

**Western Michigan University
Faculty Senate
Memorandum of Action**

MOA – 21/06

Conflict of Interest Policy for Research Investigators

Name of Council(s)/Committee(s):

Research Policies Council

Approval Date:

14 October 2021

Implementation Date:

Upon Administrative Approval

Responsible Office(s) and Responsible Enforcement Official(s):

Office of Research and Innovation, Vice President for Research

RECOMMENDATION/SUMMARY:

To move the historical 2012 policy to the current template. Add definitions, language regarding conflict reporting requirements, confidentiality provisions, and additional processes required to be compliant with federal agency requirements.

Oct. 14, 2021

Onur Arugaslan Chair, Research Policies Council

Date

Approve Disapprove Other Action

Comments:

Marilyn S. Kritzman, WMU Faculty Senate President

Date

Approve Disapprove Other Action

Comments:

Steven Carr, Interim Vice President for Research and Innovation

Date

Approve Disapprove Other Action

Comments:

Jennifer P. Bott, Provost and Vice President for Academic Affairs

Date

Approve Disapprove Other Action

Comments:

Edward B. Montgomery, WMU President

Date

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RECOMMENDATION/SUMMARY

To move the historical 2012 policy to the current template. Add definitions, language regarding conflict reporting requirements, confidentiality provisions, and additional processes required to be compliant with federal agency requirements.

RATIONALE/PURPOSE

This policy establishes the duties and responsibilities of Western Michigan University's Research Investigators to maintain objectivity in research and to ensure that the design, conduct, and reporting of research will not be biased by any conflict of interest or conflict of commitment.

This policy informs Investigators about situations that generate conflicts of interest related to research, provides mechanisms for Investigators and the Institution to manage those conflicts of interest that arise, and describes situations that are prohibited.

STAKEHOLDERS

This Policy applies to all sponsored Investigators of the Institution.

HISTORY:

- a) Effective date of current version: To be determined
- b) Date first adopted: 16 February 1979 (as part of Grants and Contracts in support of research policies governing acceptance)
- c) Revision history: 21 January 1983; 24 August 2012; 4 November 2021
- d) Proposed date of next review: November 2024

CURRENT POLICY MODIFICATION (additions in bold and deletions with strikethrough)

4. ~~The University is responsible for maintain objectivity in research by ensuring that the design, conduct, and reporting of research will not be biased by any conflicting financial interest of investigators responsible for the research. The rationale for establishing policies to manage conflict of interest in research is to protect employees and the University from potential accusations of misconduct. This policy provides guidance for investigators to help them avoid conflicts of commitment and conflicts of interest.~~
 - 4.1. ~~Full-time faculty members are expected to devote their primary professional time to teaching, research, service, and administrative responsibilities. Outside financial interests and activities should not interfere with these commitments.~~ **Every Investigator has an obligation to become familiar with, and abide by, the provisions of this policy.**
 - 4.2. **Investigators should conduct their affairs so as to avoid or minimize conflicts of interest, and must respond appropriately when conflicts of interest arise. WMU encourages employees to patent and license inventions arising from their research, develop partnerships with industry to market new technology, apply for industry-sponsored research funds, and serve as consultants for industry. The Federal government also encourages universities to commercialize the results of federally supported research for the public good (Bayh-Dole Act). However, these activities could potentially divert university employees from their primary mission of education, research, and service and are one possible source of conflicts of interest.**

4.3. Disclosures. All Investigators ~~must are required to~~ disclose their significant **outside Financial Interests** utilizing the enclosed forms and attaching all required supporting documentation. The completed disclosure form must be submitted with the proposal and the proposal approval form to the Office of Research and Sponsored programs to the **Institutional Official annually and on an ad hoc basis, as described below.** Supporting documentation should be submitted in a sealed envelope marked *confidential*. **The Institutional Official is responsible for the distribution, receipt, processing, review and retention of disclosure forms.** In accordance with federal regulations, a complete disclosure must be made by the investigator(s) prior to submission of the proposal. Resolutions to conflicts of interest will be incorporated in a memorandum of understanding that is executed between the investigator(s) and the dean/director prior to the institution's expenditure of any funds under the award.

