

Financial Conflict of Interest (FCOI) Policy: Public Health Services (PHS) Sponsored Projects

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The University of Wisconsin-La Crosse (UW-L) financial conflict of interest (FCOI) policy applies to projects sponsored by the Public Health Service (PHS) or any [PHS awarding component](#) with notices of award received on or after August 24, 2012. Examples of PHS awarding components include, but are not limited to, the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the Substance Abuse and Mental Health Services Administration (SAMHSA).

Purpose

The financial conflict of interest (FCOI) policy promotes objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research funded under PHS grants, cooperative agreements, or contracts will be biased by an investigator's conflicting financial interests. Complying with the policy ensures that potential conflicts are disclosed to the university and that the university manages, reduces, or eliminates FCOIs so there is a reasonable expectation that the research is unbiased and the public trust is preserved.

Definitions

For the purpose of this policy, several recurring terms are defined as follows:

1. Financial conflict of interest (FCOI)
 - a. A significant financial interest (SFI) that could directly and significantly affect that design, conduct, or reporting of funded research
2. Immediate family
 - a. PHS FCOI regulations ([42 CFR Part 50 Subpart F](#)) state that a significant financial interest (SFI) must be disclosed when it is held by an investigator and/or “an investigator’s spouse and dependent children.” For the purposes of this FCOI policy, at a minimum, “spouse” and “dependent children” refer to the terms as presently defined by the [Internal Revenue Service \(IRS\)](#). UW-L recognizes that the federal definitions do not necessarily reflect university values of inclusivity; thus, if an investigator wishes to disclose SFIs of significant others, he/she may do so.
3. Investigator
 - a. Any individual responsible for the design, conduct, or reporting of research funded by a PHS awarding component or proposed for such funding
 - b. Includes subgrantees, contractors, subcontractors, and collaborators
 - c. May include undergraduate or graduate students
 - d. For help in determining whether an individual meets the definition of an investigator, please refer to [PHS FCOI Determination of Investigator Status Checklist](#).
4. Public Health Service (PHS)
 - a. The Public Health Service (PHS) of the U.S. Department of Health and Human Services and any [awarding components of the PHS](#) to which the authority involved may be delegated, including but not limited to the following offices and agencies:
 - i. Agency for Healthcare Research and Quality (AHRQ)
 - ii. Centers for Disease Control and Prevention (CDC)
 - iii. Food and Drug Administration (FDA)
 - iv. National Institutes of Health (NIH)
 - v. Substance Abuse and Mental Health Services Administration (SAMHSA)
5. Public Health Service (PHS) Awarding Component
 - a. The organizational unit of the PHS that funds the research that is subject to this policy; a list of the PHS awarding components can be found on the [PHS website](#)

6. Significant financial interest (SFI)

- a. Remuneration and equity/ownership interests of the investigator and/or the investigator's immediate family as defined the table below:

Type of entity	Type of financial interest	Value
Publicly traded entity	Any remuneration, including but not limited to: <ul style="list-style-type: none"> • Salary or other payments for services (e.g., consulting fees, honoraria, paid authorship) 	Totaling \$5,000 or more in the preceding twelve months alone or in aggregate with equity interests and/or reimbursed/sponsored travel in/from same entity
	Equity interests (e.g., stocks, stock options, convertible bonds, or other ownership interests)	Totaling \$5,000 or more (as determined through reference to public prices or other reasonable measures of fair market value) alone or in aggregate with other remuneration received from same entity
Non-publicly traded entity	Any remuneration, including but not limited to: <ul style="list-style-type: none"> • Salary or other payments for services (e.g., consulting fees, honoraria, paid authorship) 	Totaling \$5,000 or more in the preceding twelve months
	Equity interests (e.g., stocks, stock options, convertible bonds, or other ownership interests)	Any amount
N/A	Intellectual property rights and interests (e.g., patents, copyrights, and royalties from such rights)	Any amount
Any entity that is <i>not</i> a federal, state, or local government agency; an institution of higher education, an academic teaching hospital, a medical center, or a research institute affiliated with an institution of higher education	<ul style="list-style-type: none"> • Reimbursed travel • Sponsored travel (i.e., that which is paid on behalf of the investigator and not reimbursed to the investigator so that the exact monetary value may not be readily available) 	Any amount

