

- I. [DEFINITIONS](#)
- II. [OVERVIEW](#)
- III. [WHAT IS REQUIRED TO BE DISCLOSED](#)
- IV. [HOW TO DISCLOSE](#)
- V. [COLLECTION AND REVIEW OF DISCLOSURE FORMS](#)
- VI. [OVERSIGHT MANAGEMENT PLANS \(OMP\)](#)
- VII. [CONFLICTS IN THE REVIEW/OVERSIGHT PROCESS](#)
- VIII. [PHS FUNDED INVESTIGATORS](#)
- IX. [NONCOMPLIANCE](#)
- X. [APPEAL/RECONSIDERATION PROCESS](#)

# **I. DEFINITIONS**

## **1. Conflict of Interest Committee (COIC):**

The committee formed at the University level responsible for advising employees about potential individual conflicts of interests. The committee is comprised of members identified by the chair.

## **2. Disclosure (also, Outside Interest Disclosure):**

An employee's disclosure to the University of outside interests (e.g. external to the University), including employment or business activities. The disclosure is required to be updated through eCompliance at <https://umsl.ecompliance.umssystem.edu/login>

## **3. Financial Interest:**

Anything of monetary value including, but not limited to, an interest in a business consisting of any stock, stock option, or similar ownership interest in such business; or receipt of, or the right or expectation to receive, any income. The following is a non-exhaustive list of examples: 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, loans, or any other form of compensation.

"Financial Interest" means anything of actual or potential monetary value, whether or not the value is readily ascertainable. The term financial interest does not include the following types of financial interests:

- a) salary, royalties, or other remuneration paid by the University to the employee if the employee 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;
- b) income from investment vehicles, such as mutual funds and retirement accounts, as long as the employee does not directly control the investment decisions made in these vehicles;
- c) 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
- d) 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.

## **4. Employee Outside Interest:**

- a. An employment, consulting, or other professional activity or service, paid or unpaid, for a third party that is not part of the Employee's University Responsibilities, and such activity or service for the third party nonetheless relates to work within the scope of the Employee's University Responsibilities. This includes, without limitation, any activity or

service that involves the use of the Employee's expertise, the practice of his or her profession, or any activity or service that contributes to the Employee's professional competence or development; or

- b. A direct or indirect financial interest in an entity that proposes to do business or is doing business with the University; or
- c. A direct or indirect financial interest in an entity that proposes to acquire or has acquired rights to University owned intellectual property; or
- d. Whenever an Employee's duties include research or investigation, a direct or indirect financial interest in an entity conducting research or business that is relevant to the scope of the Employee's University Responsibilities; or
- e. Any other activity that could be construed as relating to or overlapping or competing with the core missions of the University

#### **5. Immediate Family:**

The employee's spouse or domestic partner and dependent children.

#### **6. Investigator:**

Project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS or NSF, or proposed for such funding, which may include, for example, collaborators or consultants.

#### **7. Outside Interest:**

Per 330.015, an outside interest is defined as:

- a) An employment, consulting, or other professional activity or service, paid or unpaid, for a third party that is not part of the Employee's University Responsibilities, and such activity or service for the third party nonetheless relates to work within the scope of the Employee's University Responsibilities. This includes, without limitation, any activity or service that involves the use of the Employee's expertise, the practice of his or her profession, or any activity or service that contributes to the Employee's professional competence or development; or
- b) A direct or indirect financial interest in an entity that proposes to do business or is doing business with the University; or
- c) A direct or indirect financial interest in an entity that proposes to acquire or has acquired rights to University owned intellectual property; or
- d) Whenever an Employee's duties include research or investigation, a direct or indirect financial interest in an entity conducting research or business that is relevant to the scope of the Employee's University Responsibilities; or
- e) Any other activity that could be construed as relating to or overlapping or competing with the core missions of the University.

## **8. Significant Financial Interest (PHS):**

A financial interest consisting of one or more of the following interests of the PHS Investigator (and those of the Investigator's spouse and 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 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;
- 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 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
- c. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

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.

## **9. University Responsibilities**

Employee's responsibilities for which such Employee was hired and conducted at or undertaken on behalf of the University, which may include, but is not limited to, activities such as research, research consultation, teaching, outreach/extension, professional practice, institutional committee memberships and service on University-based panels.

## **II. OVERVIEW**

The Conflict of Interest Committee (COIC) has been charged by the Chancellor pursuant to CCR 330.015, 420.030, and 410.020 with the responsibility for management of all conflicts of interest at the University of Missouri-St. Louis. Conflicts are common and unavoidable in a modern research university. The COIC works to assist faculty and staff to appropriately structure their various interests to avoid, mitigate or manage those conflicts. No two situations are the same, therefore, the Committee works diligently to understand each scenario to find custom solutions that best meet the needs of the parties involved.

