

# Marquette University

## Promoting Objectivity in Research/Financial Conflict of Interest for Public Health Services Investigators

Approved by Academic Senate: May 7, 2012

Approved by Provost: June 6, 2012

### I. University Policy

To promote objectivity in the conduct of research, this Policy provides for disclosure by investigators of significant financial interests, institutional oversight and management of any resulting financial conflicts of interests, and institutional compliance with governmental oversight requirements.<sup>1</sup> Adopting this Policy helps to assure that high standards of scientific integrity govern the conduct of sponsored projects, thereby bolstering public understanding and trust of science. This Policy becomes effective on August 15, 2012.

### II. Definitions

- A. "Investigator" refers to those individuals who are independently responsible for the proposed or actual design, conduct, and/or reporting of research for Covered Grants or Contracts. This may include Principal Investigators, Project Directors, Co-Investigators or any other individual who meets this definition. With respect to the requirements concerning financial interests, the terms include the spouse and dependent children of such Investigators as well.
- B. "Significant Financial Interest" means anything of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees, honoraria, paid authorship, and travel expense reimbursement); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights). The term does not include (1) salary, royalties or other remuneration from Marquette University; (2) income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities; (3) income and travel expense reimbursements from service on advisory committees or review panels for public or nonprofit entities, including Marquette University; (4) income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions; (5) salary, royalties, or other payments for services that, when aggregated for the investigator and the investigator's spouse and dependent children, are not expected to exceed \$5,000 during the next twelve month period; and (6) travel expenses, to the extent that did not exceed \$5,000 from any one entity during

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<sup>1</sup> PHS: 76 FR 53256 (August 25, 2011); NSF: 60 FR 35820-35823, (July 11, 1995).

the previous twelve month period and are not expected to exceed \$5,000 during the next twelve month period.

- C. "Actual or potential financial conflict of interest" means a Significant Financial Interest that could affect the design, conduct, or reporting of the research, educational, or service activities being conducted under a Covered Grant or Contract.
- D. "Covered Grant or Contract" means any grant or cooperative agreement, subcontract, subaward, or cooperative agreement under which funds from Public Health Services (PHS) are used to fund or to support any of the research, educational, or service activities being conducted, whether awarded in response to a solicitation or otherwise, but excluding Phase I SBIR or STTR program awards and Research Construction Program contracts. A list of PHS agencies can be found on the U.S. Department of Health and Human Services website.

### III. Implementation

- A. The Executive Director of the Office of Research and Sponsored Programs (ORSP) is designated as the institutional official responsible for soliciting and reviewing disclosures of Significant Financial Interests from each Investigator and for submitting all required reports to the Public Health Service (PHS). The Vice Provost for Research is designated as the institutional official responsible for making any and all required certifications with respect to compliance with Federal regulations applicable to financial conflict of interest and for providing financial conflict of interest reports as required to the PHS prior to the expenditure of funds and within sixty (60) days of any subsequently identified financial conflict of interest. Reporting requirements to the Public Health Service shall apply to the extent mandated by 42 CFR Parts 50 and 94 or other applicable Federal regulations.
- B. ORSP shall require each Investigator on a Covered Grant or Contract to complete training with respect to the University's policy on conflicts of interest, the responsibilities of the Investigator to disclose significant conflicts of interest, and applicable Federal regulations concerning financial conflicts of interest (1) at least every four years; (2) prior to engaging in any research, educational, or service activities being conducted under any Covered Grant or Contract, as of and following the effective date of this Policy; (3) whenever this Policy is substantively amended; (4) when a funded investigator is new to Marquette University and (5) whenever the Vice Provost for Research has determined that an Investigator is not in compliance with this Policy or with any management plan or directive issued under this Policy. ORSP shall specify the content, length, and method of delivery of such training and shall maintain records documenting compliance with these requirements.
- C. In connection with all Covered Grants and Contracts, whether to subrecipients or with the University as subrecipient, ORSP shall assure that

provisions are included that specify whether the applicable policies of the University or of the other institution will apply to the Investigator involved, including those investigators at other institutions. To the extent that the policies of another institution shall apply to the University's Investigator, ORSP shall assure that (1) the University's Investigator has received training on the requirements of the other institution; (2) time periods for the University to report identified financial conflicts of interest to the other institution are specified in such agreements and are sufficient to enable the applicable institution to provide timely reports to the PHS as required by Federal regulations; and (3) records documenting compliance with this requirement are maintained.

