



MCW Office of Research Standard Operating Procedure

CONFLICT OF INTEREST FOR INVESTIGATORS AND PROJECT TEAM MEMBERS

Unit: Human Research Protections Program (HRPP), Office of Research

Applies to: Faculty and Staff involved in human research

PURPOSE:

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 Public Health Service 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).

Medical College of Wisconsin (MCW) Corporate Policies: Conflicts of Interest - General (AD.CC.030) and Financial Conflicts of Interest in Research (RS.GN.020) mandate that MCW faculty and staff must report all conflicts of interest to the institution for review and determination.

In addition to these reporting processes and to assure protection of the rights and welfare of subjects in human research, MCW IRB requires Investigators to report to the IRB all potential conflicts of interest prior to or at the time of initial submission of a research project.

DEFINITIONS:

Covered Award: sponsored award for research funded by a PHS Awarding Component, by a Non-Profit Sponsor, by the NSF, by any other federal funding agency as required per agency policy or award terms and conditions, or by an Industry Sponsor.

Covered Person: any Faculty, Exempt Staff or other individual employed by MCW or Emeritus faculty who is responsible for the design, conduct or reporting of research sponsored by a Covered Award. 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 research funded by a Covered Award as determined by MCW (e.g. other employees, collaborators or consultants). For sponsored awards funded by an Industry Sponsor, only the PI is considered a Covered Person

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 the Covered Award and is a Conflict of Interest (that relationship could possibly affect the design, conduct or reporting of those research outcomes/results).

Financial Conflict 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 Covered Award (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.

Key Personnel: The Principal Investigator and those project staff as identified by MCW in the grant application, progress report or any other report submitted to the PHS, and other employees who influence or are responsible for design, conduct or reporting of PHS funded research, whether or not they receive salaries or compensation, such that they might qualify for co-authorship on publications. Individuals who only provide clinical care or support to subjects in a research project do not need to be considered Key Personnel.

Industry Sponsor: The publicly traded or non-publicly traded entity that granted the award/contract and provided the funding.

Institutional Official (IO): MCW designates the Associate Provost of Research 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.

Immediate Family Member: as defined by *MCW Corporate Policy: Conflicts of Interest - General (AD.CC.030)* as a staff member's spouse and any person who receives more than one-half of their support from a staff member or from whom the staff member receives more than one-half of their support.

Non-Profit Sponsor: The non-federal / non-industry sponsor following federal PHS FCOI-R requirements (e.g. American Heart Association, American Cancer Society).

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)).

Staff member: defined by *MCW Corporate Policy: Conflicts of Interest - General (AD.CC.030)* means any officer, full-time faculty member, full professional effort faculty, part-time faculty, administrative officer, and exempt staff employee of MCW.

Significant Financial Interest (SFI): defined by *MCW Corporate Policy: Financial Conflicts of Interest in Research (RS.GN.020)*

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. Compensation – if the aggregated amount of income exceeds \$5,000 in the previous 12 months (prior to the Covered Person's disclosure) from the entity.

- Income includes salary and payment for services (e.g., consulting fees, honoraria, paid authorship).
- b. Equity – any amount of interest (equity) in an outside entity in the previous 12 months (prior to the Covered Person’s disclosure). Equity Interest includes stocks, stock options not yet exercised 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** are paid on behalf of the Covered Person engaged in research funded by a PHS Awarding Component or by a Non-Profit Sponsor that is related to their professional responsibilities at MCW. This disclosure must include the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. This disclosure does not apply to travel that is reimbursed or sponsored by:
- a. A US-based 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.

Significant Financial Interest does not include:

1. Salary, royalties, or other remuneration 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, or 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 healthcare work being performed at MCW. Examples include but are not limited to:

- Pharmaceutical companies
- Device manufacturers
- Health care service or provider organizations
- Information technology companies
- Biotechnology and bioengineering companies

PROCEDURE:

1. Investigators must complete training as indicated in the *MCW Corporate Policy: Financial Conflicts of Interest in Research (RS.GN.020)*.
2. Investigators must disclose all conflicts of interest to the IO according to the following schedule:
 - a. At the time of application or date of contract proposal submitted for research funded by a Covered Award via the paper MCW Registration Form for non-eBridge applications or via the electronic MCW Registration Form for eBridge 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.

4. All conflicts of interest in association with the human subjects research project under review must also be disclosed to the MCW IRB according to the following schedule:
 - a. With the initial eBridge SmartForm application
 - b. At the time of each continuing review of the project using the eBridge Continuing Progress Report Form; and
 - c. Within 10 days of becoming aware of any previously undisclosed significant financial interest, Investigators must file an amendment with the IRB and make any additional changes necessary in the eBridge SmartForm.

IRB Review Process

1. If the IRB Coordinator II (C2), identifies a possible conflict of interest during review of any eBridge submission, the IRB C2 will notify the HRPP Director or designee.
2. The HRPP Director will verify that the Investigator with a potential conflict of interest has filed a full disclosure to the MCW Institutional Official per *MCW Corporate Policy: Financial Conflicts of Interest in Research (RS.GN.020)*.
3. The MCW FCOI-R committee will issue a copy of the “conflict management plan” and “may not engage in specified research” decisions to the HRPP Director or designee, who provide the information to the IRB overseeing any affected project.
4. The IRB will review the conflict management plan and may require additional management or protections based upon the conflict of interest, or may table the research project pending review and approval of the MCW FCOI-R committee.
5. The IRB has the right to evaluate the financial interests of Investigators and research staff, and has the final authority to decide whether the financial interest and management plan, if any, allow the human research to be approved.

REFERENCES:

20 USC 1001(a)

SUPPORTING DOCUMENTS:

MCW Corporate Policy: Conflicts of Interest - General (AD.CC.030)

MCW Corporate Policy: Financial Conflicts of Interest in Research (RS.GN.020)

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Approved By	
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