**The Conflict of Interest Disclosure Form also captures information used by Supervisors and Administrators in the course of fulfilling their obligations, i.e. Conflicts of Commitment.**

## **DISCLOSURE**

**All faculty and exempt personnel are required to disclose outside interests, both paid and unpaid, annually and as new interests arise or changes occur.** All other employees regardless of title, position, or involvement in research activities shall disclose Outside Interest as such interests arise (e.g. transactional reporting) ([CRR 330.015](#), [360.020](#))

## **III. WHAT IS REQUIRED TO BE DISCLOSED**

### **A. Personal Financial Interests**

Any employment, consulting, or other professional activity or service, either paid or unpaid, which is not part of but relates to the Employee's University Responsibilities. This includes any activity or service that involves the use of the Employee's expertise, the practice of his or her profession, or any activity or service that contributes to the Employee's professional competence or development.

A direct or indirect financial interest in an entity that proposes to do business or is doing business with the University.

A direct or indirect financial interest in an entity that proposes to acquire or has acquired rights to University owned intellectual property.

If an employee's duties include research or investigation, a direct or indirect financial interest in an entity conducting research or business that is relevant to the scope of the employee's University responsibilities.

Any other activity that could be construed as relating to or overlapping or competing with the core missions of the University.

### **B. PHS and NSF Investigators Disclosure Requirement:**

- a. Each Investigator shall disclose financial interests (and those of the Investigator's spouse and dependent children) no later than the time of application for Public Health Services (PHS) or National Science Foundation (NSF) funded research.
- b. Each Investigator who is participating in PHS or NSF funded research shall submit an

updated disclosure of significant financial interests(SFI) at least annually, in accordance with the specific time period prescribed by the University, during the period of the award. Such disclosure shall include any information that was not disclosed initially to the University pursuant to paragraph (2)(a) of this section, or in a subsequent disclosure of significant financial interests (e.g., any financial conflict of interest identified on a PHS-funded project that was transferred from another Institution), and shall include updated information regarding any previously disclosed significant financial interest (e.g., the updated value of a previously disclosed equity interest).

- c. Each Investigator participating in the PHS or NSF funded research is required to **submit an updated disclosure** of significant financial interests **within thirty days of discovering or acquiring** (e.g., through purchase, marriage, or inheritance) a new significant financial interest ([CRR 420.030](#))

#### C. **PHS INVESTIGATOR: SPONSORED TRAVEL:**

When a PHS Investigator participates in any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so the exact monetary value may not be readily available), related to their University 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 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.

The University will require the following elements be submitted as part of any PHS Investigator Sponsored Travel Report:

- Purpose of the trip
- Identity of the sponsor/organizer
- Destination, and the duration
- Value of travel

The Committee will determine if further information is needed in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

#### IV. **HOW TO DISCLOSE**

All disclosures, personal and PHS/NSF required, are submitted through eCompliance at <https://umsl.ecompliance.umssystem.edu/login> through the COI module.

#### V. **COLLECTION AND REVIEW OF DISCLOSURE FORMS**

The COI Office will request annual disclosures from the various divisions of University with assistance from the deans and contacts in each Unit. The COI Office will review the Outside Interest Disclosure Forms (OIDFs) and follow up with the Units and/or the employee if questions remain or the information appears inaccurate or incomplete. The COI Office will present the information to the COI Committee, record the determinations and draft the letters associated with

each entity reviewed. The COI Office will educate faculty and staff to facilitate compliance with the Collected Rules and Regulations of the University of Missouri, and any other federal, state or local rules or regulations relating to conflict of interest.

***1. Review by the Conflict of Interest Committee Small Group (COIC-SG) or COIC:***

The COIC-SG will be constituted as deemed necessary by the COI Committee. The primary purpose of the COIC-SG is to complete an initial review of all OIDs. If additional information is needed, any clarifications or corrections will be documented within eCompliance.

The COIC-SG will make a resolution determination based on the information provided. Any disclosure that does not fall within the basic resolutions or requires additional guidance will be forwarded to the COIC. The COIC-SG will provide recommendations when referring any matter to COIC.

A list of disclosures and determinations made by COIC-SG and not referred to COIC will be made available to COIC.

***2. Analysis of Disclosed Interests:***

All outside interests will need to be managed on a case by case basis. Each situation comes with its own unique set of circumstances. Management strategies will need to be equally diverse. The information below is intended to provide guidance and may not be all inclusive.

