

UNIVERSITY OF WISCONSIN-MILWAUKEE (UWM) POLICY FOR
FINANCIAL CONFLICTS OF INTEREST IN PUBLIC HEALTH SERVICE-FUNDED RESEARCH

BACKGROUND

In 1995, the U.S. Department of Health and Human Services, in its commitment to preserve the public trust in the objectivity of biomedical and behavioral research, promulgated the Public Health Service (PHS) regulations, “Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought” and “Responsible Prospective Contractors.” These are also known as the financial conflict of interest, or FCOI, regulations (42 CFR Part 50 Subpart F and 45 CFR Part 94).

Since then, biomedical and behavioral research and the resulting interactions among government, research institutions, and the private sector have become increasingly complex. This complexity, as well as increased public scrutiny and a need to strengthen transparency and accountability, led HHS to propose a more rigorous approach to Investigator disclosure, management of financial conflicts, and federal oversight.

To that end, after reviewing public comments from HHS’ advance notice of proposed rulemaking published on May 8, 2009, HHS published a notice of proposed rulemaking on May 21, 2010. The proposed rule was published to amend the 1995 regulations by expanding and adding transparency to investigators’ disclosure of significant financial interests, enhancing regulatory compliance and effective institutional oversight and management of investigators’ financial conflicts of interests, as well as HHS’ compliance oversight.

After careful consideration of the comments to the notice of proposed rulemaking, HHS published a final rule (<http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>) that amends the 1995 regulations. The final rule established new requirements that went into effect August 24, 2012. Major changes to the 1995 regulations include:

- Lower financial disclosure thresholds
- New conflict of interest training
- New public accessibility requirements
- Increased transparency for travel reimbursement

The UWM Policy for Financial Conflicts of Interest in Public Health Service-Funded Research is proposed to bring UWM into compliance with another requirement of the final rule, that each institution receiving PHS funds establish an institutional policy for the implementation of the new FCOI regulations.

**UNIVERSITY OF WISCONSIN-MILWAUKEE (UWM) POLICY FOR
FINANCIAL CONFLICTS OF INTEREST IN PUBLIC HEALTH SERVICE-FUNDED RESEARCH
August 24, 2012**

I. PURPOSE & SCOPE

This policy implements the 2011 Public Health Services (PHS) regulations on Promoting Objectivity in Research (Code of Federal Regulations, Title 42, Part 50, Subpart F). It is applicable to all PHS Research Activities with an award issue date of August 24, 2012, or later, and to proposals for research activities submitted to PHS on or after August 24, 2012. PHS Research Activities that are ongoing as of August 24, 2012, will become subject to this policy as additional funds are requested through submission of a progress report, competing renewal application, proposal for supplemental funding, or through approval of a no-cost time extension. This Policy applies to the Principal Investigator and all other Investigators (regardless of position or title) who are responsible for the design, conduct or reporting of a PHS Research Activity.

The Policy is applicable to all research activities supported by PHS and by other sponsors and programs that specifically request review consistent with the PHS regulations on objectivity in research. This policy complements University of Wisconsin-Milwaukee Faculty Document No. 2466, Conflict of Interest Policy for Researchers and Scholars.

II. DEFINITIONS

For the purposes of this policy, the following terms shall apply:

Designated Official(s): Campus official(s) designated to solicit and conduct review of disclosures of Significant Financial Interests from each Investigator who is planning to participate in, or is participating in a PHS Research Activity. The Designated Official(s) will determine whether an Investigator's Significant Financial Interest is related to the Investigator's PHS Research Activity and if related, whether the Significant Financial Interest constitutes a Financial Conflict of Interest. For the purposes of this policy, the Designated Officials are the Vice Chancellor for Research and Investigator's Department Chair/Director and Dean.

Financial Conflict(s) of Interest (FCOI): A Significant Financial Interest that could directly and significantly affect the design, conduct or reporting of PHS Research Activity.

Institutional Responsibilities: An investigator's professional responsibilities on behalf of UWM, including research, research consultation, teaching, professional practice, UWM committee memberships, and service on panels such as institutional committee memberships.

