Corporate Policies and Procedures: Research

Financial Conflicts of Interest in Research

**Category:** General (GN)  
**Policy #:** RS.GN.020  
**Applies To:** All Faculty, Postdoctoral Fellows, Graduate Students and Exempt Staff

**Purpose:**

The integrity of biomedical research and the protection of human research subjects are of a paramount importance to the Medical College of Wisconsin (MCW). MCW’s research collaboration with pharmaceutical firms, medical device companies and other entities is important to ensure that patients benefit from the translation of biomedical research into clinical practice. Potential financial conflicts of interest that may arise from this collaboration necessitate the adoption of principles and guidelines to ensure the protection of human research subjects and the integrity of MCW’s research effort.

This policy supports Public Health Service (PHS) Regulations 42 CFR Part 50 Subpart F, *Promoting Objectivity in Research* and 45 CFR Part 94, *Responsible Prospective Contractors*. These Regulations promote objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct or reporting research funded under PHS grants or cooperative agreements or PHS contracts will be biased by any conflicting financial interest of a Covered Person.

**Definitions:**

**Covered Person** – any Faculty or Exempt Staff employed by MCW who is responsible for the design, conduct or reporting of research sponsored by any U.S. Department of Health and Human Services (DHHS), PHS agency including the National Institutes of Health (NIH). Covered Persons include but are not limited to Principal Investigators, Co-Investigators and other Key Personnel as identified by MCW in the grant application and others who influence or are responsible for the design, conduct or reporting of PHS funded research as determined by MCW (e.g. other employees, collaborators or consultants).

**Covered Person’s Professional Responsibilities** – activities performed on behalf of the institution (MCW). These responsibilities may include but are not limited to activities such as research, research consultation, teaching, professional practice, institutional committee membership and service on panels such as institutional review boards or data safety monitoring boards.

**Financial Conflict of Interest (FCOI)** – a Significant Financial Interest that has been determined by the MCW Institutional Official and/or the Financial Conflicts of Interest in Research Committee that the Covered Person’s Significant Financial Interest is related to PHS funding and is a Conflict of
Interest (that relationship could possibly affect the design, conduct or reporting of those research outcomes/results).

**Financial Conflicts of Interest in Research Committee (FCOI-R Committee)** – a person or persons appointed by the Institutional Official to provide an appropriate review of disclosed SFI(s), make a determination of the SFI relationship of the Covered Person and the PHS funded research (reasonable belief of a FCOI) and devise an appropriate management plan for all instances in which a Conflict of Interest has been determined to exist.

**Institutional Official (IO)** – MCW designates the Senior Associate Dean for Research (SADR) as the Institutional Official responsible for the implementation and administration of this Policy. The IO may delegate the day to day performance of these functions to administrative units within the Office of Research or other MCW Offices, or to a FCOI-R Committee.

**PHS Awarding Component** – the PHS agency that granted the award/contract and provided the funding (e.g. NIH, Center for Disease Control (CDC), Food and Drug Administration (FDA), Health Resources and Services Administration (HRSA)).

**Significant Financial Interest (SFI)** is

1. **Financial Interests** include but may not be limited to one or more of the following interests of the Covered Person (and those of the Covered Person’s spouse and dependent children) that reasonably appears to be related to a Covered Person’s professional responsibilities at MCW.
   a. Publicly Traded Entity – if the aggregated amount of income or interest exceeds $5000 in the previous 12 months (prior to the Covered Person’s disclosure) from the entity.
      i. Income includes salary, payment for services (e.g., consulting fees, honoraria, paid authorship)
      ii. Interest includes equity interests (stocks, stock options and/or other ownership).
   b. Non-Publicly Traded Entity – if the aggregated amount of income exceeds $5000 in the previous 12 months (prior to the Covered Person’s disclosure) from the entity; or any amount of interest.
      i. Income includes salary, payment for services (e.g., consulting fees, honoraria, paid authorship)
      ii. Interest includes equity interests (stocks, stock options and/or other ownership).
   c. Intellectual Property Rights and Interests with Entity – upon receipt of any income related to such rights and interests from the entity.

2. **Reimbursed or Sponsored Travel** paid on behalf of the Covered Person that is related to their professional responsibilities at MCW. This disclosure does not apply to travel that is reimbursed or sponsored by:
   a. a federal, state or local government agency;
   b. an institution of higher education (as defined at 20 USC 1001(a)); or
   c. an academic teaching hospital, a medical center or a research institute that is affiliated with an institution of higher education.
The term **Significant Financial Interest** does not include:

1. Salary, royalties or other payments made by MCW to the Covered Person including intellectual property rights assigned to MCW and agreements to share royalties related to such rights.

2. Income or equity in investment vehicles such as mutual funds and retirement accounts as long as the Covered Person does not directly control the investment decisions made in these vehicles.

3. Income from seminars, lectures, teaching engagements (sponsored by) or service on advisory or review panels for a federal, state or local government agency, an institution of higher education, an academic teaching hospital, a medical center or a research institute that is affiliated with an institution of higher education.