- b. Does not include:

- i. Salary, royalties, or other remuneration from the university, including intellectual property rights assigned to the university and agreements to share in royalties related to such rights

- ii. Income from investment vehicles (e.g., mutual funds, retirement accounts) so long as the investigator does not directly control the investment decisions made in these vehicles
- iii. Any ownership interests in an entity if the entity is an applicant under the SBIR or STTR programs
- iv. Income from seminars, lectures, or teaching engagements sponsored by public or non-profit entities
- v. Income from service on advisory committees or review panels for public or non-profit entities

Training Requirements

The institutional FCOI training module in Desire2Learn (D2L) must be completed by investigators according to the following guidelines:

1. UW-L investigators serving as principal investigators (PIs), co-principal investigators (co-PIs), or project directors (PDs) must successfully complete the training module before an application is submitted to the funding agency. Thereafter, training must be completed every four years.
2. All other investigators (such as students and technicians) must successfully complete the training module before sponsored project funding and activities commence. Thereafter, training must be completed every four years.

The module provides instruction regarding the PHS FCOI regulation, UW-L's FCOI policy, and investigators' SFI disclosure responsibilities and other obligations related to the policy. Completion of the FCOI training requirement is satisfied by achieving a score of 80% or higher in the module's assessment. Individuals may take the assessment an unlimited number of times. D2L documents satisfactory completion of the module. Training records are maintained by the Office of Research & Sponsored Programs in accordance with the requirements of the Wisconsin Open Records Law (State Statutes 19.31 through 19.39) and with PHS FCOI regulations (42 CFR Part 50 Subpart F).

Additionally, under the following circumstances, training must be completed by investigators within 30 days of the occurrence:

1. The university revises its FCOI policy or procedures in any manner that affects the requirements of investigators
2. When an investigator newly affiliated with UW-L has an existing PHS-sponsored project he/she will be continuing at UW-L
3. When a new investigator begins work on an ongoing PHS-sponsored project at UW-L
4. The university finds that an investigator is not in compliance with the university's FCOI policy or a prescribed FCOI Management Plan

Subrecipient Requirements

When a PHS-funded project for which UW-L is the lead institution includes a subrecipient investigator (an individual whose primary affiliation is with an entity other than UW-L) – whether a subgrantee, contractor, subcontractor, or collaborator – the subrecipient investigator is also subject to PHS FCOI regulations. To ensure compliance, the subrecipient institution must certify in writing whether subrecipient investigators will follow the FCOI policy of UW-L or the subrecipient institution; if the subrecipient institution's policy will apply, the certification verifies that the policy complies with the PHS FCOI regulation. This certification is made using templates available by request from the UW-L Office of

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Research & Sponsored Programs; the certification must be signed by the subrecipient institution's authorized organizational representative. UW-L employees serving as subrecipient investigators on PHS-funded research are subject to UW-L's FCOI policy; in such a case, UW-L investigators may request a certification from the Office of Research & Sponsored Programs to verify their compliance with the UW-L FCOI policy and PHS FCOI regulations for the sponsored project's lead institution.

Subrecipient investigators who are subject to UW-L's FCOI policy must fulfill all requirements for investigators as described in this policy, particularly in regards to responsibilities related to the [disclosure of SFIs](#) and [FCOI training](#).