4.3.1. Annual Disclosures: All Investigators must disclose their outside Financial Interests that are related to the investigator's institutional responsibilities annually. All forms should be submitted to the Institutional Official or designee by October 15 for the previous calendar year or as determined by the subrecipient.

4.3.2. Ad Hoc Disclosures: In addition to annual disclosure, Investigators must disclose ~~Significant~~ outside Financial Interests to the Institutional Official within thirty days of their initial appointment or employment.

4.3.3. Prior to entering into Public Health Service (PHS)-sponsored projects or applications for PHS-sponsored projects, where the Investigator has a Significant outside Financial Interest, the Investigator must confirm that their most recent annual disclosure is accurate or submit an updated Significant Financial Interest disclosure. The Institution will not submit a research proposal unless the Investigator(s) have submitted such ad hoc disclosures.

~~4.3.4. All Investigators must submit an ad hoc disclosure of any Significant Financial Interest they acquire or discover during the course of the year within thirty days of discovering or acquiring the Significant Financial Interest.~~

4.3.5.4.3.4. Travel: Investigators must disclose any reimbursed or sponsored travel (paid on behalf of the investigator and not reimbursed to the investigator) related to their **Institutional Responsibilities**. This does not include travel reimbursed or sponsored by government agencies, higher education institutions, teaching hospitals, medical centers, etc. Such disclosures must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and, if known, the monetary value. The Institutional Official will evaluate whether additional information is needed (e.g., the monetary value if not already disclosed) to determine if the travel constitutes a Financial Conflict of Interest (FCOI) with the Investigator's research. Review and Decision of Institutional Official

~~4.4.4.1 Review and Decision of Institutional Official~~

4.4.1. If the disclosure form reveals a significant outside Financial Interest, it will be reviewed promptly by the Institutional Official or designee for a determination of whether it constitutes an FCOI. If an FCOI exists, the Institutional Official will take action to manage the FCOI including reducing or eliminating the conflict, as appropriate. The Institutional Official may consult a COI Committee for guidance in specific cases, or in the application of the Policy to particular situations.

4.4.2. If the Institutional Official determines that there is an FCOI that can be managed, the Official must develop and implement a written management plan. The affected Investigator must formally agree to the proposed management strategies and sign the written management plan before any related sponsored research goes forward.

4.4.3. The Institutional Official will periodically review the ongoing activity disclosed as a FCOI, and monitor the conduct of the activity (including use of students and postdoctoral appointees), to ensure open and timely dissemination of the research results, and to otherwise oversee compliance with the management

plan.

4.5. Managing Conflicts:

4.5.1. For cases that require management, the Investigator and the Institutional Official or designee will develop a Management Plan collaboratively with the supervisor of the Investigator. Examples of conditions or restrictions that may be employed to manage conflicts include:

4.5.1.1. Public disclosure of significant financial interests (e.g., when presenting or publishing the research);

4.5.1.2. Disclosure of significant financial interests directly to subjects involved in human research;

4.5.1.3. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of research;

4.5.1.4. Modification of research plan;

4.5.1.5. Change of personnel or personnel responsibilities;

4.5.1.6. Disqualification from participation in all or a portion of the research;

4.5.1.7. Reduction or elimination of the financial interest (e.g., sale of an equity interest);

4.5.1.8. Severance of relationships that create the actual or potential conflict of interest;

4.5.2. If it proves impossible to reach an acceptable Management Plan, funds will be returned to the sponsor.

4.6. Subrecipient Requirements

4.6.1. For sponsor funded research that involves subcontractors, subgrantees or sub awardees (collectively, subrecipients) at other Institutions, Western Michigan University requires a written agreement that includes terms that establish whether the FCOI policy of the awardee Institution or that of the subrecipient Institution will apply to subrecipient Investigators. Subrecipient Institutions who rely on their FCOI policy must report identified financial conflicts of interests to the awardee Institution in sufficient time to allow the awardee Institution to report the FCOI to the sponsor awarding component. Subrecipients who do not have a Research COI Policy will be required to follow the Western Michigan University COI Research Policy. A subrecipient's failure to promptly comply with the WMU Policy will be considered grounds for immediate termination of any applicable award.

