



CONFLICT OF INTEREST POLICY FOR FEDERALLY FUNDED INVESTIGATORS

1. Overview

Many funding agencies have requirements for disclosures of conflicts related to sponsored research. To ensure compliance with such requirements, the Morgridge Institute for Research, Inc. (the "Institute") has implemented this *Conflict of Interest Policy for Federally Funded Investigators* (this "Policy"). The intent of this Policy is to promote objectivity in research and to ensure that the design, conduct, and reporting of federally sponsored research is not biased by the financial interests of an Investigator or other Senior/Key Personnel (as defined below). The Institute has a continued commitment to the integrity of its employees in the conduct of research and other professional activities.

This Policy applies to all Investigators and other Senior/Key Personnel who are engaged in—or are planning to engage in—federally-funded research. As described in more detail below, all outside research and business activities of Investigators and Senior/Key Personnel that reasonably appear to be related to their Institutional Responsibilities (as defined below) must be disclosed to the Institute's Conflict of Interest Advisory Committee (the "Committee").

2. Definitions

The following definitions¹ apply specifically to the terms used in this Policy:

Conflict of Interest means a situation in which an Investigator or his/her Immediate Family has Significant Financial Interests that could lead an independent observer reasonably to question whether the design, conduct, or reporting of the Investigator's federally-funded research might be influenced by the possibility of personal gain.

Entity means any domestic or foreign, public or private, organization (excluding a federal agency) from which an Investigator and/or the Investigator's Immediate Family receives remuneration or in which any of the foregoing has an ownership or equity interest.

Federal Funding means funding received from sources outside the Institute, including federal and federal flow-through to support research and research-related activities conducted by Institute personnel.

Financial Conflict of Interest ("FCOI") means a Significant Financial Interest that could directly and significantly affect the design, conduct, and/or reporting of research supported by PHS Awarding Agencies or other agencies who have adopted the PHS FCOI regulations² ("PHS Agencies").

¹ See also 42 CFR part 50.603

² See [Agencies Using the PHS FCOI Regulations](#)

Immediate Family means an Investigator's spouse, domestic partner, and anyone who receives, directly or indirectly, more than one-half of his or her support from the Investigator or from whom the Investigator receives, directly or indirectly, more than one-half of his or her support.

Institutional Responsibilities means an Investigator's professional responsibilities on behalf of the Institute, which may include activities such as research, research consultation, teaching, professional practice, and service on Institute committees or panels.

Investigator means the Project Director or Principal Investigator ("PD/PI") and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of federally-funded research or research proposed for such funding. Investigators may be full-time or part-time employees, students, consultants, individuals with joint appointments with the Institute and the University of Wisconsin-Madison or with another institution, and anyone else that receives research support from the Institute and whose actual or perceived conflicts for such research are not reviewed and managed by another institution.

Management Plan means action(s) taken to address a COI or a FCOI, which can include reducing or eliminating the COI/FCOI to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias. Examples of conditions or restrictions that might be imposed to manage a COI/FCOI include, but are not limited to, the following:

- Public disclosure of the COI/FCOI (e.g. when presenting or publishing research).
- For research involving human subjects, disclosure of the COI/FCOI directly to participants.
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias, or the appearance of bias, resulting from the COI/FCOI.
- Change of personnel or personnel responsibilities or disqualification of personnel from participation in all or in a portion of the research.
- Modification of the research plan.
- Reduction or elimination of the COI/FCOI (e.g., sale of an equity interest).
- Severance of relationships that create an actual or perceived COI/FCOI.

Research means a systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research and product development. Research may take place within the Institute's facility in the Wisconsin Institutes for Discovery or elsewhere in conjunction with the Institute.

Senior/Key Personnel means the PD/PI and any other person identified as Senior/Key Personnel by the Institute in a grant application, progress report, or any other report submitted to the funding agency by the Institute.

