

Symposium for Research Administrators

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UW Conflict of Interest & Conflict of Commitment for Research Administrators

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Forward

- Generating new knowledge through research and translating that knowledge into applications that benefit society are important aspects of the mission of UW–Madison.
- The University encourages its faculty and staff to engage in research, to share their knowledge, and to promote the application of research results.
- Since these activities may result in financial gain to investigators, the UW-Madison, as a steward of public funds and the public trust, has the responsibility to identify those interactions that create potential conflicts of interest, and to manage those conflicts in a way that ensures the integrity of UW-Madison's core activities and values.



Forward

Wisconsin Administrative Code, Chapter <u>UWS 8</u>

In view of the special relationship of the University of Wisconsin System to the state and to affirm as public policy within the system certain common standards to prevent conflicts of interest, the board hereby adopts the following code of ethics for unclassified staff pursuant to ss. 19.45 (11) (b) and 36.23, Stats.



NIH's Financial Conflict of Interest

- A potential financial conflict of interest exists when an investigator has significant financial interests that could lead an independent observer to reasonably question whether the design, conduct, or reporting of research might be influenced by the possibility of personal gain to the individual or to his or her immediate family.
- Others define conflict of interest situations in terms of obligations. Two activities may interact such that judgment in one activity may be, or may seem to be, influenced by the other activity.

Goal for today's session

- UW's Policies for Conflict of Interest & Conflict of Commitment
- UW's requirements & processes for ensuring the polices are followed
- What you can do as Research Administrators can to do help ensure researchers are in compliance



What is a Conflict of Interest



- Represent a state of affairs, not behavior,
- Frequently involve perceptions, and
- Are judged by others, not by those directly involved

State law/rules

- No use of UW position or resources in a manner conflicting with UW's interests to gain anything of substantial private benefit of UW employee, their family, or an organization with which they are associated
- No taking bribes
- No divulging confidential UW information for private gain
- No entering into contracts involving \$3000 or more over a 12 month period if in a posititon to approve or influence UW decision to enter into contract
- No nepotism



Wis. Stat. 946.13

- Applies when UW employee has a private interest in a contract between the university and an outside entity
- Can apply to sponsored research and fee for service agreements, outgoing subawards and subcontracts, and purchases
- If the contract is between a research company and UW, requires evaluation of the conflict and that a specific management plan is issued and followed (if conflict is manageable)
- If not with a research company, may need Attorney General's approval



UW's Research Conflict of Interest Policy

- To ensure that research is not biased in its design, conduct or reporting, and to ensure especially the protection of human subjects
- Requires disclosure and review of certain outside activities
- If appropriate, manage and report significant financial interests that might present a real or perceived conflict of interests with institutional responsibilities to appear to directly and significantly compromise the integrity of research

Policy definitions to know

- Financial conflict of interest (FCOI): A significant financial interest that could directly and significant affect the design, conduct, or reporting of federally funded research or research involving human subjects.
- Institutional responsibilities: An individual's professional responsibilities on behalf of UW–Madison, including research, research consultation, instruction, professional practice, extension/outreach, administrative activities, and institutional committee memberships.
- Manage: Take action to address a conflict of interest, which can include reducing or eliminating the conflict of interest, to ensure to the extent possible that the design, conduct, and reporting of research will be free from bias.



Policy definitions to know

- Significant financial interest (SFI): Any financial interest held by an individual (and/or their immediate family), or by a business entity controlled or directed by the individual or a member of their immediate family, that has monetary value, whether or not the value is readily ascertainable
- **Human subject:** A living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information.
- Immediate family: An individual's spouse and dependent children.

