

# University of Wisconsin Oshkosh Office of Sponsored Programs

<b>Financial Conflict of Interest in Federal Research</b>	
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## Financial Conflict of Interest in Federal Research

### 1. PURPOSE:

Consistent with federal regulations for grants (42 CFR Part 50, Subpart F) and contracts (45 CFR Part 94), the financial conflict of interest regulations were established to promote objectivity in research for which Public Health Service (PHS) funding is sought and to promote responsible prospective contractors. The regulations establish standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under PHS grants or contracts will be free from bias resulting from Investigator financial conflict of interest. In addition, some non-federal sponsors also require disclosure of financial interests as a condition of the award. The University of Wisconsin Oshkosh is committed to ensuring the public's trust that sponsored research is conducted with the highest scientific and ethical standards.

This financial conflict of interest policy at University of Wisconsin Oshkosh is applied to all Investigators who have research funded under federal grants or contracts or applicants seeking federal funding. In addition, this policy will apply when a non-federal sponsor requires compliance with the financial conflict of interest regulations as a term and condition of the award. This policy is developed on the expectation that Investigators should conduct their affairs to avoid or minimize conflicts of interest when possible, and explains the process for notifying the Institution if a conflict would arise.

The Institutional Official for Research (Provost/Vice Chancellor) is responsible for ensuring implementation of this policy administered by the Office of Sponsored Programs.

### 2. DEFINITIONS:

UW Oshkosh has adopted the following PHS regulatory definitions (42 CFR Part 50):

**Institution**: any domestic or foreign, public or private, entity or organization that applies for or that receives federal funding by means of a grant or cooperative agreement

**Research**: any systematic investigation, study, or experiment designed to contribute to generalizable knowledge

**Investigator**: the Project Director or Principal Investigator and any other key personnel, regardless of title or position, who are responsible for the design, conduct, or reporting of a research project that is federally funded or proposed for such funding

**Subrecipient Investigator:** any individual who will perform a portion of the scope of work or objectives of the project (e.g. subgrantee, subcontractor, or collaborator) whose primary affiliation is with an entity other than the lead Institution

**Institutional Official:** the individual within the Institution who is responsible for the solicitation and review of disclosures of significant financial interests related to the Investigator's institutional responsibilities.

**Entity:** *Entity* means any domestic or foreign, public or private, organization (excluding a Federal agency) from which an Investigator (and spouse and dependent children) receives remuneration or in which any person has an ownership or equity interest.

**Financial Interest:** anything of monetary value received or held by an Investigator or an Investigator's immediate family (spouse and dependent children), whether or not the value is readily ascertainable, including, but not limited to:

- a. salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works)
- b. any equity interests (e.g., stocks, stock options, or other ownership interests)
- c. 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

**Significant Financial Interest (SFI):** a financial interest consisting of one or more of the following interests of the Investigator and/or their immediate family (spouse and dependent children) that reasonably appears to be related to the Investigator's Institutional responsibilities:

- For a publicly traded entity:
  - Any equity interest (stock, stock options or other ownership interest) valued at \$5,000 or more in a single entity
  - Remuneration valued at \$5,000 or more from the same entity in the last 12 months; or
  - A combination of remuneration and equity interest that is valued at \$5,000 or more when aggregated
    - For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, paid authorship, and honoraria). Equity interest includes any stock, stock options, or other ownership interests, as determined through reference to public prices or other reasonable measures of fair market value.
- For a non-publicly traded entity:
  - Remuneration valued at \$5,000 or more from the same entity in the last 12 months; or
  - Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest).

- Intellectual property rights and interests (e.g., patents, copyrights)
  - Upon receipt of income related to such rights and interests
- Travel
  - Investigators must disclose the occurrence of any reimbursed or sponsored travel related to their institutional responsibilities.
    - This disclosure requirement does not apply to travel that is reimbursed or sponsored by excluded sources. Excluded sources include: U.S. federal, state, or local government agencies, U.S. institutions of higher education, academic teaching hospitals, and medical centers, or research institutes affiliated with institutions of higher education
  - If the aggregate value of any sponsored or reimbursed travel by a single entity exceeds \$5000, the following must be reported for PHS funded activities:
    - Purpose of the trip
    - Identity of the sponsor
    - Destination and duration of the trip
    - Total monetary value of the trip

**Significant Financial Interests Exclusions:**

- Salary royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution
- 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 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
- Income from service on advisory committees or review panels for a federal, state, or local government agency, Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

**For additional guidance on reporting, see [Table 1: Reportable and Non-Reportable Financial Activities](#)**

**Financial Conflict of Interest (FCOI):** a Significant Financial Interest (SFI) that could directly and significantly affect the design, conduct, or reporting of the federally-funded research

**Investigator’s Institutional Responsibilities:** an Investigator’s professional responsibilities on behalf of the institution, which may include activities in teaching, research or research consultation, professional practice, institutional committee/board memberships

**Manage:** taking action to address a financial conflict of interest (FCOI), which can include reducing or eliminating the FCOI, to ensure, to the extent possible, that the design, conduct, and reporting of the research will be free from bias.