A. **NO INTERESTS TO DISCLOSE**: if the employee has no outside interests to disclose, they will receive an automated email stating that no outside interests were reported at this time.

B. **MOOT**: The activity is part of the employee's UMSL position or the employee is no longer working at UMSL.

C. **NO APPARENT CONFLICT**: The outside interest is not related to an employee's responsibilities and it is determined there is no significant conflict of interest.

D. **OUTSIDE INTEREST MANAGED BY DISCLOSURE**: The outside interest may be related to an employee's responsibilities but that relationship presents a minimal conflict of interest with minimal risk of bias or inappropriate influence and does not meet the criteria of requiring Supervisor Approval. No additional management is needed beyond disclosure itself.

E. **OUTSIDE INTEREST MANAGED BY CONDITIONS**: The outside interest is related to an employee's responsibilities and that relationship may present an increased element of risk which requires mitigation. One or more conditions may be applied to manage the outside activity. Below are some examples of applicable conditions, when each condition may be applied, and how the condition assists to manage the outside activity:

<b>Conditions</b>	<b>When the condition may apply:</b>	<b>Management:</b>
<b>Supervisor Approval (SA)</b>	<ul style="list-style-type: none"> <li>• Employee responsibilities, professional service, or expertise with the entity overlaps with their expertise, profession, or role at UMSL</li> <li>• Consulting</li> <li>• Teaching outside of UMSL</li> <li>• Serves as director, officer, or board member with an organization, related but not required by UMSL responsibilities</li> <li>• Potential conflict of commitment to UMSL role</li> <li>• Receives a royalty revenue stream (<i>related to area of expertise</i>) from outside of UMSL</li> <li>• Activity is such that supervisor should be aware (entity may support research in faculty member’s lab, may involve students/employees, etc.)</li> <li>• Receives a textbook royalty for a book used within courses taught by the employee</li> <li>• Serving as or running for an elected public office (330.050)</li> </ul>	<p>Each disclosure resolved with supervisor approval is sent to the employee’s Chair/Supervisor followed by the Dean/Director for review to ensure:</p> <ol style="list-style-type: none"> <li>a. To the best of their knowledge, the interests are disclosed accurately and fully;</li> <li>b. The interests do not conflict with the interests of the Unit;</li> <li>c. The interests do not create an unmanageable conflict of commitment; and</li> <li>d. The interests do not result in the undocumented or improper use of university resources.</li> </ol> <p>The Chair/Directors should follow up with the employee if questions remain or the information on the form appears inaccurate or incomplete.</p> <p>The Supervisor may require stipulations to the activity which are conveyed by the COI Office to the employee in the final letter.</p> <p>The Supervisor should also follow up with the COI Office if they have any additional concerns not addressed by the initial review of the disclosure or if they are <u>withholding approval</u> on the outside activity.</p>
<b>Recusal</b>	<ul style="list-style-type: none"> <li>• Employee serves as an expert witness or consults for a legal firm or other entity.</li> </ul>	Resolution letter informs employee of the condition and any other applicable information.
<b>Textbook Royalties</b>	<ul style="list-style-type: none"> <li>• Employee earns royalties on the sale of educational textbooks/goods (<b>CRR 330.015.D.5</b>)</li> </ul>	Resolution letter informs employee of the condition and any other applicable information.
<b>Health Care Regulatory (HC Regulatory)</b>	<ul style="list-style-type: none"> <li>• This applies to optometrists (or immediate family member of such a person) when the employee has a financial interest in an outside entity and the employee’s patient treatment</li> </ul>	Resolution letter informs employee of the condition and any other applicable information. In addition, the Compliance Council is notified to address any specific concerns relating to Healthcare