Investigator: The Principal Investigator or project director and any other person regardless of title or position who is responsible for the design, conduct or reporting of research proposed for funding or funded by PHS. This includes, but is not limited to Key Personnel named on a proposal budget.

Key Personnel: The Principal Investigator or project director and any other personnel considered essential to work performance and identified as Key Personnel in the contract or grant proposal.

PHS Research Activity(ies): Any award for which research funding is available from PHS, including research contracts, research grants, career development awards, center grants, individual fellowship awards, infrastructure awards, institutional training grants, program projects or research resources awards and conference grants. Only Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer Research (STTR) awards programs are excluded.

Principal Investigator (PI): An Investigator who has primary responsibility for the scientific and technical conduct, reporting, and fiscal and programmatic administration of a sponsored project.

Significant Financial Interest (SFI): Anything of monetary value that:

- Meets the PHS thresholds (see Section III.C below) for reporting received by the Investigator and, except for travel, received by the Investigator's spouse and dependent children for the following categories; and
- Reasonably appears to be related to or is in the same field of expertise as the Investigator's Institutional Responsibilities.
- Examples of SFIs include:
 - Income or honoraria received for activities such as providing expert testimony or consulting services; serving on a board of directors, scientific advisory board, committee, panel or commission sponsored by a for-profit or non-profit organization, including professional or scholarly societies; acting in an editorial capacity for a professional journal, reviewing journal manuscripts, book manuscripts, or grant or contract proposals for a for-profit or non-profit organization; or salary received outside UWM.
 - Any equity interest in a company that is developing, manufacturing or selling products or providing services used in an Investigator's clinical practice, teaching, research, administrative or committee responsibilities.
 - Receipt of income from any organization other than UWM or the UWM Research Foundation for use or sale of patented or copyrighted intellectual property, such as software, textbooks, or other scholarly works for which royalties or licensing fees are received, including income from previous employers and other universities.
 - The occurrence of travel by the Investigator which is reimbursed or sponsored by a for-profit or non-profit entity, excluding a federal, state, or local government, a U.S. institution of higher education or an affiliated medical center/hospital or research institute.

III. PHS Policy Promoting Objectivity in Research

The PHS regulations on Objectivity in Research (revised in August 2011) are designed to promote objectivity by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of PHS Research Activities will be free from bias resulting from any Investigator's Financial Conflicts of Interest.

Each institution applying for or receiving research support from PHS must comply with the regulations by putting in place a policy to ensure that:

A. Investigators complete a training/education program:

1. Before engaging in PHS Research Activities and at least every four years thereafter while receiving PHS research funding, and
2. Whenever an Investigator is not in compliance with this Policy or has failed to comply with a plan put in place to manage or mitigate a Financial Conflict of Interest.

3. UWM revises its financial conflict of interest policies or procedures in any manner that affects the requirements of Investigators.
4. An Investigator is new to UWM.

B. Investigators disclose SFIs at the following times:

1. Initial disclosures must be made by all Investigators planning to participate on a proposed PHS Research Activity before the application for funding is submitted.
2. UWM Investigators who are engaged in PHS Research Activities have an ongoing responsibility to update their disclosures throughout the period of PHS support:
3. Within 30 days of acquiring or discovering any new SFI; and
4. At least annually
5. New Investigators must complete an initial disclosure of SFIs before joining an ongoing PHS Research Activity.

C. Investigators disclose to UWM SFIs that meet the following thresholds:

1. For a publicly traded entity: Income or other payment for services including salary, and any payment for services not otherwise identified as salary, including but not limited to, consulting payments, honoraria, paid authorship, or any other payments or consideration of value, received during the prior 12 months and the value of any equity interest (including stock, stock options or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value) in the entity as of the date of disclosure, which when aggregated, exceeds \$5,000.

[Investigators are not required to disclose SFI in mutual funds or other investment vehicles such as retirement funds as long as the Investigator does not directly control the investment decisions made for these investment vehicles]

2. For a non-publicly traded entity: Income or other payment for services including salary, and any payment for services not otherwise identified as salary, including but not limited to, consulting payments, honoraria, paid authorship, any other payments or consideration of value, received during the prior 12 months that exceeds \$5,000, or equity interest of any amount, including, but not limited to stock, stock options, or ownership interest in the entity.