Training

Training on conflict of interest regulations, UW policies and guidelines every 4 years

Disclosure

- Report all significant financial interests held by individual or their immediate families that is related to the individual's institutional responsibilities
- SFI's are report on the Outside Activities Report annual and updated with 30 days of acquiring a new SFI
- PIs conducting human subject research must submit information to IRBs
- Federally funded individuals must disclose travel reimbursement or sponsored by outside organization



- Review and management of relationships with external entities
 - COI Office & COI Committee (faculty committee with admin. & division reps)
 - Determines SFI exists & nexus between research & SFI, management plan assigned
- Data Analysis and Publication
 - Entity cannot limit the rights of an individual to receive, analyze or interpret any data generated as part of a research project or restrict publication of research results
- Employees & Students
 - SFI cannot place restrictions on the activities of employees and students
 - Required disclosure to employees and students who are under their supervision of any financial interests which the individual has in the research activity



- Payments from Entities
 - Prohibits payments to individuals from university accounts or directly or indirectly from business entities for particular research results or for research outcomes related to human subject protocols conducted at or through UW–Madison
- Public Accessibility
 - Certain information about identified conflicts of interest of investigators who are named as senior/key personnel on research funded by the Public Health Service must be made available to the public
- Reports to Funding Agencies
 - UW has to provide reports on FCOI to PHS
- Appealing COI Committee Decisions
 - Individual who was assigned a management plan, has 20 business days to request a reconsideration through the COI Committee



Ongoing Monitoring

UW monitors compliance with management plans through the year

Noncompliance

 Deliberate misrepresentation of information to the COI Committee or an IRB or failure to comply with the terms of this policy or a management plan may result in sanctions including disciplinary actions up to and including termination and/or loss of privilege to serve as an investigator on federally funded research projects or human subjects research protocols

Record Retention

 UW is required to maintain records of all financial disclosures and all actions taken covered by the COI Policy at least for three years



COMPENSATION

REPORTABLE OUTSIDE FINANCIAL ACTIVITIES

Reportable compensation is any compensation given directly to you, your spouse, or your dependent children. However, it does not include money that is given through the University.

Some examples of reportable compensation include:

- Salary, unless it falls into one of the non-reportable categories
- Spousal salary, if your spouse is employed in a field related to your institutional responsibilities
- Consulting fees
- Gifts or other awards, including gifts-in-kind, honoraria, and participation in promotional activities
- Income from editorial work (e.g., journal editorships).
- Payments connected to research, but not governed by a research agreement between the sponsor and UW-Madison or the UW Medical Foundation.
- Payments for serving on advisory boards
- Royalty and copyright income not managed by the Wisconsin Alumni Research Foundation (WARF) or Wisconsin Center for Educational Products & Services (WCEPS).
- Income from activities sponsored by a foreign institution of higher education or foreign governmental body
- Travel reimbursements from businesses that exceed your actual travel costs

NON-REPORTABLE OUTSIDE FINANCIAL ACTIVITIES

- Compensation from activities not related to your institutional responsibilities at UW-Madison
- Previous employment for individuals who do not participate in the design, conduct, or reporting of federally funded or human subjects research at UW-Madison
- Salary or other compensation from UW-Madison and affiliated entities (e.g., UW Hospital and Clinics, the VA Hospital, the UW Medical Foundation, and the Center for Advanced Studies in Business)
- Royalty income from intellectual property that arose from University employment and that was assigned to organizations that were created to manage intellectual property on behalf of UW-Madison (e.g., WARF, WCEPS)
- Payments under grant or gift agreements between the sponsor and the UW-Madison or the UW Foundation



OWNERSHIP

REPORTABLE OUTSIDE FINANCIAL ACTIVITIES

- Stock
- Stock options
- Sole proprietorships
- Partnerships
- Limited liability corporations

NON-REPORTABLE OUTSIDE FINANCIAL ACTIVITIES

- Ownership interests NOT related to your institutional responsibilities
- 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 vehicle or fund's investment decisions
- Interests in businesses or organizations that are unrelated to your institutional responsibilities

LEADERSHIP

REPORTABLE OUTSIDE FINANCIAL ACTIVITIES

Service in positions with fiduciary responsibility, which includes:

- Executive positions, such as president, CEO, CIO, etc.
- Senior management positions, such as president, treasurer, etc.
- · Service on boards of directors
- Trusteeships
- · Professional societies

NON-REPORTABLE OUTSIDE FINANCIAL ACTIVITIES

Non-reportable leadership positions do not relate to your institutional responsibilities or do not have fiduciary responsibilities. They commonly include religious organizations and political organizations.