	decisions or referral practices may benefit the outside entity.	policy. The Compliance Council is responsible for follow-up with the employee if there are any concerns and will notify COIC of any additional concerns/stipulations.
<b>Compliance Council</b>	<ul style="list-style-type: none"> <li>This applies to employees of UMSL Optometry with outside relationships.</li> </ul>	The Compliance Council is notified of the relationship to provide any specific information/education that may be applicable. The resolution letter informs the employee to contact the Compliance Council for any additional Healthcare specific policies.
<b>Institutional Animal Care &amp; Use Committee (IACUC)</b>	<ul style="list-style-type: none"> <li>Employee has a relationship (consulting, employment, etc. with an external company that may sponsor or provide products for animal research at UMSL</li> </ul>	The IACUC office is notified of the outside interest and may require specific conditions to manage any animal protocols. The IACUC Office will relay any protocol specific requirements to the employee. The resolution letter informs employee to notify IACUC of the relationship when conducting any research sponsored by or involving the outside entity. The employee is responsible for working with IACUC to ensure the conflict is managed.
<b>IRB</b>	<ul style="list-style-type: none"> <li>Employee has a relationship (consulting, employment, etc.) with external company that may sponsor or provide product to conduct human subjects research projects</li> </ul>	The IRB Office is notified of the outside interest and may require conditions to manage any human subject protocols. The IRB will relay any protocol specific requirements to the employee. The resolution letter informs employee to notify the IRB when conducting any research sponsored by or involving the outside entity. The employee is responsible for working with IRB to ensure the conflict is managed.
<b>Disclosure</b>	<p>Employee has a relationship that may require disclosure in all publications, presentations and/or reports.</p> <ul style="list-style-type: none"> <li>External relationship with an outside sponsor of their research at UMSL</li> <li>Typically required for all disclosures resolved with IRB or IACUC.</li> </ul>	The resolution letter informs employee of the condition and employee is expected to disclose outside relationship in any publications, presentation or reports.

<p><b>Contracting Office Approval</b></p>	<p>Business Services arranges contracts for speakers, management consulting, financial audits, use of UMSL space and equipment, performance agreements, etc.</p> <p>This condition applies when the employee:</p> <ul style="list-style-type: none"> <li>• Uses UMSL materials or space for outside work</li> <li>• Has equity interest (self or immediate family) in a business that contracts or plans to contract with UMSL</li> <li>• Consults for agency that a UMSL sponsored organization (e.g., charter school) hires on contract</li> <li>• Transactional reporting for sale of goods or services</li> </ul>	<p>Business Services is notified and considers the relationship when the employee requests a contract. Business Services will inform the employee if there are any specific conditions.</p> <p>The resolution letter informs the employee to notify the appropriate contracting office of the relationship when requesting a contract with the entity. The employee is responsible for working with the Office to ensure the conflict is managed.</p>
<p><b>Sourcing and Supply Chain (SSC)</b></p>	<p>SSC arranges contracts for goods readily available in the market place and for services such as custodial, printing, design, pest control, advertising, software development, etc.</p> <p>This condition applies when the employee:</p> <ul style="list-style-type: none"> <li>• Consults for company that provides deliverables to UMSL</li> <li>• Serves as director, officer, or board member with company that supplies deliverables to UMSL</li> <li>• Has interest in any local commerce (excl. personal residential properties) that has potential to benefit employee in some way</li> </ul>	<p>Sourcing and Supply Chain is made aware of the relationship and is responsible for the appropriate considerations when negotiating contracts.</p> <p>The resolution letter informs the employee to notify the Sourcing &amp; Supply Chain of the relationship when requesting a contract with the entity. The employee is responsible for working with the Office to ensure the conflict is managed.</p>
<p><b>Advancement</b></p>	<ul style="list-style-type: none"> <li>• Employee may receive a gift to either their department or lab.</li> </ul>	<p>Advancement is notified of the relationship. The employee is provided with instructions to notify advancement records management.</p>
<p><b>Campus Facilities</b></p>	<ul style="list-style-type: none"> <li>• The employee has equity in company that may contract for construction or other maintenance services for UMSL.</li> </ul>	<p>Campus Facilities is made aware of the relationship and is responsible for the appropriate considerations when negotiating contracts.</p> <p>The resolution letter informs the employee to notify the appropriate contracting office of the relationship when requesting a contract with the entity. The employee is responsible for working with the Office to ensure the conflict is managed.</p>