### **3. PROCEDURE FOR DISCLOSURE:**

When submitting an application to the Office of Sponsored Programs for federal grant or contracts, any individual meeting the federal definition of Investigator (as defined above in Section 2) and their immediate family members must disclose any Significant Financial Interests (SFIs). SFIs include financial interests that are related to an Investigator's institutional responsibilities. Please note, some non-federal sponsors also require financial disclosure.

#### **Financial Disclosure Form:**

A [Financial Disclosure Form](#) is used to disclose Significant Financial Interests and must be filled out as described below:

- a. Application Disclosure: At the time of submission of application materials for federal grants or contracts, a Financial Disclosure Form must be submitted with the Internal Review Form.
- b. Annual Disclosure: Investigators with federal funding must update their Financial Disclosure Form on an annual basis. The reporting period for the annual disclosure will be based on the calendar year and will coincide with the UW System Board of Regents Outside Activities Report.
- c. Ad hoc Disclosure: In addition to annual disclosure, certain situations require ad hoc disclosure. All investigators, to whom this policy applies, must submit to the Institution an ad hoc disclosure within 30 days of discovering or acquiring any new OR additional Significant Financial Interest.

#### **Treatment of Subrecipients or Subcontractors:**

When UW Oshkosh carries out a federally funded grant or contract through subrecipients or subcontractors, UW Oshkosh must take reasonable steps to ensure that the subrecipient or subcontractor investigator is in compliance with federal regulations relating to financial conflicts of interest. UW Oshkosh fulfills this requirement by setting forth the obligations of each party with respect to conflict of interest management and reporting in the agreement between the parties. If the subrecipient or subcontractor does not have a policy compliant with the financial conflict of interest regulations, UW Oshkosh Financial Conflict of Interest Policy will be followed.

### **4. PROCEDURE FOR EVALUATION:**

#### **Evaluation of the Financial Disclosure Forms**

The Financial Disclosure Forms are reviewed by the Institutional Official for Research, or their designee, who determines whether the investigator holds any significant financial interests related to their institutional responsibilities in which a potential conflict of interest may exist. If a potential financial conflict of interest is determined, the Institutional Official will appoint an ad hoc Research Responsibility Committee to review the case and decide if the conflict is manageable. Membership of the ad hoc Research Responsibility Committee will consist of the following expertise: (1) IRB member, (1) IACUC

member, (1) Faculty member from discloser's department, and (1) Faculty member that has no connection to the research proposed. See **Table 2. Financial Conflict of Interest Process**

a. **No Significant Financial Interests Procedure:**

1. No further action is needed.
2. The proposal is submitted to the federal funding agency.
3. Award is accepted.
4. At the time of award acceptance, a meeting is set up with the Principal Investigator, Pre-Award Staff Member, and the Grant Accountant in charge of the award.
5. An account is set up for the award.

b. **Significant Financial Interests Procedure:**

1. Proposal is submitted to the federal funding agency.
2. The Research Responsibility Committee reviews Financial Disclosure Forms and determines if the potential conflict of interest can be managed.

a. ***Committee Determines Conflict is Manageable Through A FCOI Management Plan***

1. **FCOI Management Plan** is prepared to manage, reduce, or eliminate the conflict of interest. The Institutional Official must approve the FCOI Management Plan and the Investigator must agree to the terms of the plan before any related research goes forward. For complex situations, the Research Responsibility Committee may periodically review the ongoing activity to ensure compliance with the management plan.
2. Award is accepted.
3. At the time of award acceptance, a start-up meeting is scheduled with the Principal Investigator, Pre-Award Staff Member, and the Grant Accountant in charge of the award.
5. An account is established for the award once the COI case is cleared by the Research Responsibility Committee.

b. ***Committee Determines Conflict is Unmanageable***

1. Institutional Official is notified.
2. Funding agency is notified (if required by the agency).
3. Award is not accepted.

## 5. INSTITUTIONAL RESPONSIBILITIES:

### **UW Oshkosh Responsibilities:**

- a. Take necessary actions to manage FCOIs of Investigators.
- b. Develop management plans to monitor compliance.
- c. If a significant financial interest is identified that was not disclosed or reviewed in a timely manner, the Institutional Official for Research or their designee shall review the SFI within sixty (60) days and determine if a FCOI exists. If a FCOI exists, the Institution must report it to the funding agency if required and implement an interim management plan if needed.

- d. In cases of non-compliance, the Institutional Official for Research will follow reporting requirements in accordance with the funding agency. The Institutional Official for Research may suspend all relevant activities or take other disciplinary action until the matter is resolved or other action deemed appropriate is implemented.
  1. If disciplinary action is taken, a written explanation by the Institutional Official for Research will be described in a letter to the Investigator and the Research Responsibility Committee. The Institutional Official for Research will notify the Investigator of the right to appeal the decision.
  2. The Research Responsibility Committee will complete a Retrospective Review to determine if the research conducted during the period of non-compliance was biased in the design, conduct, or reporting of the research.
    - a. If bias is determined during the Retrospective Review, the Institutional Official for Research will create an action plan and update any reports as required by the funding agency. PHS agencies require submission of a Mitigation Report in eRA Commons FCOI Module if bias is found.

