

# OBJECTIVITY IN RESEARCH

## I. Purpose

The primary goal of this policy is to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under grants, cooperative agreements and contracts will be free from bias resulting from Investigator's Financial Conflicts of Interest. This policy is designed to protect the credibility and integrity of the University of Mississippi's (UM) faculty, staff, and students so that public trust and confidence in sponsored research and educational activities is ensured.

UM faculty, staff and students are committed to the principle of free, open, and objective inquiry in the conduct of research. Multifaceted relationships between Investigators and industry exist and often complement Research. However, these relationships make conflicts of interest inevitable.

UM has a responsibility to manage any actual or potential conflict of interest arising from a financial interest of an Investigator. The University requires that Investigators disclose significant financial interests that may present an actual conflict of interest or the appearance of a conflict of interest in relationship with a sponsored project and then manage or eliminate those conflicts. Disclosure is instrumental for protecting the reputation of Investigators and the integrity of their research against challenges of potential bias.

In order to minimize the administrative burden to Investigators while meeting all regulations and state laws, this policy has separate procedures for PHS applications and awards (which require considerable effort) and for Non-PHS applications and awards (which require less effort). However, there is some overlap: PHS Investigators must complete Non-PHS self-screening questions and separate disclosures of relevant Significant Financial Interests as well as the extensive PHS form.

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

- A. **Confidentiality** means that disclosed financial interests marked "Confidential" shall be kept in a locked cabinet accessible only to the Director of Research Integrity and Compliance and /or as encrypted files on a password protected computer. To the extent permitted by law, all records of financial interest submitted by an Investigator shall be made available only to the Conflict of Interest Committee and to others on a "need to know" basis with clear understanding of the confidentiality of the information. Records will be destroyed once the record retention period expires (See Section VII.).
- B. **Conflict of Interest Committee (COIC)** means the committee appointed by the Institutional Official to 1) review Significant Financial Interests Requiring Disclosure forms when a potential or actual conflict has been identified by the Investigator, the Director of Research Integrity and Compliance, and/or the Director of Technology Management, 2) determine if an actual or a potential conflict of interest exists, 3) suggest ways to manage, reduce or eliminate conflicts, and approve a Memorandum of Understanding (Conflict of Interest Management Plan) on behalf of the Institutional Official. The Committee will be comprised of the Director of Research Integrity and Compliance, the Director of Technology Management, one or two members of the University Research Board, the Investigator's Dean or Dean's designee – or the

Investigator's division head or designee for non-academic units, and other members as deemed appropriate by the Institutional Official.

- C. **Equity Interest** means stocks, stock options, or other ownership interests, as determined through reference to public prices or other reasonable measures of fair market value.
- D. **Financial Conflict of Interest** means any Significant Financial Interests Requiring Disclosure that may significantly affect the design, conduct or reporting of Research.
- E. **Institutional Official** means the person appointed by University of Mississippi, or his/her designee(s), to solicit and review statements from Investigators of Significant Financial Interests Requiring Disclosure. [See Section [42 CFR 50.604\(b\)](#) and [45 CFR Section 94.4\(b\)](#)]. University of Mississippi has appointed the Vice Chancellor for Research and Sponsored Programs as its Institutional Official.
- F. **Institutional Responsibilities** means activities related to Investigators' research, teaching, clinical, or administrative duties at University of Mississippi.
- G. **Investigator** means faculty, staff or students serving as Project Directors, Principal Investigators, and members of the research team identified as senior/key personnel on a grant or contract application, progress report, or any other report who are responsible for and have substantial independent decision making in respect to the design, conduct or reporting of the research, such as Collaborators or Consultants named on a grant.
- H. **Memorandum of Understanding (MOU)** means the document developed by the Conflict of Interest Committee (COIC), the Investigator and the Investigator's Dean or Dean's designee – or the Investigator's division head or designee for non-academic units that constitutes the Conflict of Interest Management Plan for the resolution of an identified potential or actual conflict of interest and which includes, at a minimum, these mandatory key elements:
  - 1. The role and principal duties of the conflicted Investigator in the research project;
  - 2. Conditions of the management plan;
  - 3. How the management plan is designed to safeguard objectivity in the research project;
  - 4. Confirmation of the Investigator's agreement to the management plan;
  - 5. How the management plan will be monitored to ensure Investigator compliance; and
  - 6. Other information as needed
- I. **MURA** - The Mississippi University Research Act created in 1992 to facilitate economic development and promote the public welfare and prosperity of the people of Mississippi within the state by encouraging the development of cooperative ventures among the state's educational institutions, government and business.
- J. **Public Health Service** means the following agencies:
  - 1. Agency for Healthcare Research and Quality (AHRQ)
  - 2. Agency for Children and Families (ACF)
  - 3. Administration on Aging (AoA)
  - 4. Agency for Toxic Substances and Disease Registry (ATSDR)
  - 5. Centers for Disease Control and Prevention (CDC)
  - 6. Centers for Medicare & Medicaid Services (CMS)
  - 7. Federal Occupational Health (FOH)
  - 8. Food and Drug Administration (FDA)
  - 9. Health Resources and Services Administration (HRSA)
  - 10. Indian Health Service (IHS)

