



FINANCIAL CONFLICT OF INTEREST POLICY

I. POLICY STATEMENT

McLaughlin Research Institute (MRI) is committed to the principle of free, open and objective inquiry in the conduct of its teaching, research and service missions. In the fulfillment of these missions, it is natural that opportunities arise for faculty, staff and students to develop relationships with external entities and to explore commercial activities. MRI encourages such endeavors as they enhance personal competency, enrich instruction, and benefit the community and the institution.

These interactions, however, create the potential for Financial Conflicts of Interest where an individual's financial or personal considerations may affect or appear to affect their MRI activities related to externally sponsored programs. The existence of a real or apparent financial conflict does not necessarily mean that the activity at issue must be avoided or discontinued.

It is through disclosure of Significant Financial Interests (as defined below) to MRI that such activities may be reviewed and, if warranted, managed. This policy establishes the process of disclosure, review and management.

II. Reason for Policy/Purpose

This document sets forth MRI's policy on the disclosure, review, management and resolution of Financial Conflicts of Interest and pertains to Principal Investigators (PI's) and their designated Senior/Key Personnel.

This policy is required by, and is intended to establish compliance with, the US Public Health Service (PHS), National Institutes of Health Regulation (42 CFR Part 50, Subpart F) "Promoting Objectivity in Research". It is also intended to establish compliance with the National Science Foundation (NSF) and other granting agencies' policies on Conflict of Interest.

III. Applicability

This policy applies to all persons, including MRI employees, sub recipient personnel, collaborators and consultants, who are involved with externally sponsored programs at MRI **and** meet the definition of “Investigator” or “Senior/Key Personnel” as defined below.

IV. Definitions

1. **Conflict of Interest.** The situation in which personal considerations have the potential to compromise or bias professional judgment and objectivity.
2. **Financial Interest.** Anything of monetary value, whether or not the value is readily ascertainable.
3. **Financial Conflict of Interest (FCOI):** A Significant Financial Interest (SFI) that could directly and significantly affect the design, conduct, or reporting of research.
4. **Financial Officer.** The institutional official in charge of MRI's FCOI Policy and process.
5. **Investigator.** The Project Director or Principal Investigator, and any other person, regardless of title or position, who is responsible for the design, conduct or reporting of funded or proposed research, which may include, but is not limited to MRI research staff, sub grantees, contractors, consortium participants, collaborators or consultants.
6. **Investigator's Institutional Responsibilities.** An Investigator's professional responsibilities on behalf of and as defined by MRI, including but not limited to, activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as institutional review boards or data and safety monitoring boards.
7. **Management Plans.** Actions taken by the institution to address a FCOI, which can include reduction or eliminating the FCOI, to ensure, to the extent possible, that the design, conduct and reporting of research will be free from bias.
8. **Senior/Key Personnel.** The Project Director/Principal Investigator, Co-Principal Investigator, and any other persons listed in a grant application, progress report, or any other report of a proposed or funded research project. In addition, all of the following may be considered Senior/Key Personnel, to the extent they are responsible for the design, conduct or reporting of the research: professorial faculty, research associates, emeritus faculty, subrecipient personnel, research collaborators, visiting scientists, individuals with courtesy appointments, as well as undergraduate, graduate and post-doctoral students. The term does not commonly apply to MRI administrative professionals.

9. **Significant Financial Interest (SFI).** A Financial Interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and independent children) that reasonably appears to be related the Investigator's Institutional Responsibilities:

- With regard to any publicly traded entity, a SFI exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g. consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option or other ownership interest as determined through reference to public prices or other reasonable measures of a fair market value;
- With regard to any non-publicly traded entity, a SFI exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g. stock, stock option, or other ownership interest); or
- Intellectual property rights and interests (e.g. patents, copyrights), upon receipt of income related to such rights and interests.
- Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e. that which is paid for on behalf of the Investigator and reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities: provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by 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. Disclosure information must include the purpose of the trip, the identity of the sponsor/organizer, the destination and the duration. The Financial Officer will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes a FCOI with the research.

SFI does not include the following types of financial interest: salary, royalties, or other remuneration paid by the institution to the Investigator if the Investigator is currently employed or otherwise appointed by the institution, including intellectual property rights assigned to the institution and agreements to share in royalties related to such rights; any ownership interest in the institution held by the Investigator, if the institution is a commercial or for profit organization; income from investment vehicles, such as mutual

funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles, income from seminars, lectures or teaching engagements sponsored by 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; or income from service on advisory committees 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 institute of higher education.

V. Policy Procedure

1. Required and Annual Disclosure to MRI

- 1.1. Investigators must submit disclosures annually or at the time of a funding proposal submission. When Investigators submit PHS funding proposals, they must list all other project personnel and ensure that required disclosures have been submitted to MRI from all personnel.
- 1.2. Additionally, prior to June 30 of each year, Investigators and Senior/Key Personnel are required to complete a FCOI Disclosure Form and submit it to the Financial Officer. If a FCOI is indicated on the FCOI Disclosure Form, the FCOI Details Disclosure Form must also be completed and submitted.

2. Required Submission of Revised Forms to MRI

If there is a material change (such as an acquisition of a SFI) to the information provided on the FCOI Disclosure Form and/or the FCOI Details Disclosure Form a new form must be submitted to MRI within 30 days of that change.