Significant Financial Interest (“SFI”) means a financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator’s Immediate Family) that reasonably appears to be related to the Investigator’s Institutional Responsibilities and that should be disclosed to the Institute:

- **Publicly Traded Entity:** 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, that, when aggregated, exceeds \$5,000.
- **Non-Publicly Traded Entity:** any remuneration* received from the entity in the twelve months preceding the disclosure, that when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator’s spouse or dependent children) holds any equity interest** regardless of value.
- **Intellectual Property:** Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- **Travel:** Any reimbursed or sponsored travel (i.e., that which is paid on behalf of and not reimbursed to the Investigator so that the exact monetary value may not be readily available) related to the Investigator’s Institutional Responsibilities (other than Excepted Travel, as defined below).

*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 fair market value.

Exceptions that do not constitute SFIs and therefore do not require disclosure include:

- Salary, royalties, or other remuneration paid by the Institute to the Investigator if the Investigator is currently employed or otherwise appointed by the Institute.
- Intellectual property rights assigned to the Institute/WARF and agreements to share in royalties related to such rights.
- 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, reimbursement, or sponsorship provided by a federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education (each, a “Qualified Agency/Institution”) for:
 - Seminars, lectures, or teaching engagements.
 - Service on an advisory committee or review panel for a Qualified Agency/Institution.
 - Travel expenses (“Excepted Travel”).

3. Disclosure of Significant Financial Interests

Statements: Complete Disclosure Forms will generally fall into one of the following categories, as determined by the Committee:

- Disclosure Forms reporting no SFIs.
- Disclosure Forms reporting SFIs that do not require management because they do not pose a Conflict of Interest or Financial Conflict of Interest.
- Disclosure Forms reporting SFIs that require management because they pose a Conflict of Interest and/or a Financial Conflict of Interest.

Schedule for Completing and Submitting Disclosure Forms:

DISCLOSURE FORM	WHEN REQUIRED
Annual Disclosure Form	<ul style="list-style-type: none"> • Due by December 31st annually • For new employees hired between January 1st and November 30th who meet the definition of Investigator or Senior/Key Personnel, due within 30 days of hire; due annually thereafter • Must be up-to-date and on file with the Committee prior to the submission of proposals for federal funding • Must be up-to-date and on file with the Committee prior to award acceptance and expenditure of federal funding • Must be up-to-date and on file with the Committee prior to submission of annual progress report to federal funding agency
Updated Disclosure Form	<ul style="list-style-type: none"> • Within 30 days of acquiring a new Significant Financial Interest or experiencing a change in a previously reported Significant Financial Interest

Annual Disclosure Form: To assure the Institute’s ability to identify and manage conflicts or perceived conflicts of interest, all Institute personnel meeting the definition of Investigator or Senior/Key Personnel who (1) are currently working on federally-funded research as the prime awardee and/or via a subaward agreement or contract, (2) intend to submit a proposal for federal funding, or (3) intend to work under a subaward agreement or contract on an federally-funded project, must annually complete and submit a Disclosure Form identifying all Significant Financial Interests to the Sponsored Programs Administration office. Notification will be sent out by Sponsored Programs Administration staff annually to those individuals who are required to complete the Disclosure Form.

30-Day Period for Reporting Changes: All Investigators or Senior/Key Personnel with a change in information previously reported in their Disclosure Form, and/or with new information to report since submission of the annual Disclosure Form, are required to submit a revised Disclosure Form to the Sponsored Programs Administration office within 30 days of the change.

New Investigators: If new personnel are to be added to federally-funded projects who meet the definition of Investigator or Senior/Key Personnel, they must submit a new (if no Disclosure Form is currently on file with the Committee) or updated Disclosure Form to the Sponsored Programs Administration office identifying all Significant Financial Interests prior to joining the project.