11. National Institutes of Health (NIH)
12. Substance Abuse and Mental Health Services Administration (SAMHSA)

- K. *Remuneration*** means anything of monetary value including, but not limited to salary, consulting fees, honoraria, or other payments for services, of any type, including speaking, teaching, and educational engagements, as well as gifts to Investigators – which may include travel reimbursed by other than an educational institution or governmental agency.
- L. *Research*** means any systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge, including behavioral and social-sciences research. The term encompasses basic and applied Research as well as product testing and development. The term includes, but is not limited to, any activity for which Research funding is available from a Public Health Service component that awards funds under grants, cooperative agreements or otherwise. For PHS-funded activities, this term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project or research resources award.
- M. *Significant Financial Interests – for Both PHS and Non-PHS Grants and Contracts*** means anything of monetary value including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights, and royalties from such rights).

The term does not include:

1. Salary, royalties, or other remuneration from the University as an employee
2. Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities
3. Income from service on advisory committees or review panels for public or nonprofit entities
4. Ownership of any interest of less than ten percent (10%) in a business where the aggregate annual net income to the University employee is less than One Thousand Dollars (\$1,000)
5. Ownership of any interest of less than two percent (2%) in a business where the aggregate annual net income to the University employee is less than Five Thousand Dollars (\$5,000)

- N. *Significant Financial Interests – for PHS Grants and Contracts Only*** means Interests held individually by the Investigator, his/her spouse, and dependent children, which, when added together, the value meets the limits below:
1. With regard to any publicly traded entity: The value of any remuneration and the value of any equity interest in the entity, when aggregated, exceed \$5,000.
  2. With regard to any non-publicly traded entity: The value of any remuneration received from the entity, when aggregated, exceeds \$5,000 OR when an Investigator (or an Investigator's spouse or dependent children) hold any equity interest (e.g., stock, stock option, or other ownership interest)
  3. Any intellectual property rights and interests (e.g., patents, copyrights not assigned to UM), upon receipt of income related to such rights and interests.
  4. Any reimbursed or sponsored travel, when aggregated over 12 months and across spouse and dependent children, exceeds \$5,000 (i.e., travel paid for on the Investigator's behalf, but not reimbursed by UM and related to the Investigator's research, administrative, clinical, or teaching duties  
Excluded is travel that is reimbursed or sponsored by the following:
    - A US Federal, state, or local government agency
    - A US Institution of higher education, academic teaching hospital, medical center
    - A research institute affiliated with a US Institution of a higher education

The term does not include:

1. Salary, royalties, or other remuneration paid by UM to you if you are currently employed or otherwise appointed by UM
2. Intellectual property rights assigned to UM and agreements to share in royalties related to such rights
3. Income from investment vehicles, such as mutual funds and retirement accounts, as long as you do not directly control the investment decisions made in these vehicles
4. Income from seminars, lectures, or teaching engagements sponsored by a U.S. federal, state, or local government agency, an Institution of higher education as defined in 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
5. Income from service on advisory committees or review panels for a U.S. federal, state, or local government agency, or 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

**O. Significant Financial Interests Requiring Disclosure – for Both PHS and Non-PHS Grants and Contracts** means Significant Financial Interests – for both PHS and Non-PHS Grants and Contracts 1) held by the Investigator, his/her spouse, parents, siblings, and children or by the spouse of the Investigator’s parents, siblings, and children that would reasonably appear to be affected by the proposed research or educational activity OR 2) Significant Financial Interests – for both PHS and Non-PHS Grants and Contracts held by the Investigator, his/her spouse, parents, siblings, and children or by the spouse of the Investigator’s parents, siblings, and children in any entity whose financial interests would reasonably appear to be affected by the proposed research or educational activity.