<p><b>Real Estate Office</b></p>	<ul style="list-style-type: none"> <li>Employee owns commercial property that maybe leased or purchased by UMSL</li> </ul>	<p>The Real Estate Office is made aware of the relationship and is responsible for the appropriate considerations when negotiating a contract.</p> <p>The resolution letter informs the employee to notify the Real Estate Office of the relationship when requesting a contract with the entity. The employee is responsible for working with the Office to ensure the conflict is managed.</p>
<p><b>Technology Commercialization &amp; Economic Development Office (TCED)</b></p>	<ul style="list-style-type: none"> <li>Employee has intellectual property (patents, copyrights, licenses) which they plan to transfer outside of the University; transfer use of materials has to be codified in written agreement with TCED</li> <li>Employee may develop IP with outside entity</li> <li>Employee has students creating intellectual property which they plan to use (e.g., through capstone class projects)</li> <li>Employee hires students whose intellectual property will be used in some way</li> </ul>	<p>TCED is made aware of the outside relationship and is responsible for providing education to the employee regarding intellectual property rights and agreements. TCED works closely with COI ensuring transparency.</p> <p>The employee is notified to contact TCED with any questions or concerns regarding intellectual property.</p> <p>TCED will refer proposed agreements involving COI to the COIC.</p>
<p><b>Treasurer's Office</b></p>	<ul style="list-style-type: none"> <li>Employee is serving on a board for a bank or other financial institution that may conduct business engagements with the University.</li> </ul>	<p>The Treasurer's Office and the Vice Chancellor for Finance is notified of the relationship and considers this when entering into relationship with the outside entity where there may be a perception the employee may have influence.</p> <p>The employee is notified to ensure the Treasurer's Office is aware if they have any influence in any contracts.</p>
<p><b>Student or employee awareness</b></p>	<p><b><i>The COI Office is required to be notified in advance to work with all parties to implement an agreement.</i></b></p> <ul style="list-style-type: none"> <li>Employees/students engaged in an outside activity in which the person they report to at UMSL has an interest in that outside entity.</li> </ul>	<p>Graduate studies, the chair, dean or other appropriate party is made aware of the involvement of students/employees. A meeting is arranged and an awareness agreement implemented. The non-conflicted representative will meet with the student/employee until the relationship is complete.</p>

	<ul style="list-style-type: none"> <li>• Student/employee working on subcontract from entity that faculty member has equity.</li> </ul>	Employees are notified of the requirement to report relationships prior to engagement with the outside entity.
<b>Export Controls</b>	<ul style="list-style-type: none"> <li>• Entity is outside of the U.S. and export controls may apply (<b>note: the review is only for UMSL employee as it relates to their UMSL position</b>)</li> </ul>	Export Controls is notified of the relationship. The employee is made aware that export control issues may impact the relationship and they can reach out to Export Controls regarding their UMSL position.
<b>IT Security</b>	<ul style="list-style-type: none"> <li>• Entity is outside of the U.S and individual will be traveling/teaching at the entity (<b>note: review is only for UMSL employee as it relates to their UMSL position</b>)</li> </ul>	IT Security is notified of the relationship. The employee is made aware to contact IT Security for any questions or concerns.
<b>No Referrals</b>	<ul style="list-style-type: none"> <li>• Employee cannot refer students or other UMSL employees to the business unless they go through the same channels as any other outside entity to advertise (advertising on unrestricted billboards is acceptable)</li> </ul>	The employee is made aware that they cannot promote the outside activity in their UMSL role.
<b>Use of UMSL email and letter head:</b>	<ul style="list-style-type: none"> <li>• When an employee has equity in an outside entity, they need to be aware that no UMSL endorsement or acknowledgement of any kind may be used in the promotion or conduct of Company without the appropriate approvals in advance. This includes, but is not limited to, the use of UMSL email, letterhead or other resources bearing UMSL markings.</li> </ul>	The employee is made aware that they cannot use the UMSL logo, stationary or other markings to promote the outside entity per <a href="#">CRR 170.060</a>
<b>Political Office (CRR 330.050)</b>	<ul style="list-style-type: none"> <li>• Any employee before he or she officially announces as a candidate for or accepts any public office must first inform his or her superior officer of such intention and such officer must make the fact known to the President of the University through appropriate channels.</li> </ul>	The employee is made aware of the notification requirements of the <a href="#">Collected Rule 330.050 for Political Offices</a> .
<b>Sponsored Programs/Pre-Award</b>	<ul style="list-style-type: none"> <li>• Employee has a relationship with an outside entity may contract to UMSL and the employee may be involved in the subcontract.</li> </ul>	The employee is notified to inform Sponsored Programs/Pre-Award each time the entity contracts with the University of Missouri-St. Louis and the employee has a role in the sub-contract.

<b>Oversight Management Plan</b>	<p><b><i>All potential applicable conditions apply and the entity is placed on a plan</i></b></p> <ul style="list-style-type: none"> <li>• Has a very active relationship with the outside entity (ownership, contracting with UMMSL, licensing of IP, etc.)</li> <li>• COI meets with individual <u>at least annually</u> to discuss activities (use of space, equipment expendable materials, time commitment, student involvement, any contracts to UMMSL or to the company, etc.)</li> <li>• May have project specific management plans as well</li> </ul>	<p>All applicable conditions are applied to manage the outside interest. In addition, the entity is placed on an Oversight Management Plan which covers all University rules as well as any specific management strategies. Each entity on a plan will have an assigned representative to ensure the relationship between UMMSL and the entity is managed and the plan will be reviewed at least annually. See below for further information.</p>
----------------------------------	--	---

F. **Other Management Strategies:** Not all outside activities can be managed with the conditions listed above and therefore the management may require other strategies, or a combination of the conditions listed and other additional strategies, to address the outside activity. Some, but not all examples, of potential strategies are:

- a. Time/Income Caps
- b. Review by an independent party
- c. Divestiture of a financial interest

G. **Unmanageable:** It is also possible that an outside interest will present an unmanageable situation. The full COI Committee has the option to deny approval of the outside interest when appropriate. If the outside activity is deemed unmanageable, the employee and chair will be informed. Employees may appeal the decision.