4.7. —Monitoring:

The Institutional Official and designees will monitor Investigator compliance with Management Plans. The frequency of monitoring will be dictated by sponsor/agency requirements and Management Plan provisions.

4.8. Record Retention:

The Institutional Official will retain all disclosure forms, conflict management plans, and related documents for five years from the date the final expenditure report is submitted to the sponsor or to the prime sponsor awardee. If any litigation, claim, financial management review, or audit is started before the expiration of the five-year period, the records shall be retained until all litigation, claims or audit findings involving the records have been resolved and final action taken.

4.9. Confidentiality:

The Institutional Official will maintain records of disclosed potential COIs. To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be confidential. This information will remain confidential within Western Michigan University unless disclosure is requested by a funding agency, if required pursuant to a governmental authority having jurisdiction by a demand or regulation, or if otherwise legally required. If the Institution is requested to provide disclosure forms, conflict management plans, and related information to an outside entity, the Investigator will be informed of this disclosure.

4.10. Reporting to Sponsors:

When applicable, the Institutional Official will report financial conflicts of interest or non-compliance to a sponsor in accordance with sponsor regulations. If the funding for the Research is made available from a prime sponsor-awardee, such reports shall be made to the prime awardee prior to the expenditure of any funds and within 60 days of any subsequently identified FCOI such that the prime awardee may fulfill their reporting obligations to the sponsor.

4.11. Enforcement and Noncompliance:

4.11.1. The Institutional Official is responsible for ensuring implementation of this Policy and may suspend all relevant activities until the FCOI is resolved or other action deemed appropriate by the Institutional official is implemented. Violation of any part of these policies may also constitute cause for disciplinary or other administrative action pursuant to Institutional policy.

4.11.2. Disciplinary Action: Failure to comply with this Policy will may result in disciplinary action and/or sanctions which may include formal reprimand, non-renewal/termination of appointment or affiliation, additional training requirements, additional supervision, closing existing research or denying future research by the Investigator, and/or any other enforcement action mandated by the applicable funding agency or Western Michigan University. ~~Any disciplinary procedures will be consistent with applicable Collective Bargaining Agreements as appropriate.~~ In the case of bargaining unit eligible employees, disciplinary action will proceed in accordance with the current relevant bargaining agreement. In the case of a non-student and a non-bargaining unit eligible employee, disciplinary action will proceed based on the current relevant employee handbooks.

4.11.3. Retrospective Review: If the Institutional Official determines that a FCOI was not identified or managed in a timely manner, including but not limited to an Investigator's failure to disclose a Significant Financial Interest that is determined to be a FCOI, or failure by an Investigator to materially comply with a management plan for a FCOI, a committee appointed by the Institutional Official will complete a retrospective review of the Investigator's activities and the sponsored research project to determine whether the research conducted during the period of non-compliance was biased in the design, conduct or reporting of the research.

4.11.4. Documentation of the retrospective review shall include the project number, project title, PI, name of Investigator with the FCOI, name of the entity with which the Investigator has the FCOI, reason(s) for the retrospective review, detailed methodology used for the retrospective review, and findings and conclusions of the review.

4.11.5. When applicable the Institutional Official will update any previously submitted report to the sponsor or the prime sponsor-awardee relating to the research, specifying the actions that will be taken to manage the FCOI going forward. This retrospective review will be completed in the manner and within the time frame established in sponsor regulations. If bias is found, the institution will promptly notify the sponsor awarding component and submit a mitigation report in accordance with the sponsor regulations. The mitigation report will identify elements documented in the retrospective review, a description of the impact of the bias on the research project and the plan of action to eliminate or mitigate the effect of the bias.