For subrecipient investigators who are subject to their affiliated institution's FCOI policy, subrecipient institutions must report all identified FCOIs to the UW-L Office of Research & Sponsored Programs as soon as possible following internal review of disclosed SFIs and prior to the expenditure of funds. Early reporting will help to ensure timely commencement of funding following a notice of award. For subsequently identified FCOIs, subrecipient institutions must provide a FCOI report to UW-L within 30 days of when a new FCOI is discovered or acquired. FCOI reports made to UW-L for subrecipient investigators must include the following information:

1. Name of the entity with which the investigator has an FCOI
2. Nature of the FCOI (e.g., equity, consulting fees, travel reimbursement, honoraria)
3. Value or estimated value of the financial interest
4. Description of how the financial interest relates to PHS-funded research and the basis for the determination that it conflicts with the research
5. Key elements of the management plan
 - a. Role and principal duties of investigator in the research project
 - b. Conditions of the management plan
 - c. How the management plan will safeguard objectivity in the research project
 - d. Confirmation of the investigator's agreement to the management plan
 - e. How the management plan will be monitored to ensure compliance
 - f. Other pertinent information

In the event a subrecipient investigator has an FCOI to report, UW-L will provide a subrecipient FCOI report with the above information to the PHS awarding component prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

Significant Financial Interest Disclosure

An investigator is responsible for disclosing all of their significant financial interests (and those of their [immediate family](#) [hyperlink to "Definitions"]) that meet the definitions in this policy ([refer to "Definitions"](#)) that would reasonably appear to be related to the investigator's institutional responsibilities and/or field of professional interest. Significant financial interests (SFI) are reported through the [SFI Disclosure form](#), which must be completed and routed to the Office of Research & Sponsored Programs before an application can be submitted. Investigators are responsible for disclosing the following information:

1. Remuneration for outside activities in investigator's institutional responsibilities and/or field of professional interest
 - a. Name of organization or business
 - b. Type of activity (e.g., consulting, teaching, etc.)
 - c. Amount or estimated value

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2. Remuneration from a non-governmental sponsor of university research, teaching, or training for which investigator is a principal investigator
 - a. Name of sponsor
 - b. Amount or estimated value
3. Equity/ownership interests
 - a. Name of business or organization
 - b. City and state of business or organization location
 - c. Present market value or estimated value
4. Intellectual property rights
 - a. Name of rights
5. Travel support
 - a. Entity providing reimbursement or sponsorship
 - b. Purpose of the trip
 - c. Destination
 - d. Duration
 - e. Actual or estimated value received

The SFI Disclosure form must be completed and signed by the investigator and the cognizant dean/division director. It is then routed to the Office of Research & Sponsored Programs; this process must be completed before the application for funding is submitted. Thereafter during the period of the award, an updated SFI Disclosure form must be submitted to the Office of Research & Sponsored Programs annually by June 30 and within 30 days of when new SFIs are discovered or acquired. Subsequent SFI Disclosure forms should disclose newly acquired SFIs and should provide updated information regarding any previously disclosed SFIs (e.g., the updated value of a previously disclosed equity/ownership interest).

Investigator(s) who are new to participating in an ongoing sponsored research project must also complete the SFI disclosure process described above. Before a new investigator may begin work on the research project, the SFI Disclosure form must be completed, routed for signatures, submitted to the Office of Research & Sponsored Programs, and reviewed to determine whether a potential FCOI may exist. If a potential FCOI is identified, the [review process described below](#) must be completed and a FCOI Management Plan implemented before a new investigator may begin work on the research project.

Review Process

Once the SFI Disclosure form is submitted, it is reviewed by the Associate Vice Chancellor for Academic Affairs who determines whether any disclosed SFIs may relate to the sponsored research and whether a potential FCOI may exist. Forms with no disclosures will be filed in the Office of Research & Sponsored Programs with no further review required. If the Associate Vice Chancellor determines there is a potential FCOI, a FCOI committee will be convened that is comprised of the following members:

1. Associate Vice Chancellor for Academic Affairs
2. Dean or appointed designee of College of Business and Administration
3. Dean or appointed designee of College of Liberal Studies
4. Dean or appointed designee of College of Science and Health
5. Human resources representative (as a non-voting member acting in an advisory capacity)

