

# OBJECTIVITY IN RESEARCH

## I. Purpose

The purpose 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 an 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 to ensure public trust and confidence in sponsored research and educational activities.

UM has a responsibility to manage any real or perceived conflict of interest arising from an investigator's financial interest(s). The University requires that Investigators disclose financial interests that may present a real or perceived conflict of interest in relationship with their Institutional Responsibilities; and then, manage or eliminate those conflicts. Disclosure is instrumental in not only protecting the University and its Investigators from regulatory and reputational risk; but, in safeguarding the integrity of the Investigator's research against challenges of potential bias.

## II. Definitions

- A. **Confidentiality** – to the extent permitted by law, including the Mississippi Public Records Act, 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 VI.).
- B. **Conflict of Interest Committee (COIC)** – the committee appointed by the Institutional Official to 1) review disclosed Significant Financial Interests when a potential or actual conflict has been identified, 2) determine if a real or perceived conflict of interest exists, 3) suggest ways to manage, reduce or eliminate real or perceived conflicts, and approve a Conflict of Interest Management Plan. Committee membership will be comprised of representatives from The Office of Research and Sponsored Programs, The Office of the Provost, the University Research Board, tenured faculty, and other members as deemed appropriate by the Institutional Official. A representative from the Office of General Counsel will serve ex-officio.
- C. **Conflict of Interest Manager (COI Manager)** – the person assigned, by mutual agreement between Investigator and Investigator's Unit Head, and approved by the Conflict of Interest Committee to oversee day-to-day compliance with a Management Plan.
- D. **Equity Interest** – stocks, stock options, or other ownership interests.
- E. **Fiduciary Role** – a role in which one has the duty to act for someone else's benefit over that of one's personal interests.
- F. **Financial Conflict of Interest** – any Significant Financial Interest that reasonably could or appear to significantly affect the design, conduct, or reporting of Research.
- G. **Institutional Official** – the person appointed by University of Mississippi, or his/her designee(s), to solicit and review Investigator-disclosed Significant Financial Interests. [See Section [42 CFR 50.604\(b\)](#) and [45 CFR Section 94.4\(b\)](#)]. The University of Mississippi has appointed the Vice Chancellor for Research and Sponsored Programs as its Institutional Official.
- H. **Institutional Responsibilities** – activities related to Investigators' research, teaching, clinical, or administrative duties at University of Mississippi.
- I. **Investigator** – faculty, staff or students serving as Project Directors, Principal Investigators, and any member of the research team who is responsible for the design, conduct or reporting of the research, including collaborators, consultants, Subrecipients, contractors, and consortium participants.
- J. **Investigator's Unit Head** – the Investigator's Dean or Dean's designee – or the Investigator's division head or designee for non-academic units.
- K. **Management Plan** – the document developed by the Conflict of Interest Committee (COIC), the Investigator and the Investigator's Unit Head that constitutes the plan for the resolution of an identified real or perceived 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.

**L. Remuneration** – anything of monetary value.

**M. Research** – any systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge, including behavioral and social-sciences research.

**N. Significant Financial Interest** – a financial interest, received by an Investigator, and/or their spouse or dependent children, in the past 12 months, consisting of one or more of the following that is related to Institutional Responsibilities:

1. Equity interest in a domestic or foreign publicly traded company of 0-1.99% with aggregate income totaling greater than \$5,000;
2. Equity interest in a domestic or foreign publicly traded company of 2-9.99% with aggregate income totaling greater than \$1,000;
3. Equity interest in a domestic or foreign publicly traded company of 10% or greater;
4. Any equity interest in a domestic or foreign private company (including start-ups);
5. \$5,000 or more in salary, consulting fees, advisory board fees, honoraria, gifts, "in kind" compensation, or any other remuneration from a domestic or foreign outside entity;
6. An appointment to serve in a fiduciary role (director, officer, partner, trustee, or any position of management) for a domestic or foreign outside company, whether or not remuneration is received;
7. Any commercialization proceeds, such as licensing fees and royalties, from intellectual property (patents and copyrights);
8. Any travel sponsored or reimbursed by a domestic or foreign outside entity;
9. Any other compensation whose value could be affected by the outcome of research conducted at UM.