**3. Notification of determinations to the employee:**

After a final disposition has been reached and supervisor's approval obtained, a letter will be sent by the COI Office from the committee to the employee containing the decision and any conditions. Ideally, all employees will receive a response from the COI Office within 90 days of the submission of the report by the employee.

**VI. OVERSIGHT MANAGEMENT PLANS (OMP)**

An Oversight Management Plan is implemented when an employee has a dynamic relationship with an entity both externally and within their UMMSL role. Oversight Management Plans are designed to mitigate risk and manage the relationship between the outside entity and the University. Examples include but are not limited to:

- 1. The faculty member or his or her department receives University-supervised sponsored research support or contributions (in dollars or in kind) from a business in which they, an immediate family member, or an associated entity has a financial or business interest.

2. The faculty member assigns students, postdoctoral fellows, or other trainees or employees to projects of interest to or supported by a business (through sponsored research or a contribution) in which they, an immediate family member, or an associated entity has a financial or business interest.
3. The faculty member is as an owner or employee in a private firm or business entity that is proposing to license or otherwise acquire University-owned intellectual property.
4. In addition, employees may request an Oversight Management Plan for any of their outside interests to provide transparency and oversight if the outside interest interconnects with the employee's University role.

The COI Committee will determine when an Oversight Management Plan is needed and will determine the appropriate oversight needed to ensure:

- a. Activities between the University and Entity are managed
- b. Any research sponsored by the entity is without bias
- c. Any research deemed to have a FCOI is appropriately managed

The independent monitor/monitoring team will create (determined from COIC membership or outside COIC if expertise is needed) a plan to mitigate the risk of the relationship between UMSL and the outside entity including any sponsored research. The employee's Chair or Director is responsible for ensuring the conflict of commitment and separation of University responsibilities is appropriately addressed. A Management Plan Checklist may be utilized to identify any areas that may require additional management strategies. The COI Committee will review the plan. A report from the managed party will be provided to the COI Committee for review at least annually. Changes to the plan may occur at any time, either initiated by the managed party or the COIC.

#### **A. Project Specific Management**

An outside interest may not require immediate implementation of an Oversight Management Plan by the COI Committee. A project specific plan may be necessary to manage issues may be managed by the particular area. For example:

- An employee with an advisory relationship with a pharmaceutical company flagged for IRB so that a clinical trial submitted by that investigator is managed for the COI.
- A research project deemed to have a FCOI, however the outside relationship may not rise to the level of requiring an Oversight Management Plan.

## **VII. CONFLICTS IN THE REVIEW/OVERSIGHT PROCESS**

To avoid real or perceived conflicts of interest by committee members, individual COIC members and Oversight member will disclose any relationships or conflicts they may have related to the case under review and recuse him/herself from the review.

## **VIII. PHS FUNDED INVESTIGATORS:**

### **1. Review and Reporting to the Public Health Services**

#### **A. Initial Award:**

For all PHS-funded investigators, the COI Committee shall review all Investigator disclosures for a determination of Significant Financial Interest (SFI); determine whether any SFI relates to the research and determine whether a financial conflict of interest (FCOI) exists prior to the University expenditure of any funds. An Investigator's SFI is related to PHS-funded research when the COIC reasonably determines that the SFI could be affected by the PHS-funded research, or is in an entity whose financial interest could be affected by the research. The COIC may involve the Investigator in its determination of whether an SFI is related to the PHS-funded research. A FCOI exists when the COIC reasonably determines that the SFI could directly and significantly affect the design, conduct or reporting of PHS-funded research. Once the COI Committee determines a FCOI exists, a management plan must be developed and implemented specifying the actions that have been, and shall be, taken to manage such financial conflict of interest.

#### **B. Initial reports:**

Prior sending the University expenditure of any funds for a PHS-funded research project, the University shall provide to the PHS Awarding Component an FCOI report regarding any Investigator's FCOI ensuring a management plan has been implemented in accordance to the PHS rule. In cases in which the University identifies a financial conflict of interest and eliminates it prior to the expenditure of PHS-awarded funds, the University shall not submit an FCOI report to the PHS Awarding Component.