[Investigators are not required to disclose (a) payments made by UWM, including salary, stipends, royalty payments, honoraria, reimbursement of expenses, or any other remuneration from the University of Wisconsin; or (b) income for seminars, lectures, teaching engagements, or service on advisory committees or review panels sponsored by federal, state or local governments, a US institution of higher education, or a research institute, academic medical center or hospital that is affiliated with an institution of higher education]

3. Intellectual property rights and interests: Income received during the previous 12 months that exceeds \$5,000 for such rights and interests.

[SFIs do not include royalties received from UWM or the UWM Research Foundation related to patents or copyrights]

4. Travel: The occurrence of any sponsored or reimbursed travel must be disclosed (purpose, sponsor, destination, and duration) whether payment is made to the Investigator directly or expenses are paid on his/her behalf by a for-profit or non-profit organization:
- a. Either prospectively, by listing all travel that the Investigator anticipates will be sponsored or reimbursed during the next 12 months, or
 - b. Within 30 days of the occurrence if the trip wasn't reported prospectively.

[Investigators are not required to disclose travel that is reimbursed or sponsored by federal, state or local governments, a US institution of higher education, or a research institute, academic medical center or hospital that is affiliated with an institution of higher education]

IV. DISCLOSURES BY COLLABORATORS

Collaborators from other institutions who share responsibility for the design, conduct or reporting of research results, and who will be conducting research under a subaward from UWM are expected to comply with the policies and procedures of the organization at which they are employed. Subawards issued by UWM will indicate that the subrecipient organization is responsible for reviewing SFI disclosures and, if FCOI are identified, for sending UWM notification of their ability to manage the identified conflicts, in accordance with PHS reporting requirements.

Collaborators who share responsibility for the design, conduct, and reporting of research results, and who will participate in research under an independent consulting agreement issued by UWM should be identified as Investigators by the UWM PI and must complete the UWM disclosure forms. If, upon review, UWM determines that an SFI could directly and significantly affect the design, conduct, or reporting of the research to be performed under the agreement, these collaborators will be expected to adhere to the mitigation plans put in place to manage the identified conflicts of interest.

V. REVIEWS AND REPORTING

- A. Disclosed SFIs will be reviewed by the Investigator's Department Chair/Director and Dean prior to acceptance of new and renewal awards, and with the submission of progress reports, proposals for supplemental funding, or requests for no-cost time extensions. Investigators may be asked to provide additional information about the SFIs that they previously disclosed. This information will be used by the Investigator's Department Chair/Director and Dean to conduct a preliminary review in order to reasonably determine whether any of an Investigator's SFIs:
- Could be affected by the PHS Research Activity; or
 - Are in an entity whose financial interest could be affected by the research.

If after review it is determined that an SFI is related to the proposed PHS Research Activity, the Vice Chancellor for Research (VCR) will conduct a second review to determine whether the SFI(s) reasonably appears to directly and significantly affect the design, conduct or reporting of the PHS Research Activity and thereby constitute an FCOI that may need to be managed. The VCR will refer the matter to the Conflict of Interest Committee. The Committee will recommend to the VCR what conditions and restrictions, if any, should be imposed by UWM to manage the actual or potential conflicts.

In accordance with the PHS regulations, plans put into place to manage identified FCOI will be monitored for compliance until the completion of the PHS Research Activity. Each management plan will specify the way in which that will be accomplished.

- B. Initial reports of FCOI must be made to PHS prior to UWM's expenditure of any funds provided under a PHS Research Activity. UWM is not required to submit a report to PHS if conflicts of interest are eliminated before research funds are expended.