**P. Significant Financial Interests Requiring Disclosure – for PHS Grants and Contracts Only** means an Investigator’s Significant Financial Interests – for PHS Grants and Contracts where:

1. Those Interests reasonably appear to be related to the Investigator’s Institutional Responsibilities (i.e., research, teaching, administrative, or clinical duties at UM  
-AND-
2. Are received during the past 12 months

<sup>1</sup> Organizational titles at the University change over time and titles specified in this policy are meant to convey the types of duties and responsibilities performed by the personnel administering this policy. Personnel with substantially similar organization titles may perform these administrative duties.

### III. Regulatory Authority

**A. This policy is derived directly from requirements of:**

1. State of Mississippi Conflict of Interest laws. MISSISSIPPI CODE: SEC 25-4-101 to 25-4-105  
[http://www.ethics.state.ms.us/ethics/ethics.nsf/PageSection/A\\_ethics\\_laws\\_laws/\\$FILE/Ethics%20Laws.htm?OpenElement#s25\\_4\\_103](http://www.ethics.state.ms.us/ethics/ethics.nsf/PageSection/A_ethics_laws_laws/$FILE/Ethics%20Laws.htm?OpenElement#s25_4_103)
2. The regulations for objectivity in research of the National Science Foundation  
[http://www.nsf.gov/pubs/manuals/gpm05\\_131/gpm5.jsp#510](http://www.nsf.gov/pubs/manuals/gpm05_131/gpm5.jsp#510)
3. The regulations for objectivity in research of the Public Health Service  
[42 CFR Part 50 and 45 CFR Part 94](#)

## **B. MURA Exception to State of Mississippi Conflict of Interest laws**

The Mississippi Legislature created MURA in 1992 (MISSISSIPPI CODE: SEC. 37-147-1 to 37-147-15) to facilitate economic development and promote the public welfare and prosperity of the people of Mississippi within the state by encouraging the development of cooperative ventures among the state's educational institutions, government and business. The MURA Act provides that "notwithstanding any other provision of state law" [the Ethics in Government Act], an employee of a university may apply to MURA for permission to establish and maintain a material financial interest in a private entity which provides or receives equipment, material, supplies or services in connection with the university in order to facilitate the transfer of technology developed by the employee from the university to commercial and industrial enterprises for economic development.

Investigators interested in applying for MURA approval should meet with the Director of Technology Management to initiate technology licensing discussions and obtain assistance in completing the necessary documentation. Prior to making application to MURA, UM Investigators must first receive approval in writing from their line management and the Chancellor. Permission may be granted by the Chancellor only if all of the following conditions are met:

The Investigator

1. Provided a detailed description of interest in private entity to the Chancellor
2. Fully described the nature of the undertaking to the Chancellor
3. Demonstrated to the satisfaction of the Chancellor that the proposed undertaking may benefit the economy of the state
4. Demonstrated to the satisfaction of the Chancellor that the proposed undertaking will not adversely affect research public service or instructional activities at the university; and
5. The employee's interest in the private entity, or benefit from the interest, will not adversely affect any substantial state interest

After approval is given by UM, the application is submitted to MURA for review by the Institutional Official. MURA may authorize an employee to maintain a material financial interest in a private entity if it considers the same information and factors submitted to UM, makes positive findings on all conditions, and reflects this fact in its minutes. The Chancellor is required to submit an annual report to MURA detailing the status of each MURA approved project.

## **IV. Applicability**

### **A. Applicability for PHS Grant and Contract Applications and Awards, PHS Excluded Awards, and Initiation of Policy**

1. This policy does not apply to research funded solely by PHS SBIR/STTR Program Phase I awards subsequent to August 24, 2012. However, human subjects research funded by PHS SBIR/STTR Programs are subject to this policy.
2. The procedures for PHS Investigators ([42 CFR Part 50 Subpart F](#)) apply to PHS funded grants or cooperative agreements with an issue date of the Notice of Award that is subsequent to August 24, 2012 and to solicitations issued and contracts awarded subsequent to August 24, 2012.