Providing FCOI reports to the PHS Awarding Component regarding all financial conflicts of interest of all sub-recipient Investigators consistent with this policy, i.e., prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

For any significant financial interest that the Institution identifies as conflicting subsequent to the University' initial FCOI report during an ongoing PHS-funded research project (e.g., upon the participation of an Investigator who is new to the research project), the University shall provide to the PHS Awarding Component, within sixty days, an FCOI report regarding the financial conflict of interest and ensure that the University has implemented a management plan in accordance with this policy.

Pursuant to paragraph (VIII)(2) of this section, where such FCOI report involves a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed or managed by the University (e.g., was not timely reviewed or reported by a sub-recipient), the University also is required to complete a retrospective review to determine whether any PHS-funded research, or portion thereof, conducted prior to the identification and management of the financial conflict of interest was biased in the design, conduct, or reporting of such research. Additionally, pursuant to paragraph VIII(2)(B) of this

section, if bias is found, the University is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component.

All FCOI reports shall include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the financial conflict, and to assess the appropriateness of the management plan. Elements of the FCOI report shall include, but are not necessarily limited to the following:

- Project number;
- PO/PI or Contact PD/PI if a multiple PO/PI model is used;
- Name of the Investigator with the financial conflict of interest;
- Name of the entity with which the Investigator has a financial conflict of interest;
- Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- Value of the financial interest (dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000 - \$100,000, by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;
- A description of how the financial interest relates to the PHS-funded research and the basis for the determination that the financial interest conflicts with such research; and
- A description of the key elements of the management plan, including:
  - Role and principal duties of the conflicted Investigator in the research project;
  - (b) Conditions of the management plan;
  - (c) How the management plan is designed to safeguard objectivity in the research project;
  - (d) Confirmation of the Investigator's agreement to the management plan;
  - (e) How the management plan will be monitored to ensure Investigator compliance; and
  - (t) Other information as needed.

For any financial conflict of interest previously reported by the University with regard to an ongoing PHS-funded research project, the University shall provide to the PHS Awarding Component an annual FCOI report that addresses the status of the financial conflict of interest and any changes to the management plan for the duration of the PHS-funded research project. The annual FCOI report shall specify whether the financial conflict is still being managed or explain why the financial conflict of interest no longer exists. The University shall provide annual FCOI reports to the PHS Awarding Component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS Awarding Component.

### **C. New Investigator and/or New Outside Interest added to a Project:**

During an ongoing research project, if a new Investigator is added to the project or an existing



Investigator discloses a new significant financial interest to the University, the COI Committee will review the disclosure within sixty days. A determination is required for whether any SFI is related to the research and whether a FCOI exists. All FCOIs require a management plan (See Section 5) specifying the actions that have been, and will be taken, to manage the financial conflict of interest.

#### **D. FCOI Management Plans:**

Whenever the University implements a management plan pursuant to this policy, the University shall monitor Investigator compliance with the management plan on an ongoing basis until the completion of the research project.

#### **2. Failure to disclose or review in a timely manner:**

When a significant financial interest is not disclosed in a timely manner by an Investigator or, for whatever reason, was not previously reviewed by the University during an ongoing research project (e.g., was not timely reviewed or reported by a sub-recipient), the Committee shall within sixty days: review the significant financial interest; determine whether it is related to research; determine whether a financial conflict of interest exists. Implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest going forward. The FCOI management plan will be submitted as required.

##### **A. Retrospective Review:**

Whenever a FCOI is not identified or managed in a timely manner including:

- failure by the Investigator to disclose within 30 days a SFI that is determined to constitute a FCOI;
- failure by the University to review or manage a FCOI within sixty days; or
- failure by the Investigator to comply with a financial conflict of interest management plan,

the University shall, within 120 days of the University determination of noncompliance, complete a retrospective review of the Investigator's activities and the research project to determine whether any research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research. The University shall document the retrospective review.

Based on the results of the retrospective review, if appropriate, the University shall update the previously submitted FCOI report to PHS, specifying the actions that will be taken to manage the financial conflict of interest going forward.

##### **B. Retrospective Review, Bias Found:**

If bias is found, the University is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report must include, at

a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and the plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, the University will submit FCOI reports annually, as specified elsewhere in this policy. Depending on the nature of the financial conflict of interest, an Institution may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date that the financial conflict of interest or the Investigator's noncompliance is determined and the completion of the retrospective review.

