

## Financial Conflict of Interest (FCOI) Policy: Federal Sponsored Projects (non-PHS)

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### *Purpose*

This policy describes procedures and guidelines to be followed in identifying and resolving actual and potential grant applicants' conflicts of financial interests pertaining to grants and sponsored research projects funded by federal agencies, such as the National Science Foundation and the U.S. Department of Education. **Investigators applying to or conducting research sponsored by the Public Health Service (PHS) or PHS awarding component (e.g., National Institutes of Health) should refer to the [FCOI policy specific to that agency](#).** UW-La Crosse benefits from faculty and staff participation in grants and sponsored research projects. The University has no interest in setting forth detailed rules that may interfere with faculty and staff outside interests. However, full-time and part-time faculty must ensure that their outside financial interests, and participation in outside activities, do not conflict or interfere with their obligations to the university or funding agencies.

This policy specifically addresses financial conflicts of interest (FCOIs), situations in which grant applicants may have the opportunity to influence the university's business decisions in ways that could lead to personal gain or give improper advantage to themselves, co-applicants (anyone involved in the design, conduct and reporting of the research results), or their immediate family. Such conflicts could affect the design, conduct or reporting of research results.

### *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 the design, conduct, or reporting of funded research
2. Immediate family
  - a. Federal 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.

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3. Investigator
- a. Principal investigators and co-principal investigators responsible for the design, conduct, or reporting of sponsored research
  - b. PIs and co-PIs are responsible for screening other participants in sponsored research projects to ensure they have no potential significant financial interest (SFI) to report. If an individual has a SFI to report, PIs/co-PIs should direct them to fill out a SFI Disclosure form and route the form to the Office of Research & Sponsored Programs for review.
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. 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:

| <b>Type of entity</b>      | <b>Type of financial interest</b>   | <b>Value</b>  |
|----------------------------|---|---|
| Publicly traded entity     | Any remuneration, including but not limited to: <ul style="list-style-type: none"> <li>• Salary or other payments for services (e.g., consulting fees, honoraria, paid authorship)</li> </ul> | Totaling \$5,000 or more in the preceding twelve months alone or in aggregate with equity interests in the 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 the same entity |
| Non-publicly traded entity | Any remuneration, including but not limited to: <ul style="list-style-type: none"> <li>• Salary or other payments for services (e.g., consulting fees, honoraria, paid authorship)</li> </ul> | 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  |

- 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. Income from seminars, lectures, or teaching engagements sponsored by public or non-profit entities
- iv. Income from service on advisory committees or review panels for public or non-profit entities

### *Significant Financial Interest Disclosure*

An investigator is responsible for disclosing all of their significant financial interests (and those of their immediate family) 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 (SFIs) 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 associated with SFI
  - b. Type of activity (e.g., consulting, teaching, etc.)
  - c. Amount or estimated value
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

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 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)

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 their 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 and FCOI Management Plan development and approval 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.

### *Compliance and Monitoring*

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.

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.

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 funding agency 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 and document 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. If bias is found during the retrospective review, the university will promptly notify the funding agency. Additionally, the committee will complete a mitigation report.
4. 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](#).

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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 funding agency and other applicable federal regulations. Actions taken by a funding agency may include but are 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:

1. Grants or cooperative agreements – for four years from the date of submission of the final expenditures report
2. Research contracts – for four years after final payment

The Office of Research & Sponsored Programs shall maintain records pertaining to each disclosure in accordance with the requirements of the Wisconsin Open Records Law, State Statutes 19.31 through 19.39. Certain sponsors may have requirements that differ from this policy with regard to the timing and frequency of disclosures and other conflict considerations. In the case of such discrepancies, the sponsor's requirements will generally prevail.