## **B. PHS Subrecipient Requirements:**

For Research sponsored by the Public Health Service that involves subcontractors, subgrantees or subawardees (collectively “Subrecipients”) at other Institutions, UM requires a written agreement from Subrecipients that establishes whether UM’s policy or the subrecipient’s policy shall apply to the subrecipient’s Investigators. In all cases, UM must report to the PHS funding agency any Subrecipient Financial Conflicts of Interest prior to the execution of the subcontract or within 60 days of identification of a new Financial Conflict of Interest by the Subrecipient or UM that arises during the term of the subcontract.

1. If the subrecipient’s policy is used, the subrecipient must certify that its financial conflict of interest policy is compliant with 42 CFR Part 50 and 45 CFR Part 94 and will be responsible for ensuring that the Subrecipient Institution and its Investigators comply with the federal regulations. Subrecipients must report to UM as the awardee Institution, any identified Financial Conflict of Interest within 10 business days of the management plan agreement with the Subrecipient’s Investigator, but no later than 45 days after identification of the Financial Conflict of Interest by the Subrecipient. The details of the Financial Conflict of Interest will be reported to the funding agency as required under applicable regulations or policies.
2. If UM’s policy is used, the Subrecipient must ensure that all of its Investigators submit the PHS Significant Financial Interest Disclosure Form to UM prior to the time of application by UM (or at the time the Subrecipient signs an institutional letter of support if during an on-going award grant or contract).

## **V. Procedures**

UM will manage, minimize, or eliminate Investigators’ Financial Conflicts of Interest to ensure that research will be free from potential bias resulting from Investigator financial interests. All Investigators pursuing sponsored research projects are required to report all financial interests that could affect or be affected by Research on which they are working or proposing to work on to the Office of Research and Sponsored Program’s (ORSP) Director of Research Integrity and Compliance. Investigators who are applying to or are funded by a PHS agency must follow a separate disclosure process for Significant Financial Interests related to their Institutional Responsibilities that is described in section V.A. The Director of Research Integrity and Compliance will review the Investigator Significant Financial Interests Requiring Disclosure form and coordinate development of an appropriate management plan when a Financial Conflict of Interest exists. In developing these plans, UM aims to meet the following goals:

- Safeguard the integrity of Research
- Ensure that Research is objective and without bias in the design, conduct or reporting of it
- Address unique circumstances and conditions that may be presented by individual cases

### **A. Investigator Reporting Requirements**

All Investigators must provide Significant Financial Interests Requiring Disclosure to the Director of Research Integrity and Compliance in a sealed envelope marked ‘Confidential’ at the following time points:

1. Prior to submission of a proposal
2. Within thirty (30) days after a new Significant Financial Interest Requiring Disclosure is received or acquired (e.g. through purchase, marriage, or inheritance)
3. Annually at the time of Progress Report submission

Significant Financial Interest Disclosure Forms are available on the ORSP Objectivity in Research web page

1. Non-PHS Investigators must complete
  - a. the 'General Significant Financial Interest Disclosure Form'
2. PHS Investigators must complete BOTH
  - a. the 'PHS Significant Financial Interest Disclosure Form'

AND

  - b. the 'General Significant Financial Interest Disclosure Form'

Note: One meets requirements for PHS regulations and the other for Mississippi State Law

Investigators who need assistance deciding what interests apply and their categorization should contact the ORSP Office of Research Integrity and Compliance for guidance.