3. Management Plans

- 3.1. Upon reviewing an Investigator's FCOI Details Disclosure Form, MRI's Financial Officer will decide whether a Management Plan is needed. Should management of a potential or actual FCOI be required, MRI's Director and Financial Officer will work with the Investigator to draft a Management Plan. MRI's Financial Officer, Director, and Investigator will confer as needed to draft the Management Plan. If the parties involved are in agreement, the Director, Financial Officer and the Investigator will approve the Management Plan. If the parties involved do not reach an agreement, the FCOI Committee will review the Management Plan and make a recommendation to the MRI Director, Financial Officer, and the Investigator.
- 3.2. These written plans will manage, reduce, or eliminate the FCOI(s). Such plans may also address the use of institute facilities, involvement of students and overlap between private and institute activities. Such plans will be designed to meet

applicable legal requirements, facilitate the local resolution or management of any conflict, and protect the sensitivity of disclosed information.

3.3. Management Plans may include a single element or several elements such as:

- Monitoring of the sponsored program by independent researchers or reviewers, or the FCOI Committee or their designee
- Modifications to the research or program plan
- Appointment of an oversight panel or person to review research/scholarship
- Limitations on the employees' involvement in personnel decisions on behalf of MRI
- Divestiture of SFIs and/or
- Other arrangements that manage, reduce, or eliminate a potential FCOI

4. Responsibilities of the FCOI Committee

4.1. The FCOI Committee will be comprised of:

- Financial Officer
- Director
- At least two MRI faculty or Board members who represent a balance of disciplines and have training and/or experience relate to Financial Conflict of Interest in research.

The Investigator may request that an ad hoc member be added to the committee for the purpose of including a representative familiar with the Investigator's field.

4.2. The FCOI Committee has the following primary responsibilities:

- Reviewing complex disclosures, as requested by MRI, to assure that all issues have been considered and addressed.
- Reviewing draft Management Plans where the Investigator, Director, and Financial Officer have been unable to reach an agreement or make a recommendation for resolution of the disagreement.

The Director, after consideration of the FCOI Committee recommendation, shall make the final determination on Management Plans.

5. Retrospective Review

MRI is required by federal regulation to conduct a retrospective review in those cases of non-compliance with the federal regulations. This must be done within 120 days of determination of non-compliance. MRI will notify the awarding agency promptly and submit a report to the awarding agency in cases where bias is found. The report will address the impact of the bias on a research project and the actions taken by or to be taken by MRI to eliminate or mitigate the bias.

6. Monitoring

MRI may conduct random and for-cause monitoring of FCOI Management Plans.

7. Non-Compliance

7.1. Failure to comply with this policy or to follow an agreed upon Management Plan will result in a Retrospective Review (described above) and may result in the following actions:

- Termination of Investigator's external funding project(s) at MRI.
- Termination of Investigator's ability to submit proposals for external funding through MRI.

7.2. Failure to comply with this policy may subject a MRI employee to other disciplinary processes within MRI in accordance with other MRI policies and procedures.

7.3. Violations of this policy include, but are not limited to:

- Failure to comply with the disclosure processes (by refusal to respond; by deliberately responding with incomplete, inaccurate, or misleading information, or otherwise;
- Failure to remedy FCOI; and
- Failure to comply with a prescribed Management Plan.

8. Training Requirement

Each investigator and Senior/Key Personnel must complete Conflict of Interest training prior to engaging in research related to any PHS-funded grant or contract and at least every four years. In addition, training must be completed immediately under the following circumstances:

- MRI FCOI policies change in a manner that affects Investigator requirements
- An Investigator is new to MRI
- MRI finds an Investigator noncompliant with the institutional policy or his/her Management Plan

At the time of training, Investigator and Senior/Key Personnel shall provide acknowledgement that they have read and understand this policy.

MRI will make available tools and training opportunities.

9. Public Disclosure

9.1. MRI will make this policy available to the general public by posting it in MRI's website.

9.2. MRI is required by federal regulation to make certain information about FCOIs related to PHS-funded research by Senior/Key Personnel available to the public. MRI will do so by responding to any request for information about these specifically covered FCOIs within five business days. Information that must be made available is:

- Investigator's Name
- Investigator's title and role with respect to a research project
- Name of the entity in which the SFI is held
- Nature of the SFI
- Approximate dollar value of the SFI (dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,000; \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through references of public prices or the other reasonable measures of fair market value).

10. Additional Responsibilities

10.1. MRI maintains this written FCOI Policy and will implement a process to identify and manage, reduce or eliminate these conflicts.

10.2. MRI shall, for any federal research funding from the PHS or any other federal funding agency that imposes FCOI requirements:

- Include in the subaward agreement terms that establish whether this policy or that of the subrecipient will apply to the subrecipient's Investigators and provide FCOI reports regarding subrecipient Investigators to the awarding federal funding agency;
- Maintain the records of, and related to, FCOI disclosures;
- Report conflicting SFI to the awarding component of the funding agency;
- Inform the National Science Foundation Office of the General Counsel if it is unable to satisfactorily manage a FCOI related to a project funded by the NSF;
- Report to the NIH the existence of any conflicting Financial Interests and assure that the interest has been managed, reduced, or eliminated in accordance with the NIH regulations; and
- Maintain records related to Investigator disclosures of Financial Interests and the institution's review of, or response to, such disclosures and all actions under this policy or retrospective review for at least three years from the date of the final expenditure report.

VI. Links to Related Policies and Forms

1. [Financial Conflict of Interest Disclosure Form](#)
2. [FCOI Disclosure Details Form](#)
3. [FCOI Supplemental Disclosure Form for PHS Researchers](#)

VII. Links to Related Information

1. [NIH](#)
2. [NSF](#)

VIII. Contacts

If you have any questions on the policy or procedure for FCOI you may:

Contact Coleen Balzarini, Financial Officer, at 406-454-6015 or
cbalzarini@mri.montana.edu

IX. History/Revision Dates

Effective August 24, 2012

X. Policy Adoption

Approved George A. Carlson, Director (signature on file) Date 08/24/2012