its earnings, or the sales of its products, or the organization is a proposed subcontractor or participant in the project.

Based on information provided in the Disclosure, the Designated Reviewing Official may determine that there is no reasonable basis on which to conclude that a project could directly and significantly affect the financial interest and that the financial interest is not likely to affect the design, conduct or reporting of the project. In this case, a record should be made of the Reviewing Official's action and the project can proceed without further review. In the event that either the Investigator or the Designated Reviewing Official concludes that the project might have a direct and significant impact on the financial interest could affect the design, conduct, and reporting of the project, the Disclosure and appropriate documentation shall be forwarded to the ISRC for consideration. The ISRC makes a final recommendation to Vice President for Research, or their designee about whether the project should proceed and whether any conditions or restrictions should be placed on the project to manage the conflict of interest. The same review process takes place when an Investigator files an Update form reporting a new, related financial interest.

MANAGEMENT, REDUCTION OR ELIMINATION OF CONFLICTS OF INTEREST When an Investigator has financial interests that would reasonably appear to be directly and significantly affected by the sponsored project, the ISRC may recommend to the Vice President for Research, or their designee that the project may not proceed. Alternatively, under certain circumstances, the ISRC may recommend that the Office of Sponsored Programs impose special conditions or restrictions to manage the conflict of interest so the effect of the Related Financial Interest(s) on the design, conduct, or reporting to the sponsored project(s) can be minimized. Investigators may also be asked to make recommendations about how to manage the conflict of

interest. Examples of conditions or restrictions that may be imposed to manage, reduce or eliminate conflicts of interest include:

- * Public disclosure of the Related Financial Interest(s);
- * Monitoring of the project by independent reviewers;
- * Modification of the research or project plan;
- * Disqualification from participation in all or a portion of the project;
- * Divestiture of the Related Financial Interest(s), or
- * Severance of relationships that create actual or potential conflicts.

The review of the Disclosure(s) and adoption of conditions or restrictions to manage, reduce, or eliminate the conflict of interest must be complete within sixty (60) days of receipt of the award, (unless the sponsor requires action by an earlier date) and prior to expenditure of funds. Some sponsors may also require a report of the existence of a conflict of interest and assurances that is has been managed, reduced or eliminated.

Conflict resolution plans will be in writing, approved by the VPR and implemented before the award is activated.

Failure to file a complete Disclosure of Financial Interests or Update or to comply with any conditions or restrictions imposed on the conduct of the project under this Policy will be grounds

on the conduct of the project under this Policy will be grounds for discipline of the researcher, up to and including termination for adequate cause. In addition, Federal regulations may require reports to the Federal sponsor regarding any violations of this policy. Sponsors may suspend or terminate the award and/or debar an Investigator from receiving future awards in the event of failure to comply with applicable Federal regulations on disclosure, review, and management of significant financial

interests related to Federally sponsored projects.

In order to ensure that all employees engaging in sponsored research recognize, manage and report financial conflicts of interest, training is required at the following points:

- 1. Prior to engaging in sponsored research
- 2. Updated training every four years
- 3. Annual training if there is an active financial conflict of interest

SANCTIONS

TRAINING

4. If the researcher is found to be not in compliance with this financial conflict of interest policy.

The required training is the course "Conflicts of Interest" available for all University of Memphis employees at citiprogram.org.

RESPONSIBILITIES AND ADMINISTRATION

Records regarding investigator disclosures, Reviewing Official's determinations, ISRC recommendations, and University actions regarding management, reduction and elimination of a conflict of interest must be retained for at least three years from the date the final expenditures report is submitted, or until resolution of any action by the sponsor involving the records, whichever is longer.

Implementation of this Policy shall include compliance with applicable sponsor regulations governing institutional responsibilities, certification of compliance, reporting requirements, and other duties required under the sponsor's regulations. The Office of Sponsored Programs will examine local conditions and obligations to determine what additional actions and procedures need to be implemented to bring local practices into conformance with this Policy. Copies of guidelines, procedures, and forms developed by individual laboratories should be sent to the Office of Sponsored Programs.

Links

Financial Conflict of Interest web page with link to training.

Financial Conflict of Interest form

Sub-recipient Commitment Form

Revision Dates

UM1798 -- revised with same issued date July 19, 2017 UM1798 -- issued May 25, 2016 RE7003 supersedes UM1798

Subject Areas:

Academic	Finance	General	Human Resources	Information Technology	Research	Student Affairs
\boxtimes	\boxtimes	\boxtimes	\boxtimes		\boxtimes	