#### **B. *Conflict of Interest Review Procedures***

1. Initial Review

The Director of Research Integrity and Compliance will conduct a preliminary review of all Significant Financial Interest Disclosures 1) to determine if Investigators' disclosure information is sufficiently complete for review or whether the Investor must be contacted for additional information or clarification and 2) to make an initial assessment in consult with the Director of Technology Management whether there is definitely no conflict of interest that could directly and significantly affect the design, conduct, or reporting of the Research (both Directors must concur here) or whether there is a possible or clear conflict of interest that could affect the Research.
2. Conflict of Interest Committee (COIC) Functions and Review

The COIC will:

  - a. Review any reports made regarding Significant Financial Interests
  - b. Request and review any additional materials needed to evaluate the relationship of the Significant Financial Interests to the Research
  - c. Determine whether the Significant Financial Interests require a plan to manage, reduce, or eliminate the financial interest and to develop such a plan
  - d. Determine, for PHS funded activities, whether a Significant Financial Interest is related to a particular research project and whether such interest is a Financial Conflict of Interest pursuant to 42 CFR Part 50/45 CFR Part 94
  - e. Consult with the Investigator to get clarification on Significant Financial Interests
  - f. May suggest ways to manage, reduce, or eliminate the conflict
  - g. Review a Conflict of Interest Management Plan that the Investigator, in collaboration with the COIC member representing the Investigator's Dean or Dean's designee – or the Investigator's division head or designee for non-academic units, develops that details

proposed steps to manage, reduce, or eliminate any actual or potential conflict of interest presented by Significant Financial Interests

- h. Approve the proposed Conflict of Interest Management Plan or add further management measures before approval, as the COIC deems necessary, communicate added measures to the Investigator, and take into consideration the Investigator's comments.

Examples of such measures include:

- Public disclosure of financial conflicts of interests (e.g., when presenting or publishing the research; to staff members working on the project; to the Institutional Review Board)
  - For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants
  - Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the Financial Conflict of Interest
  - Modification of the research plan
  - Change of personnel or personnel responsibilities, or disqualifications of personnel from participation in all or a portion of the research
  - Reduction or elimination of the financial interest (e.g., sale of an equity interest)
  - Severance of relationships that create financial conflicts
1. If the COIC determines that there is no conflict of interest that could directly and significantly affect the design, conduct, or reporting of the Research, the documentation of the review and determination will be filed along with the Disclosure Forms and retained as per the recordkeeping retention requirement. (Section VII.)
  2. If the COIC determines that there is a Financial Conflict of Interest and a Conflict of Interest Management Plan is developed, it shall be incorporated into a Memorandum of Understanding (MOU) that details the conditions or restrictions imposed upon the Investigator in the conduct of the project or in the relationship with the sponsoring entity. The MOU shall be signed by the Investigator, the Investigator's Dean or Dean's designee – or the Investigator's division head or designee for non-academic units, and the Institutional Official.
  3. **Notification of Conflict of Interest Committee's Decision and Recommended Approval of Plan:** The Institutional Official will be informed by the COIC when it 1) determines that an Investigator's Significant Financial Interest Requiring Disclosure must be managed, reduced, or eliminated and 2) when an MOU containing the management plan has been approved by all signing parties. The Institutional Official will sign the proposed plan or notify the COIC within seven (7) days with an objection to the plan. In the latter case, the Institutional Official, Investigator, and COIC will work towards developing a mutually agreeable plan. If agreement on a plan cannot be reached within fourteen (14) days after receipt of an objection from the Institutional Official, then the recommendations of all parties shall be presented for a final decision to the Provost, which decision shall be provided within 10 days of receipt of the recommendations.
  4. **Investigator Notification and Appeals:** The Director of Research Integrity and Compliance will notify Investigators when a Significant Financial Interest Requiring Disclosure must be managed and when a Financial Conflict of Interest exists. The final recommended plan for the management, reduction, or elimination of the Significant Financial Interest Requiring Disclosure in the form of an MOU will be sent to the Investigator for signature. Investigators can appeal the plan with justifications in writing to the COIC within 10 business days of receipt of the notification. Should the Investigator not file a written

appeal with the COIC by such time, then the Investigator shall be considered to have waived his/her right to appeal and the MOU will be final, except for noting refusal of the Investigator to sign the MOU where valid. If the Investigator's appeal is denied by the COIC, the Investigator can appeal to the Provost within 10 business days of receipt of the notification from the COIC. The Provost will notify the Investigator within 10 business days as to whether the appeal is granted or denied. During any appeal to the COIC or Provost, Investigators must not expend any funds under any award from a sponsor for the conduct of the Research at issue and either (a) agree to abide by the initial recommendations of the COIC or (b) remove themselves from any participation in the Research.