- D. Not later than at the time of application for funding that would result in a Covered Grant or Contract, ORSP shall inform each Investigator of the University's policies on financial conflict of interest and his/her responsibilities regarding disclosure of Significant Financial Interests by providing the Investigator with a copy of, or a Web link to, this Policy; the required Disclosure of Financial Interests Form; and access to the relevant training materials.
- E. Each Investigator must disclose to the Executive Director of the Office of Research and Sponsored Programs all Significant Financial Interests, existing at the time of certification or that existing over the previous twelve-month period, prior to the time of application for funding that would result in a Covered Grant or Contract. The Disclosure of Financial Interests Form shall be returned to the Investigator if not complete. Disclosure of any travel expense reimbursements that constitute Significant Financial Interests must include the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration of the trip; and the total monetary value of all travel paid by each entity during the previous twelve month period, as well as the monetary value of all travel expected to be paid by each entity during the next twelve month period from each entity.
- F. In addition, all Investigators shall file with ORSP updated Disclosure of Financial Interest Forms (1) within thirty (30) days of discovering or acquiring (through purchase, marriage, inheritance, or other means) a new Significant Financial Interest and (2) not less than annually. ORSP shall (1) notify all Investigators who have failed to provide the annual updated Disclosure of Financial Interests Forms and (2) notify the Vice Provost for Research, who shall immediately notify the affected Principal Investigators and Project Directors. No Principal Investigator or Project Director shall engage in any research, educational, or service activities under any Covered Grant or Contract until the required updated Disclosure of Financial Interests Form has been filed with ORSP.
- G. Upon the identification of a Significant Financial Interest, the Executive Director of ORSP shall make an initial determination as to whether the Investigator's Significant Financial Interest is related to the research and, if so

related, whether it is an actual or potential financial conflict of interest. This determination shall be made in consultation with others as appropriate, including, but not limited to, the department chair, the Associate Dean for Research, the Deans of the colleges affected, the Office of General Counsel, the Director of Internal Audit, and the Office of Finance. ORSP shall maintain records documenting compliance with this requirement.

H. If an actual or potential conflict of interest is determined to exist, the Executive Director of Research and Sponsored Programs shall propose to the Vice Provost for Research, within forty-five (45) days of the submission of the Disclosure of Financial Interest Form or other identification of the Significant Financial Interest, a management plan intended to manage, reduce, or eliminate such financial conflicts of interest. These conditions or restrictions specified in the management plan might include, but are not limited to, the following:

1. Public disclosure of Significant Financial Interests when presenting or publishing the research, on the University Web site, and in other locations or venues;
2. Disclosure of Significant Financial Interests directly to participants in human subjects research, as part of informed consents or otherwise;
3. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias;
4. Modification of the research plan;
5. Change of personnel or personnel responsibilities, including disqualification of personnel from some or all of the research;
6. Reduction or elimination of the Significant Financial Interest; or
7. Severance of relationships that create Significant Financial Interests.

I. The Vice Provost for Research shall review the proposed management plan and shall, within sixty (60) days of the submission of the Disclosure of Financial Interests Form or other identification of the Significant Financial Interest, approve a management plan and communicate it to all affected Investigators. No affected Investigator shall engage in any research, educational, or service activities under any Covered Grant or Contract after the plan is developed except in full compliance with the approved management plan.

J. Prior to the expenditure of any funds under a Covered Grant or Contract, ORSP shall provide to the PHS Awarding Component, as that term is defined in applicable Federal regulations, a financial conflicts of interest report regarding any applicable Significant Financial Interest. Such reports shall be updated within sixty (60) days of receipt of new information by ORSP.

K. If Investigators fail to disclose a Significant Financial Interest as required by this Policy, or if the University fails to manage the Significant Financial Interest as required by this Policy, or if an Investigator fails to comply with any material

requirement of a management plan, the Vice Provost for Research shall, within one hundred twenty (120) days of identification of the noncompliance, complete a retrospective review and mitigation report in accordance with 42 CFR § 50.605. ORSP shall report such information to the PHS as required.

- L. The Vice Provost for Research shall have the authority to suspend or to terminate any and all Covered Grants or Contracts, and any and all research, educational, or service activities under any Covered Grant or Contract, individually or together, to the extent the Vice Provost for Research determines that such action is necessary to assure compliance by Investigators with the requirements of this Policy and applicable Federal regulations. In addition, a failure to file a timely and complete Disclosure of Financial Interests Form or to comply with any conditions or restrictions imposed in any management plan constitutes grounds for University discipline, up to and including termination of employment. Specific sanctions will be determined in accordance with applicable University procedures. In addition, if the Vice Provost for Research determines that, in connection with clinical research to evaluate the safety or effectiveness of a drug, medical device, or treatment involved an Investigator with a Significant Financial Interest that was not managed or reported as required, the Vice Provost for Research shall require the Investigator involved to disclose the Significant Financial Interest in each public presentation of the results of the research thereafter made and to request an addendum to previously published presentations.
- M. ORSP and responsible parties will maintain records of all financial disclosures and of all actions taken to resolve actual or potential conflicts of interest until at least three (3) years after the termination or completion of the Covered Grant or Contract to which those records relate, or the resolution of any government action involving those records.
- N. This Policy shall be made available on a publicly available page of the University Web site. In addition, the publicly available page shall include a listing of the Significant Financial Interests of each Investigator that is the subject of a mitigation plan that includes the name, title, and role of the Investigator; the name of the entity in which the Significant Financial Interest is held; the nature of the Significant Financial Interest; and the approximate value of the Significant Financial Interest. The value shall be expressed as \$0-\$4999; \$5,000-\$9,999; \$10,000-\$19,999; \$20,000-\$39,999; \$40,000-\$59,999; \$60,000-\$79,999; \$80,000-\$99,999; \$100,000-\$150,000; and thereafter in increments of \$50,000. The date of the most recent update shall also be included. Information shall be updated within sixty (60) days of ORSP's receipt of information requiring update. Information shall remain on the publicly available Web site for at least three (3) years from the date on which the information was most recently updated.