5. Training:

Each Investigator must complete COI training on this Policy, the Investigator's responsibilities regarding disclosure, sponsor COI regulations prior to engaging in externally funded research, and at least every four years thereafter while funded or as otherwise required by the Institutional Official.

6. Public Accessibility:

6.1. Institutions are required by federal regulations to ensure public accessibility to information concerning any significant financial interest disclosed to the Institution that meets the following criteria:

- 6.1.1. The significant financial interest was disclosed and is still held by senior/key personnel involved in the research;
 - 6.1.2. The Institution has determined that the significant financial interest is related to funded research; and
 - 6.1.3. The Institution has determined that the significant financial interest is an FCOI.
- 6.2. When a financial conflict of interest in funded research has been identified, the following will be made available within 5 business days of a request for information:**
- 6.2.1. The investigator's name; The investigator's title and role with respect to the research;
 - 6.2.2. The name of the entity in which the financial interest is held;
 - 6.2.3. The nature of the financial interest that constitutes a financial conflict of interest; and
 - 6.2.4. The approximate value of the financial interest by range or, if the dollar value cannot be determined by reference to public prices or other reasonable measures of fair market value, a statement to that effect.

RELATED PROCEDURES AND GUIDELINES

ORI procedures and guidelines for obtaining COI review, the Significant Financial Interest Disclosure Form, and the Conflict Avoidance Statement Form may be found at the WMU ORI webpage <https://wmich.edu/policies/conflict-interest>

RELATED POLICIES

- University Conflict of Interest Policy
- Conflict of Interest Policy for Board of Trustees and Executive Officials

REFERENCES

- Title 45 Code of Federal Regulations (CFR), Part 94, Responsible Prospective Contractors
- National Science Foundation 05-131 Chapter V, 510, Conflict of Interest Policies
- Code of Federal Regulations 42: Part 50, Subpart F--Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought.
https://grants.nih.gov/grants/compliance/42_cfr_50_subpart_f.htm
- Bayh–Dole Act or Patent and Trademark Law Amendments Act (Pub. L. 96-517, December 12, 1980). <https://www.govinfo.gov/content/pkg/USCODE-2011-title35/pdf/USCODE-2011-title35-part11-chap18.pdf>

3. KEY DEFINITIONS/GLOSSARY

- 3.1. Institutional Official:** the individual within the Institution who is responsible for the solicitation and review of disclosures of significant financial interests including those of the Investigator's Family related to the Investigator's institutional responsibilities. For the purposes of this policy, the Institutional Official is designated as the Vice President, Office of Research and Innovation.
- 3.2. Institutional responsibilities:** the Investigator's professional responsibilities associated with their Institutional appointment or position, such as research, teaching, clinical activities, administration, and institutional, internal and external professional committee service.
- 3.3. Investigator:** means the principal investigator/project director, co-principle investigator(s), and any other person, regardless of title or position, **any individual** who is responsible for the design, conduct, or reporting of **sponsored** research, or educational activities funded or proposals for **such** funding by an external sponsor. In this context, the term investigator includes the sub-grantees, contractors, and collaborators. This definition is not limited to those titled or budgeted as principal investigator or co-investigator on a particular proposal, and may include postdoctoral associates, senior scientists, or graduate students. The definition may also include collaborators or consultants as appropriate.
- 3.4. Family:** a spouse, domestic partner, dependent child, or anyone else with whom a

University Employee has a close, continuing personal or business relationship. Siblings, parents and non-dependent children (including step- and in-law variants of those relationships) are included in this definition in circumstances where the University Employee has actual knowledge that such relative is likely to, or will, benefit from a particular University transaction.