FOREIGN ACADEMIC APPOINTMENTS

REPORTABLE OUTSIDE ACTIVITIES

All academic appointments with foreign entities, paid or unpaid.

FOREIGN RESEARCH SUPPORT

REPORTABLE OUTSIDE FINANCIAL ACTIVITIES

Investigators with relationships with foreign entities must report *all* resources made available to them in support of their research endeavors including but not limited to:

- Grants
- Contracts
- · Unrestricted gifts
- · Materials and equipment
- · Laboratory space or personnel

NON-REPORTABLE OUTSIDE FINANCIAL ACTIVITIES

Research support managed or expended through the University of Wisconsin–Madison does not need to be reported.

TRAVEL (RESEARCHERS WITH FEDERAL GRANTS)

REPORTABLE OUTSIDE FINANCIAL ACTIVITIES

Investigators with federally funded research must report travel events, such as:

- · Corporate-sponsored travel
- · Compensated vacation travel
- · Participation in a conference for a professional society
- Travel sponsored by foreign institutes of higher education or foreign governmental agencies

NON-REPORTABLE OUTSIDE FINANCIAL ACTIVITIES

For investigators with federally funded research, the following types of travel need not be reported:

- Self-funded travel
- Travel covered through University of Wisconsin-Madison e-Reimbursement system
- Travel funded through the University of Wisconsin-Madison
- Travel reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education [defined at 20 USC 1001(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).
- Travel reimbursed or sponsored by the National Research Commission or the related National Academies



What is a significant financial interest (SFI)

- Publicly traded entities
 - Value of remuneration and with the value of any equity interest in the entity >\$5,000
- Non-publicly traded entities:
 - Value of remuneration >\$5,000

OR

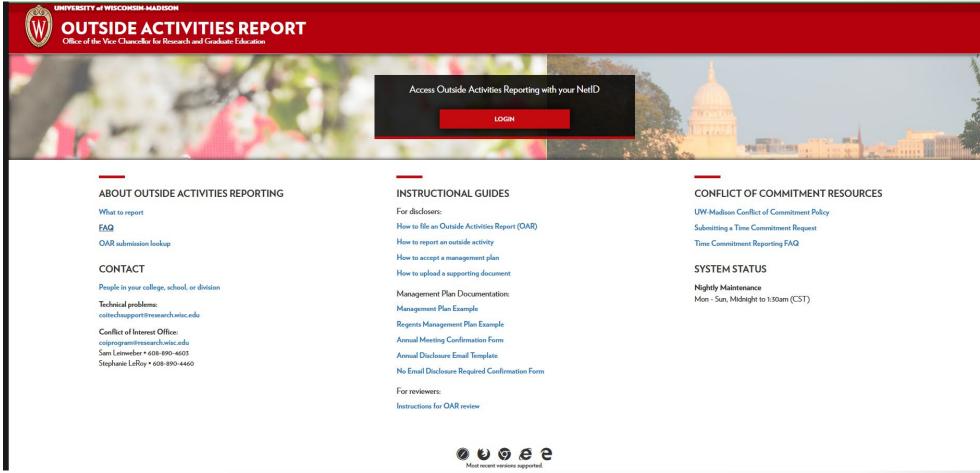
- Holds any equity interest in the entity
- Income from IP rights not assigned to WARF
- Services in positions with fiduciary responsibility