Excluded Financial Interests

1. Salary or other remuneration paid by UM to you if you are currently employed or otherwise appointed by UM;
2. 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;
3. 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;
4. 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. Subrecipient** – subcontractor, subgrantee or subawardee.

### III. Applicability

#### A. Applicability, Exclusions, and Initiation of Policy

1. This policy applies to all Investigators engaged in sponsored research.
2. This policy applies to Public Health Service (PHS) funded grants or cooperative agreements with an issue date of the Notice of Award that is subsequent to August 24, 2012. Where the research is funded solely by

PHS Small Business Innovation Research (SBIR)/Small Business Technology Transfer (STTR) Program Phase I awards, only those involving human subjects research are subject to this policy.

**B. Subrecipient Requirements:**

For Research that involves Subrecipients at other Institutions, UM requires a written agreement from Subrecipients that establishes whether UM's or the Subrecipient's financial conflict of interest policy shall apply to the Subrecipient's Investigators. For PHS sponsored research, UM must report to the PHS funding agency any Subrecipient Financial Conflicts of Interest prior to the execution of the subcontract or within 45 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 applied and controls, the Subrecipient must certify in writing 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 applied and controls, the Subrecipient must ensure that all of its Investigators submit a Significant Financial Interest disclosure 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).

## IV. Procedures

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. The Director of Research Integrity and Compliance will review the Investigator-disclosed Significant Financial Interests and coordinate development of an appropriate Management Plan when a Financial Conflict of Interest exists.

**A. Annual Investigator Disclosures**

All Investigators must disclose Significant Financial Interests to the Director of Research Integrity and Compliance at least annually but no later than the following:

1. Prior to first submission of a proposal.
2. Prior to participating in an active, funded research project.
3. Within thirty (30) days after a new Significant Financial Interest occurs.

Significant Financial Interest disclosure procedures are described on the ORSP Objectivity in Research [web page](#).

**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 Investigator must provide additional information or clarification and 2) to make an initial assessment on the impact of a given Significant Financial Interest on the Research and either determine the Significant Financial Interest does not represent a real or perceived conflict or refer the matter to the Conflict of Interest Committee (COIC) for review and management.

2. Conflict of Interest Committee (COIC) Functions and Review

The COIC will:

- a. Review Significant Financial Interest disclosures referred by the Director of Research Integrity and Compliance or informal reports made by other parties with direct knowledge of real or perceived conflicts of interest; and, determine whether the Significant Financial Interest(s) require a plan to manage, reduce, or eliminate the financial interest and to develop and approve such a plan.

- b. The Management Plan shall be formally documented in writing and shall detail the conditions or restrictions imposed upon the Investigator in the conduct of the project or in the relationship with the sponsoring entity. The Management Plan shall be signed by the Investigator, the COI Manager, the Investigator's Unit Head, the Director of Research Compliance and Integrity, and the Institutional Official.

Examples of management strategies include, but are not limited to the following:

1. 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).
  2. For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants.
  3. 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.
  4. Change of personnel or personnel responsibilities, or disqualifications of personnel from participation in all or a portion of the research.
  5. Reduction or elimination of the financial interest (e.g., sale of an equity interest).
  6. Severance of relationships that create financial conflicts.
- c. Determine 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.
3. 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. Unless appropriately managed, UM Investigator shall not participate in any Research involving human subjects that encompasses evaluation of such a strategy or product if he/she has a Financial Conflict of Interest that impacts the Research. The IRB must review and approve any management plan for Research involving human subjects. 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.