5. **Research with Human Subjects:** Special precautions must be taken to avoid bias with respect to Research involving Human Subjects involving the evaluation of strategies or products that may affect or be affected by the financial interests of UM or UM Investigators. A UM Investigator shall not ordinarily participate in any Research involving human subjects that encompasses evaluation of such a strategy or product if he/she has a Significant Financial Interest that could directly and significantly affect the design, conduct or reporting of the Research unless the Investigator presents a compelling justification for a waiver of this policy based on unique qualifications as an Investigator. The degree of risk to human subjects and the justification will be reviewed by the Committee. If compelling circumstances justify a waiver of this policy, the Research will be subject to stringent management measures to ensure the safety of the human participants and the integrity of the Research. The IRB must review and approve any management plan for human subject Research. The IRB may require additional safeguards to protect human subject participants. In accordance with 42 CFR Section 50.606(c), in any case in which the Department of Health and Human Services determines that a Public Health Service-funded project of clinical Research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device or treatment has been designed, conducted or reported by an Investigator with a conflicting interest that was not reported or managed as required by this Policy or the applicable regulations, then UM shall, at minimum, require the Investigator involved to disclose the conflicting interest in each public presentation of the results of the Research and to request an addendum to previously published presentations. An Investigator who has failed to report a Significant Financial Interest Requiring Disclosure related to clinical Research will be subject to sanctions described in Section VI. If the project is funded by a PHS agency, the Investigator will also be subject to the mandatory Retrospective Review procedures described in Section VI.

#### **C. *Reporting and Expenditure of Funds***

No expenditure of sponsor funding for Research shall occur with respect to any Research project for which the Committee has determined that a management plan is required unless and until all reporting requirements have been met. For any Significant Financial Interest Requiring Disclosure that is identified after the funding for the Research is awarded, the COIC will determine whether a Financial Conflict of Interest exists and whether a management plan is required (or whether an existing plan must be amended). As required by the sponsor's regulations or policies, ORSP shall report to the funding agency any management plans or Financial Conflict of Interest within 60 days of the interest's identification. The outcome of Conflict of Interest Committee reviews will be communicated to the Institutional Review Board (IRB) for all Research involving human subjects and to the Institutional Animal Care and Use Committee (IACUC) for all Research involving animal subjects. The IRB may require additional measures to protect the safety and welfare of Research subjects under their purview.

#### **D. PHS Awards**

Procedures and requirements for reporting and training for PHS Awards

## 1. Reports to PHS Funding Agency

As required by federal regulations, ORSP shall report the following information regarding Financial Conflicts of Interest to the funding agency through the eRA Commons:

- a. Project Number
- b. PD/PI or Contact PD/PI if multiple PD/PI model is used
- c. Name of the Investigator with the Financial Conflict of Interest
- d. Name of the entity with which the Investigator has a Financial Conflict of Interest
- e. Nature of the Significant Financial Interest (e.g. equity, consulting fee, travel reimbursement, honorarium)
- f. Value of the Significant Financial Interest, or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measure of fair market value
- g. A description of how the Significant Financial Interest relates to the PHS-funded research and the basis for the COIC's determination that the Significant Financial Interest conflicts with such research
- h. A description of key elements of the Conflict of Interest Management Plan including:
  - Role and principal duties of the conflicted Investigator in the research project
  - Conditions of the management plan
  - How the management plan is designed to safeguard objectivity in the research project
  - Confirmation of the Investigator's agreement to the management plan
  - How the management plan will be monitored to ensure Investigator compliance
  - Other information as needed or requested by the funding agency

Additionally, each award year ORSP must provide the funding agency 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 project period (including extensions with or without funding). 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. ORSP must report to the agency the annual FCOI report at the time of the progress report.