Pre-Submission and Pre-Award Acceptance/Expenditure Review and Updates: Prior to any grant proposals, subaward agreements, contracts, or cooperative agreements being submitted for federal funding, and prior to the acceptance of/expenditures on federal funding awards, including supplements, carryovers, no-cost extensions, and noncompeting continuations, all Investigators and Senior/Key Personnel must have an up-to-date, signed Disclosure Form on file with the Committee. Sponsored Programs Administration staff will verify that a Disclosure Form is on file with the Committee. ***It is the responsibility of all Investigators and Senior/Key Personnel to ensure that their Disclosure Form on file with the Committee is up-to-date and that changes are reported within the 30-day period.***

4. Reporting and Confidentiality

Conflict of Interest and Financial Conflict of Interest Reports: Notification of actual or perceived Conflicts of Interest will be provided to federal funding agencies per the prime award terms, conditions, and regulations. In cases where the Institute is serving as a subawardee or contractor, COI/FCOI information and Management Plans will be reported to the direct funder per the subaward/ contract terms, conditions, and regulations.

In cases where a FCOI is determined to exist with a project funded by a PHS Agency, the Institute must submit a formal report of the FCOI and details of the Management Plan to the applicable agency within 60 days after determining a FCOI exists and prior to expenditure of any award funds. Any new FCOIs, changes in a previously reported FCOI, changes to a Management Plan, or the addition of new personnel to a project who meet the definition of Investigator or Senior/Key Personnel also must be reported by the Institute to the funding agency within 60 days of identification. Finally, an annual FCOI report must be submitted by the Institute to the funding agency concurrently with the annual progress report.

Confidentiality: Disclosure Forms, Management Plans, and related records and information submitted by Investigators and Senior/Key Personnel will be maintained confidentially unless they are requested by an appropriate federal agency, or as required to be shared by law or regulation. In the case of FCOIs related to projects funded by a PHS Agency, the Institute shall ensure public accessibility, via a written response to any requestor within five business days of a request, of information concerning any SFI disclosed to the Institute that meets the following three criteria:

- (A) The SFI was disclosed and is still held by the Investigator or Senior/Key Personnel;
- (B) The Institute determines that the SFI is related to PHS-funded research; and
- (C) The Institute determines that the SFI is a FCOI.

5. Required Training for PHS Funded Projects

All Investigators and Senior/Key Personnel who are engaged in—or are planning to engage in—federally-funded research must complete a required COI training module prior to engaging in the federally-funded research and at least every four years thereafter. This requirement applies both to newly-funded research and continuation awards. Notification will be sent out by Sponsored Programs Administration staff to those individuals who are required to complete the COI training.

6. Subawardees, Subcontractors, and Other Collaborators

Prime award COI/FCOI terms, conditions, and regulations flow down to all subawardees, subcontractors, and other collaborators as appropriate³. When the Institute carries out a project funded by a PHS Agency which includes subcontractors, subawardees, or other collaborators, the Institute is responsible for reporting to the funding agency any FCOI arising from the outside Investigators and Senior/Key Personnel. To meet this obligation, outside Investigators and Senior/Key Personnel will be required to comply either with the Institute's Policy or with a policy at their own institution that complies with the PHS FCOI regulations.

In the event that other institutions have their own policy in place, those institutions will be required to provide the Institute with sufficient certifications and assurances to allow the Institute to comply with PHS FCOI regulations. The timeline for obtaining this information from subawardees, subcontractors, or other collaborators will correspond with the timeline for obtaining this information from Investigators and Senior/Key Personnel at the Institute. If the other institutions choose to follow the Institute's policy, those institutions' Investigators and Senior/Key Personnel will be required to participate in the Institute's required training module as well as SFI disclosure/reporting process and schedule.

When the Institute carries out other federally-funded research which includes subawardees, subcontractors, or other collaborators, the Institute will take reasonable steps to ensure that the collaborating entity has its own policies in place that meet the funding agency's conflict of interest requirements or that Investigators and Senior/Key Personnel working for such entities follow the policies of the Institute.

³ See also 42 CFR part 50.604(c)