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Prior to initial committee service, all voting committee members will have successfully completed the institutional D2L FCOI training module within the past four years. The voting members should begin the initial meeting by selecting a chair who is a voting member. The FCOI committee will determine whether a FCOI exists; if a FCOI is identified, the committee will develop a plan to manage, reduce, or eliminate each conflict using the [FCOI Management Plan form](#). Investigators may be invited to participate in the FCOI Management Plan development process. In reviewing potential FCOIs, the FCOI committee will be guided by the committee operating guidelines and will accomplish the following:

1. Assure adherence to relevant state law and university policies, such as the Unclassified Staff Code of Ethics (Chapter UWS 8), including Outside Activities and Interest (UWS 8.025 and UWL 8.025), Standards of Conduct (UWS 8.023 and UWL 8.023), and Action to Avoid Possible Conflict (UWS 8.04 and UWL 8.04).
2. Consider the nature and extent of the financial interests in the relationship of the investigator and their immediate family and the external organization.
3. Give special consideration to the terms and conditions of sponsored project agreements that may mitigate or complicate the given situation.
4. Consult with and obtain information from the investigator as either the FCOI committee or the investigator feels may be helpful in resolving actual or potential conflicts.
5. Act in a timely manner so as not to delay unduly the conduct of a sponsored project.
6. Determine whether the SFI is related to the funded research. If so, the committee will determine if a FCOI exists (whether the SFI could directly and significantly affect that design, conduct, or reporting of the funded research).
7. If a FCOI is identified, the committee will develop and document a FCOI Management Plan to appropriately manage, reduce, or eliminate the conflict.

Any substantive actions and/or determinations require the majority support of the committee per the [committee operating guidelines](#). All committee meetings will begin in open session and then move into closed session to discuss personal financial matters. Following FCOI Management Plan development, the plan will be signed by the investigator to indicate their acceptance of the prescribed plan or their intent to appeal to the Chancellor ([see "Appeals"](#)).

Based on the outcomes of the FCOI Management Plan development process, the university may take one of the following actions:

1. Accept the sponsored project award.
2. Not accept the sponsored project award.
3. Accept the sponsored project award subject to the prescribed actions/modifications prescribed in the FCOI Management Plan.

The SFI review, FCOI management plan development and approval, and [reporting process](#) will be completed before the university's acceptance of the sponsored project and commencement of funding. Whenever, during the course of an ongoing sponsored research project, an investigator discloses a new SFI, the review process described above will take place within 60 days of the disclosure. Depending on the nature of the SFI, the university may determine that interim measures are necessary with regard to the investigator's participation in the funded research project between the date of disclosure and the completion of the review process.

Reporting to Funding Agency

After a FCOI Management Plan is completed and approved by all parties, UW-L will provide a FCOI report to the PHS awarding component with the following information prior to the expenditure of funds:

1. Project number
2. Principal investigator (PI)/project director (PD) or designated contact in the case of multiple PIs/PDs
3. Name of the investigator with the FCOI
4. Name of the entity with which the investigator has an FCOI
5. Nature of the FCOI (e.g., equity, consulting fees, travel reimbursement, honorarium)
6. Value of the financial interest or statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measure of fair market value
7. Description of how the financial interest relates to funded research and the basis for the determination that it conflicts with the research
8. Description of the key elements of the management plan:
 - a. Role and principal duties of the investigator in the research project
 - b. Conditions of the management plan
 - c. How the management plan is designed to safeguard objectivity in the research project
 - d. Confirmation of the investigator's agreement to the management plan
 - e. How the management plan will be monitored to ensure compliance
 - f. Other pertinent information as needed

Following the submission of the initial FCOI report, UW-L will provide annual and, when necessary, revised reports to the PHS awarding component regarding the status of the FCOI – i.e., whether the FCOI is still being managed or to explain why the FCOI no longer exists – and changes to the management plan. Annual FCOI reports will be provided to the PHS awarding component concurrently with annual progress reports and at the time of a requested extension (if applicable). In the event of any subsequently identified FCOI held by existing investigators or by new investigators joining an ongoing sponsored project, the university will provide a FCOI report to the PHS awarding component within 60 days of when the FCOI is identified. If a [retrospective review is conducted](#), at the review's conclusion, UW-L will provide the PHS awarding component with an updated FCOI report.

