

## FAQs for FACULTY and INVESTIGATORS

On August 23, 2012, The Offices of Compliance and Internal Audit (OCIA) and Office of Sponsored Programs (OSP), rolled out the new Conflict of Interest (COI) policy and training for investigators in compliance with the 2011 Public Health Service (PHS) regulations- Responsibility of Applicants for Promoting Objectivity in Research for which PHS funding is sought (42 CFR Part 50 Subpart F) and Responsible Prospective Contractors (45 CFR Part 94).

The following year, a new ad-hoc committee, the Research Conflict of Interest Committee (RCOIC), was established to review actual and potential conflicts disclosed to the institution. In April of 2013, at the request of the RCOIC, the OCIA made a presentation during the monthly faculty assembly, and those slides are available [here](#). Some of the questions in this FAQ were asked during the session; others were discussed during committee sessions or emailed to the OCIA.

Below are the FAQs as of **August 14, 2013**. In addition, general questions related to the new regulations are listed on the National Institutes of Health (NIH) Financial Conflict of Interest (FCOI) frequently asked questions webpage and are available at [http://grants.nih.gov/grants/policy/coi/coi\\_faqs.htm](http://grants.nih.gov/grants/policy/coi/coi_faqs.htm) or [here](#).

### **What is the Purpose of this Regulation?**

The 2011 revised regulation promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research performed under NIH grants or cooperative agreements will be free from bias resulting from investigator financial conflicts of interest. This regulation is commonly referred to as the [FCOI regulation](#).

### **Who is an Investigator?**

An investigator is defined as the principal investigator and any other person responsible for the design, conduct, or reporting of research funded by an agency of the U.S. Public Health Service (including the NIH), the National Science Foundation and other federal sponsors. This also includes collaborators, sub-grantees, or contractors on federal applications.

### **How Often are Investigators Required to Report?**

All principal investigators and key personnel must disclose their financial interests and the interests of their spouses/domestic partners and dependent children in COI-SMART at <https://msm.coi-smart.com>:

- Prior to engaging in research related to a PHS-funded grant
- At on boarding as a new employee at Morehouse School of Medicine (MSM) or Morehouse Healthcare (MHC)
- At least annually during the period of award
- Within 30 days of discovering or acquiring a Significant Financial Interest (SFI) (the definition of SFI was amended in 2011 to include a de minimis threshold of \$5,000 for disclosure that generally applies to payments and/or equity interests, as well as any equity interest in non-publicly traded entities).
- Within 30 days of reimbursed or sponsored travel where the PHS investigator is reimbursed directly from an outside organization (reimbursed or sponsored travel is defined as travel paid on behalf of the investigator and/or the investigator's spouse and/or dependent children. It excludes 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, and therefore, is not subject to this disclosure requirement).

### **Does a PI Have to Disclose Travel to Present Research Paid Through Grant Funds?**

No. Any travel that is itemized as a part of an approved grant award is already an allowable expense; therefore it does not have to be disclosed again.

### **Does a PI Have to Disclose Travel Awards from Research Societies to Attend Meetings?**

When the travel awards exceed the \$5,000 de minimis threshold when aggregated per entity then it must be disclosed. Subsequently, the OCIA and the OSR will perform a review to determine if a FCOI exists.

### **What is required to be 100% Compliant with the new rule and MSM policy on Research COI?**

There are two requirements to be met: (1) Timely completion of all conflict of interest training requirements in Cornerstone LMS. Please contact HR if you have questions regarding your transcript. (2) Full and timely disclosure of all SFI and attestation of having read Conflicts of Interest policies. Please contact OCIA if you have questions.

## **What is Required to be 100% Compliant with the New Rule and MSM Policy on Research COI?**

All significant financial interest should be a complete and timely disclosure, timely completion of all training requirements and attest to reading the Research COI policy found in MSM Policies Plus.

## **What are the Training Requirements?**

Each investigator must complete training prior to engaging in research related to any PHS-funded grant or contract every four years and if:

- MSM FCOI policies change affecting investigator requirements
- An investigator is new to MSM
- MSM finds an investigator noncompliant with this FCOI policy or management plan

The Research COI and Scientific Misconduct training is located in Cornerstone at <https://msm.csod.com>.

## **Who Serves on the RCOIC committee?**

The committee is comprised of at least seven (7) voting members including members of: faculty, clinical departments, Office for Sponsored Research Administration (OSR), and administrative offices. Other non-voting ad-hoc participants may assist in discussions and decisions as needed.

## **What is the Process for Reviewing Disclosures?**

An initial review of **ALL** disclosures is evaluated by the Office of Compliance, Internal Audit and OSR. If there is a potential or actual conflict, the disclosure is brought before the RCOIC for evaluation and management.

Non-research related conflicts will be escalated to the appropriate chair of the academic department, administrative chair or the dean.

## **What is the Escalation Process when an Investigator has not Disclosed or Responded to the RCOIC's Request for Additional Information?**

1. The OCIA will request to meet personally with the PI.
2. The chair of the academic department is notified.
3. The administrative chair is contacted.
4. The dean is contacted.

The timing of each step will depend on the nature and severity of the actual or potential conflict.

### **What is the definition of "Outside Authorship?"**

The term refers to a combination of the terms: outside and paid authorship. Outside defines any entity not owned or operated by MSM or MHC. Paid authorship is a type of payment for services or remuneration. Receipt of payment from an entity in exchange for drafting a publication constitutes payment for services. The NIH believes it is important to reference this form of payment with particular concern regarding investigators accepting payment from private entities in exchange for publishing credits with limited author input.

### **What is a Conflict Management Plan?**

A Conflict Management Plan (CMP) is developed to identify actions necessary to ensure objectivity in research projects. The CMP is sent to the principal investigator for their acceptance and may include but is not limited to:

- Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
- For research projects involving human subjects research and 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 disqualification 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); or
- Severance of relationships that create financial conflicts.

Depending on the nature of the Significant Financial Interest (SFI), MSM may determine that additional interim measures are necessary with regard to the investigators' participation in PHS-funded research.

### **How do I Submit a Question to the RCOIC?**

Please submit your questions to the Chair of the RCOIC, Dr. Charlotte Owens, at [cowens@msm.edu](mailto:cowens@msm.edu), or to the Office of Compliance and Internal Audit COI Administrator, Leah Taylor, at [ltaylor@msm.edu](mailto:ltaylor@msm.edu). All questions will be presented when the committee is in session for discussion and a response.