3.5. Conflict of Commitment (COC): when a University Employee's external relationships or activities may, in actuality or in appearance, interfere or compete with the University Employee's commitment to WMU's mission to provide leadership in teaching, research, learning, and service, or with that individual's ability or willingness to perform the full range of responsibilities associated with their position

3.6. Conflict of Interest (COI): outside interests and activities that may, in actuality or in appearance, interfere with principal investigator-faculty member's ability to maintain objectivity in research or a bias that may significantly affect the design, conduct, and reporting of research. Unless specifically stated, for purposes of this Policy, the phrase Conflict of Interest will also include Conflict of Commitment and FCOI

3.7. Financial Interest:

3.7.1. anything of monetary value, received or held by an Investigator or an Investigator's Family, whether or not the value is readily ascertainable, including, but not limited to: salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works); any equity interests (e.g., stocks, stock options, or other ownership interests); or intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights), upon receipt of royalties or other income related to such intellectual property rights and interests. For Investigators, Financial Interest also includes any reimbursed or sponsored travel undertaken by the Investigator and related to his/her institutional responsibilities. This includes travel that is paid on behalf of the Investigator as well as travel that is reimbursed, even if the exact monetary value is not readily available. It excludes travel reimbursed or sponsored by U.S. Federal, state or local governmental agencies, U.S. institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers.

3.7.2. Financial Interest does NOT include:

- 3.7.2.1.** salary, royalties, or other remuneration from Western Michigan University;
- 3.7.2.2.** income from the authorship of academic or scholarly works;
- 3.7.2.3.** income from seminars, lectures, or teaching engagements sponsored by or from advisory committees or review panels for U.S. Federal, state or local governmental agencies; U.S. institutions of higher education; research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers; or
- 3.7.2.4.** equity interests or income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions made in these vehicles.

3.8. Significant Financial Interest: a Financial Interest that consists of ~~one or more of the following interests of an Investigator and those of the Investigator's spouse and dependent children~~ that reasonably appears to be related to the Investigator's Institutional Responsibilities, and:

- 3.8.1.** if with a publicly traded entity, if ~~the value of a remuneration received from the entity in the 12-month period preceding the disclosure, and the value of any equity interest in the entity as of the date of disclosure,~~ **the aggregate value of any salary or other payments for services received during the 12-month period preceding the disclosure, and the value of any equity interest in the entity as of the date of disclosure, during the 12-month period preceding or as of the date of disclosure, when aggregated, exceeds \$5,000;** or
- 3.8.2.** if with a non-publicly traded entity, if ~~the value of an remuneration received from the entity in the 12-month period preceding the disclosure, when aggregated,~~ **the aggregate value of any salary or other payments for services received during the 12-month period preceding the disclosure, when aggregated, exceeds \$5,000;** or
- 3.8.3.** if with a non-publicly-traded company, ~~when the investigator (or the Investigator's spouse or dependent children) holds~~ **is an equity interest of any value during the 12-month**

- 3.8.4. is income exceeding \$5,000 related to intellectual property rights and interests not reimbursed through the Institution, or**
- 3.8.5. is reimbursed or sponsored travel related to their institutional responsibilities.**
- 3.9. Financial Conflict of Interest (FCOI):** a Significant Financial Interest (or other required Financial Interest disclosure) of an Investigator or Investigator's Family that the Institution reasonably determines could directly and significantly affect the design, conduct, or reporting of sponsored research.

Remuneration: includes salary and payments for services ~~not otherwise identified as salary~~, such as consulting fees, honoraria or paid authorship, **and cash or in-kind gifts from entities for which you provide services.**

- 3.10. Equity interest:** stock, stock option, or other ownership interest, **the value of which is** determined through reference to public prices or other reasonable measures of fair market value.
- 3.11. Conflict of Interest Committee (COI Committee):** the Institution's committee or individual that advises the Institutional Official on conflict of interest matters.
- 3.12. Research:** a systematic investigation, study, or experiment designed to contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., published articles, books, or book chapters) and product development (e.g., a diagnostic test or drug).

8. FAQs

- 8.1.** Where do I go to find out if I have a FCOI?
 - 8.1.1.** Contact the Vice President, Office of Research and Innovation 269-387-8270.
- 8.2.** Where do I go to find out more information about COI as it pertains to the protection of human subjects?
 - 8.2.1.** Contact the research compliance coordinator at 269-387-8293.