Additional FCOI reports must be submitted to PHS under the following circumstances:

1. Throughout the lifetime of an award when progress reports are submitted, or when an award is extended (either through extension notification or an NIH prior approval request). When during the course of an ongoing PHS Research Activity an FCOI ceases to exist, updated information about the status of that FCOI should be provided with the subsequent progress report.
 2. Within 60 days of determining that an FCOI exists based on disclosure of a newly acquired SFI by an Investigator during the course of an ongoing PHS Research Activity.
 3. Within 60 days of determining that an FCOI exists for an Investigator who joins an ongoing PHS Research Activity.
- C. When during the course of an ongoing PHS Research Activity, UWM identifies an SFI that was not disclosed in a timely manner by an Investigator, or which was not previously reviewed, the Designated Officials will review the SFI within 60 days to determine whether it is related to PHS Research Activities and whether an FCOI exists. If an FCOI is identified after such a review, a management plan must be implemented, at least on an interim basis.

Whenever an FCOI is not identified or managed in a timely manner, regardless of whether the Investigator did not disclose an SFI that was later determined to be an FCOI, or UWM did not review or manage the FCOI, or because the Investigator failed to comply with a previously implemented management plan, UWM must, within 120 days of the determination of non-compliance, complete a retrospective review of the Investigator's activities and the PHS Research Activities. The purpose of this retrospective review is to determine if the ongoing PHS Research Activity was biased in its design, conduct or reporting.

- Based on the results of the retrospective review, the previously submitted FCOI report must be updated to specify the actions that UWM will take to manage the identified FCOI.
- If bias was found during the retrospective review, UWM will promptly notify PHS and will draft a mitigation report that at a minimum documents the key elements of the retrospective review, describes the impact of the bias on the research, and outlines UWM's plans to eliminate or mitigate the effect of the bias.

VI. RECORDS ACCESS AND RETENTION

- A. PHS regulations require that UWM respond within 5 business days to any request for information about SFIs held by Key Personnel when UWM has determined that the disclosed SFIs are related to PHS Research Activities and constitute FCOIs.
- B. The information provided in the disclosure forms may be released or transmitted to PHS upon request. Completed disclosure forms also may be released in response to a public records request, pursuant to the terms of the Wisconsin Public Records law.
- C. Records of financial disclosures, Designated Official's determinations, Conflict of Interest Committee recommendations, and University actions regarding management of an FCOI will be retained for at least 3 years beyond the date of submission of the award's final expenditure report, or until the resolution of any actions by PHS involving the records, whichever is longer. Records relating to unfunded projects need not be retained.

VII. SANCTIONS

Employees will be held accountable for full disclosure of significant financial or other personal interest, or potential activities that might be presumed to interfere with the employee's duties or responsibilities to UWM as defined in this policy and for compliance with any conditions or restrictions imposed by UWM in order to manage any actual or potential conflict of interest. Failure to abide by the policy may result in sanctions imposed on the employee under, for all persons holding faculty rank, UWS 6.01, Wis. Admin. Code and UWM Policies and Procedures 5.40 *et seq.* or, for all academic staff members, UWS 13.01, Wis. Admin. Code and UWM Academic Staff Policies and Procedures Chapter 111. Agreements with consultants who either fail to file a complete disclosure or fail to comply with any conditions or restrictions imposed may be terminated for cause. Similarly, an agreement with a subrecipient organization may be terminated for cause if that organization fails to comply with its obligations under the PHS regulations. In addition, federal regulations may require reports to the federal sponsor of any violations of federal regulations and University policy.

VIII. REFERENCES & RELATED POLICIES

- 1. University of Wisconsin-Milwaukee Faculty Document No. 2466, February 17, 2005
- 2. Public Health Service (PHS) "Objectivity in Research," Code of Federal Regulations (42 CFR, Part 50, Subpart F and 45 CFR, Part 94), August 25, 2011
- 3. Wisconsin Statutes sec. 19.31-19.37, Public Records and Property
- 4. UWS 6.01, Wisconsin Administrative Code
- 5. UWS 13.01, Wisconsin Administrative Code
- 6. UWM Academic Staff Policies and Procedures Chapter 111

This policy is implemented on August 24, 2012 in order to bring the University into compliance with State and Federal Regulations, within a time frame required by new Federal Regulations. The policy is subject to review by the UWM Faculty Senate which may require changes to elements of the policy or to the procedures that implement it, but which will not affect full compliance with Wisconsin Administrative Code and the Code of Federal Regulations, Title 42, Subpart F, "Promoting Objectivity in Research."