

Marquette University

Promoting Objectivity in Research/Financial Conflict of Interest

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 requirements¹ and any other non-governmental sponsor who has similar requirements. 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 revised Policy becomes effective on April 1, 2022.

II. Definitions

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 the grantor 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. Covered Grants and Contracts primarily include those issued by the Public Health Services, including the National Institutes of Health, and the U.S. Department of Energy, but may include other grantors with similar requirements. A list of PHS agencies can be found in the USJen.33 0 Td6 (.)

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 grantor 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 and the required Disclosure of Financial Interests Form.
- E. Each Investigator must

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 President for Research and Innovation, 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 (R)6 (j)10 (b) (es)432e (m)-3m628(h);

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 President for Research and Innovation shall, within one hundred twenty (120) days of identification of the noncompliance, complete a retrospective review and mitigation report. ORSP shall report such information to the grantor as required.
- L. The Vice President for Research and Innovation 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 President for Research and Innovation 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 President for Research and Innovation 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 President for Research and Innovation 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