### **C. Retrospective Review Documentation:**

Such documentation shall include, but not necessarily be limited to, all of the following key elements:

- Project number;
- Project title;
- PD/PI or contact PD/PI if a multiple PD/PI model is used;
- Name of the Investigator with the FCOI;
- Name of the entity with which the Investigator has a financial conflict of interest;
- Reason(s) for the retrospective review;
- Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
- Findings of the review; and
- Conclusions of the review.

### **3. Public Accessibility**

Prior to the University expenditure of any funds under a research project, the University shall ensure public accessibility. Such accessibility is coordinated through the University of Missouri System Custodian of Records. Following submission of a written request and via a written response to the requestor within the time frame required under Chapter 610 of the Missouri Revised Statutes (as of August 2012: three business days), information will provided concerning any significant financial interest disclosed to the University that meets the following three criteria:

- (a) The significant financial interest was disclosed and is still held by the senior/key personnel as defined by this policy;
- (b) The University determines that the significant financial interest is related to the research; and
- (c) The University determines that the significant financial interest is a financial conflict of interest.

The information that the University of Missouri makes available via written response to any requestor shall include, at a minimum, the following:

- the Investigator's name;
- the Investigator's title and role with respect to the research project;
- the name of the entity in which the significant financial interest is held;
- the nature of the significant financial interest; and
- the approximate dollar value of the significant financial interest (dollar ranges are permissible: \$0-\$4,999; \$5,000-9,999; \$10,000 - \$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value

The University of Missouri will note in its written response that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60 days of the University's identification of a new financial conflict of interest, which should be requested subsequently by the requestor.

Information concerning the significant financial interests shall remain available, for responses to written requests for at least three years from the date that the information was most recently updated. The University will retain records of investigator financial disclosures and of actions taken to manage conflicts of interest for three years after the submission of the final research expenditures report.

#### **4. SPONSORED PROGRAMS/PRE-AWARD RESPONSIBILITIES**

##### **1. Subrecipient Monitoring:**

When the University carries out research through a sub-recipient on a PHS funded project (e.g., subcontractors or consortium members), Sponsored Programs/Pre-Award will take reasonable steps to ensure that any Subrecipient Investigator complies with this policy by incorporating as part of a written agreement with the subrecipient terms that establish that the financial conflicts of interest policy of the subrecipient will apply to the subrecipient's Investigators.

##### **2. Certification:**

###### **a. Certify, in each application for funding to which this policy applies, that the University:**

1. Has in effect an up-to-date, written, and enforced administrative process to identify and manage financial conflicts of interest with respect to all research projects for which funding is sought or received;
2. Shall promote and enforce Investigator compliance with this policy's requirements including those pertaining to disclosure of significant financial interests;

3. Shall manage financial conflicts of interest and provide initial and ongoing reports as required;
4. Agrees to make information available, promptly upon request, relating to any Investigator disclosure of financial interests and the University review of, and response to, such disclosure, whether or not the disclosure resulted in the Institutional Official's determination of a financial conflict of interest; and
5. Shall fully comply with the requirements of this policy.

## **IX. NONCOMPLIANCE**

Should it come to light that a potential conflict of interest concerning an employee exists and that employee failed to disclose such potential conflict to the appropriate authority, the COI Director should be contacted in addition to the employee's departmental chair/supervisor and dean/director. The Director will contact the employee and request that a formal disclosure of the potential conflict be made. This request shall be copied to the employee's departmental chair/supervisor and dean/director. The Director will also request that the employee provide specific reasons and justification for the failure to disclose. The information will then be provided to the COI Committee for review.

COIC has authority to recommend sanction of an employee for failure to cooperate with or upon finding a violation of COI policy (CRR 330.015.A.3). The Chancellor may apply sanctions as he/she feels is appropriate. Possible sanctions include, but are not limited to, the following:

- a) Letter of warning or admonishment.
- b) Suspension or termination of research compliance committee approvals.
- c) Suspension or termination of the privilege to submit sponsored activity proposals.
- d) Suspension or termination of sponsored research activity spending authority.
- e) Demotion or removal from assigned administrative roles.
- f) Referral to University Committee on Tenure or other appropriate committee for discipline or dismissal for cause of faculty.
- g) Suspension or termination of employment (pursuant and subject to CRR 310.060, Procedures in Case of Dismissal for Cause, for those faculty covered by that rule).

## **X. APPEAL/RECONSIDERATION PROCESS**

If an employee believes the determined course of action is inappropriate, the employee may ask for the decision to be reconsidered by the full COIC by submitting a request to the Institutional Official. Should attempts to resolve appeals in such fashion fail, procedures set forth in the University of Missouri Collected Rules and Regulations 370.010 or 380.010, as applicable, may be followed.