For the reporting responsibilities required of subrecipient institutions and investigators, please refer to the [“Subrecipient Requirements” section of this policy](#). In the case of subrecipient investigators who have an identified FCOI, both those subject to the subrecipient entity's FCOI policy and those subject to UW-L's FCOI policy, UW-L will provide the PHS awarding component with a FCOI report prior to the expenditure of funds and within 60 days of subsequently identified FCOIs.

Compliance and Monitoring

Compliance with a prescribed FCOI Management Plan will be monitored in an immediate and ongoing manner. Following the completion of action(s) described within a FCOI Management Plan, the investigator will notify the Office of Research & Sponsored Programs via email of the action(s)' completion. The prescribed actions and notification must be completed before the funded research begins. Additionally, an investigator will certify their ongoing compliance with a prescribed FCOI Management Plan in revisions and annual updates of their SFI Disclosure form.

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Examples of noncompliance with the FCOI policy may include but are not limited to failure by an investigator to disclose a [SFI in accordance with policy guidelines](#) or failure to comply with a FCOI Management Plan. In the event noncompliance is identified, the investigator(s) will be expected to cooperate with university efforts to resolve the noncompliance. Upon determination of noncompliance with the university's FCOI policy, the PHS awarding component will be promptly notified.

SFIs that are not disclosed in a timely manner will be evaluated to determine whether the SFI is a FCOI. The [SFI review process](#) will be completed within 60 days of when the previously undisclosed SFI is discovered. Depending on the nature of the potential FCOI, the university may determine that additional interim measures are necessary with regard to the investigator's participation in the funded research between the date that the potential FCOI is determined and the completion of the evaluation process and possible retrospective review (as described below). If the FCOI committee determines an investigator's FCOI may have biased the design, conduct, or reporting of the funded research, the university will promptly notify the PHS awarding component of the corrective action taken or to be taken.

If a FCOI is identified during the above review process or an investigator is found to be noncompliant with a prescribed FCOI Management Plan for an ongoing sponsored research project, within 120 days of the determination, a retrospective review will be completed by the university:

1. The [FCOI committee will be convened](#).
2. The FCOI committee will complete a retrospective review of the investigator's activities and the funded research project to determine whether any funded research, or portion thereof, conducted during the period of the investigator's noncompliance was biased in the design, conduct, or reporting of such research.
3. The committee will document the following information during the retrospective review:
 - a. Project number
 - b. Project title
 - c. Principal investigator (PI)/project director (PD) (or primary PI/PD if multiple PIs/PDs are noted)
 - d. Name of the investigator with the FCOI
 - e. Name of the entity with which the investigator has a FCOI
 - f. Reason(s) for the retrospective review
 - g. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed, etc.)
 - h. Findings of the review (i.e., facts and observations)
 - i. Conclusions of the review (i.e., determination and recommended actions)
4. If bias is found during the retrospective review, the university will promptly notify the PHS awarding component. Additionally, the committee will complete a mitigation report, which will be submitted to the PHS awarding component. The mitigation report will address the following elements:
 - a. Key elements documented during the retrospective review
 - b. Description of the impact of the bias on the research project
 - c. University's plan of action(s) taken to eliminate or mitigate the effect of the bias (i.e., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable)
5. Thereafter, the university will [submit FCOI reports](#) to the PHS awarding component annually.

6. Depending on the nature of the noncompliance, the university may determine that additional interim measures are necessary with regard to the investigator's participation in the funded research between the date that the noncompliance is determined and the completion of the retrospective review.