* For purposes of this policy, “reasonably appears to be related” includes organizations or persons that develop, market or sell products or services related to the research or health care work being performed at MCW. Examples include but are not limited to:

   a. pharmaceutical companies
   b. device manufacturers
   c. health care service or provider organizations
   d. information technology companies
   e. biotechnology and bioengineering companies

**Policy:**

MCW promotes objectivity in its research by establishing standards to ensure that there is no reasonable expectation that the design, conduct or report of research funded under PHS grants or cooperative agreements will be biased by any conflicting financial interest of the Covered Person.

Notwithstanding all other language in this Policy, MCW prohibits any arrangement where the amount of compensation, or potential compensation, will be directly affected by the outcome of the research (e.g. an arrangement has been made where the value of the compensation will change depending on the outcome of the research).

**Procedure:**

**Covered Person’s Obligation to this Policy**

1. Complete training as indicated in this Corporate Policy:
   a. prior to a Covered Person engaging in PHS funded research,
   b. every four years thereafter,
   c. any time that MCW revises this Policy or procedures in a manner that affects the Covered Person’s professional responsibilities at MCW,
   d. new Covered Persons as they become employed with MCW,
   e. in the event that a Covered Person is found to be non-compliant with either this policy or a prescribed Management Plan.
2. Disclose all SFI(s) to the IO according to the following schedule:
   a. at the time of application or date of contract proposal submitted for PHS funded research via the paper MCW Registration Form for non-eBridgeMCW applications or via the electronic MCW Registration Form for eBridgeMCW Funding Proposals/Projects,
   b. during annual updates via the Disclosure of Significant Financial Interests process as part of MCW’s Annual Conflict of Interest & Outside Activities process,
   c. within 30 days of discovering or acquiring a new SFI.
3. Comply with the Management Plan put in place by MCW (or MCW’s IO) for a disclosed SFI determined to be a FCOI.

**Institutional (MCW) Obligations to the Federal Regulation**

1. **Institutional Official** – MCW designates the Senior Associate Dean for Research as the IO responsible for:
   a. the implementation and administration of this policy, and
   b. the solicitation and review of disclosures of SFI to determine if there is a reasonable expectation that a financial conflict of interest exists.
2. **Training** –
   a. MCW shall provide appropriate training to all applicable employees (Covered Persons) as defined in this Policy and PHS Regulation 42 CFR Part 50 Subpart F, Promoting Objectivity in Research and 45 CFR Part 94, Responsible Prospective Contractors. Further, MCW shall:
      i. identify Covered Persons for training,
      ii. prepare content for training to meet regulatory requirements, and
      iii. deliver that training at appropriate times.
   b. Such training shall occur according to the following frequency:
      i. prior to a Covered Person engaging in PHS funded research,
      ii. every four years thereafter,
      iii. any time MCW revises this Policy or procedures in a manner that affects the Covered Person’s professional responsibilities at MCW,
      iv. when a new Covered Person becomes employed by MCW, and
      v. in the event that a Covered Person is found to be non-compliant with either this Policy or a prescribed Management Plan.
3. **Certification** – in each application for PHS funding, MCW shall certify that:
   a. The Institution has in effect a written and enforced administrative process to identify and manage, reduce or eliminate financial conflicts of interest in research with respect to all research projects for which funding is sought;
   b. The Institution will report to the awarding agency (prior to MCW’s expenditure of any funds under the PHS award), the existence of a financial conflict of interest found by it and assure that the interest has been managed, reduced or eliminated in accordance with this policy and for any interest that MCW identifies as presenting a financial conflict of interest subsequent to its initial report under the award, the report will be made and the conflict of interest managed, reduced or eliminated (at least on an interim basis) within 60 days of that identification; and
c. The Institution agrees to make information available as required by regulation (or upon request) to the funding agency regarding all financial conflicts of interests in research that it has identified and how those interests have been managed, reduced or eliminated to protect the research from bias.

4. **Receipt of SFI by Covered Persons (Disclosures)** – all Covered Persons are required to disclose, to the IO, all SFI(s) according to the following schedule:
   a. at the time of application for PHS funded research – the MCW Grants and Contracts Office shall solicit all Disclosures via the *paper MCW Registration Form for non-eBridgeMCW applications or via the electronic MCW Registration Form for eBridgeMCW Funding Proposals/Projects (electronic applications)*,
   b. during annual updates via the Disclosure of Significant Financial Interests as part of *MCW’s Annual Conflict of Interest & Outside Activities process*, and/or
   c. within 30 days of discovering or acquiring a new SFI.