### **C. 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 requirements under this policy have been met.

### **D. PHS Investigators**

Procedures and requirements for reporting and training for PHS Awards

#### 1. Reports to [PHS Funding Agency](#)

As required by federal regulations at [42 CFR 50.605\(b\)](#) ORSP shall send reports to the funding agency through eRA Commons. The following information regarding Financial Conflicts of Interest(s) will be included in the report:

- 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 key elements of the Conflict of Interest Management Plan including:
  - 1. 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 or requested by the funding agency
- h. 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; and,
- i. Each award year, at the time of the progress report, ORSP will 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 report shall specify whether the FCOI is still being managed or explain why the FCOI no longer exists.

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

As required by federal regulations at [42 CFR 50.605\(a\)\(5\)\(i-iv\)](#) 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 response. 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. Name of the Investigator with a conflicted interest;
- b. Investigator's title and role with respect to the research project;
- c. Name of the entity in which the Significant Financial Interest is held;
- d. Nature of the Significant Financial Interest (e.g. equity, consulting fee, travel reimbursement, honorarium); and,
- e. Value of the Significant 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 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 new to the Institution.
- c. When an Investigator is not in compliance with this policy or a Management Plan.

Prior to release of initial or subsequent increments of funds, ORSP will verify each named Investigator has completed conflict of interest training within the previous four years.

## V. **Compliance with this Policy**

### A. **Monitoring and Noncompliance**

The Investigator is responsible for ensuring that accurate and timely disclosures required by this Policy are made. The Investigator must follow any applicable Management Plan for an identified Financial Conflict of Interest. Failure to comply is a violation of this University Policy.

The COIC, in coordination with the COI Manager, Investigator's Unit Head, will regularly inspect any necessary records to ensure compliance with the Management Plan. For any Significant Financial Interest that is identified and not disclosed by the Investigator in a timely manner, 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 implement and report to the funding agency any Management Plan(s) or Financial Conflict of Interest within 60 days of the interest's identification.

The COIC is responsible for investigating and resolving any alleged violations of this Policy and will recommend appropriate actions to the Institutional Official to enforce this Policy. The Institutional Official shall take appropriate action to implement such recommendations. Sanctions for noncompliance include, but are not limited to, enhanced monitoring, formal reprimands, loss of privileges, or termination of employment.

The COIC will determine if any violation of this Policy has biased the design, conduct or reporting of the Research. In the event it is determined that such bias has occurred, the COIC will implement an appropriate corrective action plan.

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 or corrective action will be deferred until the research misconduct process is completed.

#### ***B. PHS 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 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.

1. 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;
2. 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;
3. 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; and,
  9. Conclusions of the review.
4. 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 COIC finds 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.

## VI. 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 to manage any real or perceived Financial Conflict of Interest for the longer of three (3) years from: (a) the date of submission of the final expenditures report, for federally funded grants; (b) the date of termination or completion of the award; or (c) 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.

## VII. Regulatory Authority

This policy is derived directly from requirements of:

- A. State of Mississippi Conflict of Interest laws. [Miss. Code Ann. § 25-4-101 to 25-4-121](#).
  - 1. Mississippi's ethics laws, cited above, prohibit public servants from engaging in activities which would be in conflict with their public positions. These statutes effectively prohibit university faculty from commercializing their research. The Mississippi University Research Authority ("MURA") Act, was created to provide a legal and ethical mechanism for the appropriate commercialization of technology by faculty members. Miss. Code Ann. § 37-147-1 et. seq. The Act authorizes MURA to create policies, rules, and regulations by which a university employee, notwithstanding any other provision of state law, may apply to the authority 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 technological innovations from the university to commercial and industrial enterprises for economic development. Miss. Code. Ann. § 37-147-11 (West).
  - 2. Investigators interested in learning more about the applicability of the MURA Act with regards to their commercialization efforts should meet with the Director of the Office of Technology Commercialization.
- B. 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)
- C. The regulations for objectivity in research of the Public Health Service. [42 CFR Part 50 and 45 CFR Part 94](#)