Investigators have the right to appeal the findings and decisions of the FCOI committee according to the procedures described in the ["Appeals" section of this policy](#).

Additional sanctions will apply to violations of the policy by investigators conducting clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment. Such investigators who have an FCOI that was not managed or reported in a timely manner according to the guidelines of this policy will be required to disclose the FCOI in each public presentation of the research results. For previously published presentations, investigators will be required to request an addendum to disclose the FCOI.

If noncompliance with this policy (including but not limited to failure to disclose SFIs and failure to adhere to a FCOI Management Plan) is determined, then an investigator may be required to complete additional training, research funding can be withheld, and/or other appropriate enforcement mechanisms (including suspension/termination of employment) can be recommended to the appropriate university administrator. Per Section B: Code of Ethics in the [UW-L Employee Handbook](#), "Employees have responsibilities under the Wisconsin Code of Ethics and UW System Chapter 8 Unclassified Staff Code of Ethics. [...] Violation of any provision under the Code of Ethics could result in disciplinary action, up to and including termination." Additionally, an investigator may be subject to sanctions and penalties imposed or directed by the PHS awarding component in accordance with its FCOI regulation (42 CFR Part 50 Subpart F), [Grants Policy Statement](#) (GPS 10-1-2011, Chapter 8.5 Special Award Conditions and Enforcement Actions), and other applicable federal regulations (e.g., 45 CFR parts 74.61, 74.62, and 92.43). Depending on the severity and duration of the noncompliance, in addition to actions taken by the university, the PHS awarding component may take actions including but not limited to the following: imposing special conditions on a grant to allow the investigator to take corrective action, action to wholly or partly suspend the grant pending corrective action, or termination of the grant.

Appeals

If the investigator is dissatisfied with the outcomes of a prescribed FCOI Management Plan, retrospective review findings, or prescribed mitigation report, within 30 days, the investigator may make a written appeal to the Chancellor, also directing a copy of the appeal to the Associate Vice Chancellor for Academic Affairs. The Chancellor will consult with the investigator and the FCOI committee as deemed necessary and appropriate to the particular circumstances. The decision of the Chancellor upon appeal shall be final.

Maintenance of Records

The Office of Research & Sponsored Programs shall maintain all FCOI-related records as follows:

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1. Grants or cooperative agreements – for four years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR 74.53(b) and 92.42(b) for different situations
2. Research contracts – for four years after final payment or, where applicable, for other time periods specified in 48 CFR Part 4, subpart 4.7

Public Access to Records

The Office of Research & Sponsored Programs shall maintain records pertaining to each financial disclosure in accordance with the requirements of the Wisconsin Open Records Law, State Statutes 19.31 through 19.39. In accordance with PHS FCOI regulations, information concerning identified significant financial interests (SFIs) held by investigators will be publicly accessible via written request if the interests meet all of the following criteria:

1. The SFI was disclosed and is still held by the investigator for the PHS-funded research project identified by UW-L in the grant application, progress report, or any other required report submitted to the PHS awarding component.
2. UW-L determines that the SFI is related to the funded research.
3. UW-L determines that the SFI is a financial conflict of interest.

To obtain information concerning a SFI that meets all of the above criteria, a written request should be submitted to the UW-L Assistant to the Vice Chancellor for Administration and Finance; the information will be made available within five business days of such a request and will include the following information:

1. Investigator's name
2. Investigator's title and role with respect to the research project
3. Name of the entity in which the SFI is held
4. Nature of the SFI
5. Approximate dollar value of the SFI (with the exception of interests whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value)

In the case of subrecipient investigators (e.g., subcontractors, consultants) who are required to comply with the subrecipient institution's FCOI policy, the subrecipient institution will be responsible for making SFI information for its affiliated investigators publicly available in accordance with the PHS FCOI regulation. If subrecipient investigators are required to comply with UW-L's FCOI policy, identified SFI information is subject to UW-L's policy on public accessibility. Information described above will remain publicly available for three years from the date the information was most recently updated.