## **6. TRAINING:**

### **Financial Conflict of Interest Training Requirements:**

- a. Each Investigator must complete training prior to engaging in research related to any federally funded grant. The training course ***Conflicts of Interest*** is provided through [CITI Program](#) which includes a module with UW Oshkosh specific guidelines.
- b. A refresher training course through CITI Program must be completed at least every 4 years.
- c. Training must occur immediately under the following circumstances:
  1. Institutional FCOI policies change in a manner that affects Investigator requirements.
  2. An institution finds an Investigator noncompliant with Institution's FCOI policy or FCOI Management Plan.

## **7. RECORD RETENTION:**

The Institutional Official for Research has designated the Office of Sponsored Programs to retain all disclosure forms, conflict management plans, and related documents for a period of seven years from the date of the final closure report.

## **8. CONFIDENTIALITY:**

To the extent permitted by the law, all disclosure forms, conflict management plans, and related information will be confidential. However, the Institution may make such information available to an agency funding research of the faculty or staff member or to a requestor within five business days of information concerning financial conflict of interest related to the funding. 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 the disclosure.

**Table 1. Reportable and Non-Reportable Financial Activities\***

(\*Table adapted for UW Oshkosh use with permission from UW-Madison FCOI Policy)

<b>Remunerative Relationships/Compensation</b>	
<b>Reportable</b>	<b>Non-Reportable</b>
<ul style="list-style-type: none"> <li>• Salary, unless it falls into one of the non-reportable categories</li> <li>• Spousal salary, if your spouse is employed in a field related to your institutional responsibilities</li> <li>• Consulting fees</li> <li>• Gifts or other awards, including gifts-in-kind, honoraria, and participation in promotional activities</li> <li>• Teaching services to another entity, unless it falls into one of the non-reportable categories</li> <li>• Income from editorial work (e.g., journal editorial work or editing compilations of scholarly papers)</li> <li>• Payments that are connected to research, but are not governed by a research agreement between the sponsor and UW Oshkosh</li> <li>• Payments for serving on advisory boards</li> <li>• Royalty and copyright income not managed by WISYS</li> <li>• Income from activities sponsored by a foreign institution of higher education or a foreign governmental body</li> <li>• Travel reimbursements from businesses that exceed your actual travel costs</li> </ul>	<ul style="list-style-type: none"> <li>• Compensation from activities NOT related to your institutional responsibilities at UW Oshkosh</li> <li>• Salary or other compensation from UW Oshkosh</li> <li>• Royalty income from intellectual property that arose from University employment and that was assigned to WISYS to manage intellectual property on behalf of UW Oshkosh</li> <li>• Payments from grant or gift agreements between the sponsor and UW Oshkosh</li> </ul>
<b>Equity/Ownership Interests</b>	
<b>Reportable</b>	<b>Non-Reportable</b>
<ul style="list-style-type: none"> <li>• Stock</li> <li>• Stock options</li> <li>• Sole proprietorships</li> <li>• Partnerships</li> <li>• Limited liability corporations</li> <li>• Salary, unless it falls into one of the non-reportable categories</li> </ul>	<ul style="list-style-type: none"> <li>• Income from investment vehicles, such as mutual funds and retirement funds, is NOT reportable as long as you, your spouse, or dependent children do not directly control the vehicles' or funds' investment decisions</li> <li>• Interests in businesses or organizations that are unrelated to your institutional responsibilities</li> </ul>

<b>Leadership Positions (Directors, Trustee, Officers)</b>	
<b>Reportable</b>	<b>Non-Reportable</b>
<ul style="list-style-type: none"> <li>• Service in positions with fiduciary responsibility, including executive positions, senior management positions, or membership on boards of directors.</li> </ul>	<ul style="list-style-type: none"> <li>• Leadership positions that do not relate to your institutional responsibilities, or that do not have fiduciary responsibilities.</li> </ul>
<b>Travel</b>	
<b>Reportable</b>	<b>Non-Reportable</b>
<ul style="list-style-type: none"> <li>• Corporate-sponsored travel</li> <li>• Compensated vacation travel</li> <li>• Participation in a conference for a professional society</li> <li>• Travel sponsored by foreign institutes of higher education or foreign governmental agencies</li> </ul>	<ul style="list-style-type: none"> <li>• Self-funded travel</li> <li>• Travel covered through University of Wisconsin Oshkosh e-Reimbursement system</li> <li>• Travel funded through the University of Wisconsin–Oshkosh</li> <li>• Travel reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education (defined at <a href="#">20 USC 1001(a)</a>), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education (the exception described here applies only to U.S.-based institutions and agencies)</li> <li>• Travel reimbursed or sponsored by the National Research Commission or the related National Academies</li> </ul>

**Table 2.** Financial Conflict of Interest Process

## Financial Conflict of Interest Process

Each individual meeting the federal definition of Investigator (PI, Co-PI, Key Personnel) completes and signs a Financial Disclosure Form: 1) at the time of proposal submission with the Internal Review Form, 2) annually if funded, and 3) ad hoc within 30 days of acquiring new significant financial interest.