5. **MCW Subrecipients** – if MCW carries out PHS-funded research through a subrecipient (e.g., subcontractors or consortium members), MCW must ensure that any subrecipient Covered Person(s) complies with Title(s) 42 (CFR 42) Part 50 Subpart F and 45 CFR Part 94. To this end, MCW must incorporate in its Subaward Agreement the terms that establish whether the MCW FCOI policy or that of the subrecipient will apply to the subrecipient’s Covered Person(s).
   a. If the subrecipient will comply with its own FCOI policy, the MCW Subaward Agreement must:
      i. contain certification from the subrecipient that its policy complies with the Title 42 (CFR 42) Part 50 Subpart F and 45 CFR Part 94,
      ii. specify the time period(s) for the sub-recipient to report all identified FCOIs to MCW, and
      iii. outline the subrecipient’s plan for managing, reducing, or eliminating any identified FCOI.
   b. If the subrecipient does not have a written, active and enforced FCOI policy or is not able to provide certification, (see 8.a.i.) the Subaward Agreement will state that the subrecipient is subject to MCW’s FCOI policy for disclosing SFIs that are directly related to the subrecipient’s work for MCW.
      i. If the subrecipient must comply with MCW’s FCOI policy, the Subaward Agreement must specify the time period(s) for the subrecipient to submit to MCW all Covered Person(s) disclosures of SFIs that are directly related to the subrecipient’s work for MCW.
      ii. If an FCOI exists, MCW will require a change in the Covered Person with the identified FCOI or elimination of the Covered Person’s SFI, or it will not issue the Subaward.
   c. MCW must report subrecipient identified FCOI(s) to the PHS Awarding Component prior to the expenditure of funds and/or within 60 days of any new or subsequently identified FCOI.

6. **MCW Covered Person Disclosed SFI(s)** – MCW has 60 days to complete the following:
   a. Review disclosures by Covered Persons to determine whether the Covered Person’s SFI:
      i. is related to PHS funding and
ii. is a FCOI where the SFI could be affected by the research (e.g. grow in value) or the interest is in an entity whose financial interest could be affected by the research.

b. Manage identified FCOI by creating a Management Plan for every FCOI that has been determined to exist. Examples of conditions or restrictions that may be imposed to manage FCOIs in research include but are not limited to:
   i. public disclosure of FCOI;
   ii. disclosure of FCOI to each research participant when research involves human subjects;
   iii. appointment of an independent monitor;
   iv. modification of the research plan;
   v. change of personnel or federal award responsibilities, or disqualification of personnel, including Covered Persons, from participation in the research;
   vi. reduction or elimination of the SFI; and
   vii. severance of the relationship(s) that create the actual or potential conflict(s).

c. Develop Management Plans (as are applicable)
   i. prior to the expenditure of funds, or
   ii. during the course of an ongoing PHS funded research project for new Covered Persons or new SFI(s) that are determined to be a FCOI.

d. Monitor the Covered Person’s compliance with the Management Plan until the completion of the PHS funded research project.

7. **Discovery of a SFI not disclosed by a Covered Person as required by this Policy** – the IO shall within 60 days:
   a. review the SFI (see #6 (a));
   b. develop a Management Plan (see #6 (b)(c) and (d)); and
   c. complete, within 120 days of discovery of such non-compliance, a retrospective review to determine if the failure of a Covered Person to report a SFI (per this Policy) has biased the design, conduct or reporting of the funded research and, based on the results of the review, shall notify the PHS Awarding Component if bias is found.

8. **Reporting FCOI(s)** - MCW shall report any FCOI to its PHS Awarding Component with sufficient information to enable PHS to understand the nature and extent of the FCOI and to assess its Management Plan. It will use the following reporting timeframe:
   a. prior to MCW’s expenditure of funds on the related funded research and/or
   b. on FCOI(s) reported during an ongoing PHS funded research project.

9. **Maintenance of Records** – MCW shall maintain records of all disclosures of SFI(s) and all actions taken by the Institution with respect to an identified FCOI in research for at least three years from the date of submission of the final expenditures on its related PHS funded research project or later as required in other applicable laws or regulations.

10. **Public Access to Information** – any SFI that has been determined to be a FCOI shall be made publicly available by MCW, as required by the regulation.

11. **Enforcement and Sanctions** - Any failure of a Covered Person to comply with this Policy or a FCOI Management Plan will result in a retrospective review of the Covered
Person’s activities and the correlating PHS-funded research; and may result in disciplinary action and/or sanctions to be imposed. MCW shall enforce and otherwise maintain this Policy by applying appropriate enforcement and sanctions consistent with MCW Human Resources and Faculty Affairs policies and procedures related to disciplinary action.

12. **Policy Maintenance** – This Policy is the responsibility of, and shall be jointly maintained and updated, by the MCW Office of Research and the MCW Corporate Compliance Office. MCW will maintain a current version of this Policy on a website accessible to the public.

13. **Other MCW Corporate Policies Concerning Conflicts of Interest** – MCW Covered Persons must also comply with:
   a. [Conflict of Interest - General (AD.CC.030)]
   b. [Conflict of Interest - Health Care Industry Product Interactions (AD.CC.040)]

**References:**

- [PHS Regulation 42 CFR Part 50 Subpart F](#)
- [PHS Regulation 45 CFR Part 94](#)
- [FDA Guidance for Industry - Financial Disclosure by Clinical Investigators](#)
- [NSF Grant Policy Manual, Chapter V.510 – Conflict of Interest Policies](#)

**Attachments:**

Not applicable

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**Effective Date:** 05/2001

**Revision History:** 11/20/2010, 5/2011, 08/24/2012

**Supersedes Policy:** N/A

**Review Date:** N/A

**Approved By:**

/S/ John R. Raymond, Sr., MD, President and CEO
Medical College of Wisconsin