## 2. Reports in Response to Public Requests for Information

As required by federal regulations and upon written request, UM shall provide written information to any requestor. Requests must be in writing and must identify the specific PHS project number. The request must include a named recipient and return address with a physical street address (P.O. Boxes are not acceptable). The written response will state that the information is current as of the date of the correspondence. It will also state that the information is subject to updates at least annually and within 60 days of the identification of a new conflict of interest, and that this updated information must be requested under separate cover. The following information will be provided to requestors:

- a. Project Number
- b. Name of the Investigator with a conflicted interest
- c. Investigator's title and role with respect to the research project
- d. Nature of the financial interest (e.g. equity, consulting fee, travel reimbursement, honorarium)

- e. Value of the financial interest (in ranges), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measure of fair market value

### 3. **Mandatory PHS Investigator Training**

Each PHS Investigator must complete conflict of interest ethics training prior to engaging in Research, at least every four years thereafter, and immediately under these circumstances:

- a. When this policy changes in a manner that affects Investigator requirements
- b. When an Investigator is not in compliance with this policy or a management plan

## **VI. Compliance with this Policy**

The Investigator is responsible for ensuring that all disclosures required by this Policy are made with accuracy and within time limits. The Investigator must also follow prescribed plans for the management, reduction, or elimination of an identified Financial Conflict of Interest. Failure to comply is a violation of this University Policy. The Investigator's Dean or Dean's designee – or the Investigator's division head or designee for non-academic units, or the Conflict of Interest Review Committee may inspect any necessary records to ensure compliance with the plan.

The COIC, in consultation with the Institutional Official, is responsible for investigating and resolving any alleged violations of this Policy and may recommend appropriate actions to the Institutional Official to enforce this Policy and/or to impose a sanction for noncompliance. The Institutional Official shall review and take appropriate action to implement such recommendations as deemed appropriate. Sanctions for noncompliance may include reprimands or other measures, up to and including termination of employment. In investigating any violation of this Policy, the COIC must determine if any violation of this Policy has biased the design, conduct or reporting of the Research. The COIC will take appropriate steps to maintain the objectivity of the Research and other corrective actions as deemed appropriate. The COIC shall promptly notify the Institutional Official of any conflicts not resolved to the satisfaction of the COIC, along with recommended actions. The COIC will promptly notify the Research sponsor and affected UM units of any violations and/or corrective actions, as described above.

If a violation is associated with a collateral proceeding under the Responding to Allegations of Research Misconduct policy, then recommendations on sanctions will be deferred until the research misconduct process is completed.

### **PHS Procedures for failure to comply with this policy or a Conflict of Interest Management Plan (MOU): Procedures for Mandatory Retrospective Review**

In addition to the above review and sanctions, UM and PHS Investigators are subject to the following procedures when a Financial Conflict of Interest is not identified or managed in a timely manner including failure by the Investigator to disclose a Significant Financial Interest Requiring Disclosure that is determined by the COIC to constitute a Financial Conflict of Interest; failure by UM to review or manage such a Financial Conflict of Interest; or failure by the Investigator to comply with a Conflict of Interest Management Plan.

- A.** UM must 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;

- B. Within 120 days of the COIC's determination of noncompliance, it must complete a retrospective review of the Investigator's activities and the PHS funded research project to determine whether any PHS -funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.
- C. The COIC must document the retrospective review and include, at minimum, the following information:
  - 1. Project number
  - 2. Project title
  - 3. PD/PI or contact PD/PI if a multiple PD/PI model is used
  - 4. Name of the Investigator with the FCOI
  - 5. Name of the entity with which the Investigator has a Financial Conflict of Interest
  - 6. Reason(s) for the retrospective review
  - 7. Detailed methodology used for the retrospective review (*e.g.*, methodology of the review process, composition of the review panel, documents reviewed)
  - 8. Findings of the review
  - 9. Conclusions of the review
- D. Based on the results of the retrospective review, if appropriate, ORSP shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the Financial Conflict of Interest going forward.

If the retrospective review team members find bias, ORSP must notify the PHS agency promptly and submit a mitigation report to agency. 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 UM's 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, UM will submit annual FCOI reports to the PHS agency. Depending on the nature of the Financial Conflict of Interest, UM 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 UM's retrospective review.

## VII. Records Maintenance

The Director of Research Integrity and Compliance is responsible for maintaining records, identifiable to each project, all transactional reports of Significant Financial Interests, and all actions taken by the COIC or other appropriate units within UM to manage any actual or potential Financial Conflict of Interest for the longer of at least three (3) years from: (a) the date of submission of the final expenditures report, for federally funded grants; (b) from the date of termination or completion of the award; or (c) from the date of the resolution of any action by any governmental agency involving the records; or (d) as applicable, from any other date specified in 45 CFR Section 74.53(b) for different situations, as appropriate.