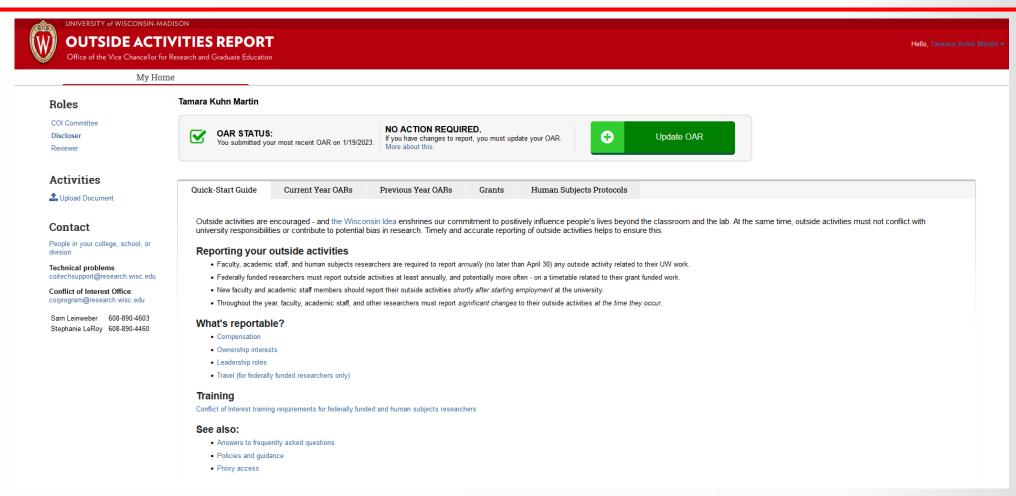
Who completes an Outside Activities Reporting (OAR)

- Chapter 8 of UWS Board requires all faculty, academic staff with a 50% or greater appointment to annually file
- Individuals with active management plans from the COI Committee must file annually
- PHS requires any individuals listed on a human subjects protocols or federal grants

Where to Report: Outside Activities Reporting (OAR)



Where to Report: Outside Activities Reporting (OAR)



Management Plan – Example

- Publications and Presentations
- Interactions with Student and Staff
- Contracts between University and Entity
- Purchasing
- Use of University Facilities and Services
- Human Subjects Research
- Payments and Incentives
- Reporting of Outside Activities
- Outside Activities Agreement
- Annual Review



COI Lookup Tools

- COI Portal
- Discloser Details
- Entity Relationships
- OAR Submission
- Training Status



What is a Conflict of Commitment

- COC is a type of conflict of interest that may occur when outside professional activities interfere with a university employee's ability to fulfill university expectations, obligations, and responsibilities.
- An activity or financial interest that may align or overlap with the obligations associated with the unclassified staff member's appointment and their expected primary contributions to teaching, research, or other activities that advance the University's interests.

UW's Conflict of Commitment Policy

- Policy applies to all unclassified staff
- All Outside Professional Activities must be disclosed on OAR
- Shall not engage in Outside Professional Activities that create a conflict of commitment
- Ordinary Institutional Activities, are encouraged by UW and do not count toward the allowable time limits for outside activities, but unclassified staff member must make sure they do not negatively impact primary responsibilities to UW
- Time limits
- Annual basis appointments 2 days per month (24 total days)
- Academic year appointments 2 days per month (18 total days)
- What about summertime It depends!



What are Outside Professional Activities

- Responsibilities of employment at UW that they participate in outside of the scope of their university employment
- Reportable on Outside Activities Report (paid or unpaid)
- Examples
 - Teaching, research or administrative activities under an agreement at an institution, organization government agency foundation or any other entity outside of UW
 - Employment outside of UW with duties related to UW responsibilities
 - Having a role in founding a company or in their ongoing operation
 - Consulting services outside of UW
 - Leadership role for entity outside of UW
 - Scientific advisory board for a company
 - Serving as an expert witness
 - Present at a symposium or workshop on behalf of a company



What are Ordinary Institutional Activities

- Activities which extend institutional responsibilities of teaching, research or service to other public institutions, organizations and professional societies.
- Examples:
- Occasional lectures, colloquia, seminars, etc., given at colleges and universities and at meetings of professional societies.
- Evaluation of colleagues at other colleges and universities through participation in program evaluations and tenure and promotion reviews.
- Preparation of monographs, chapters, and editorial services for nonprofit educational organizations.
- Service on review panels for the federal government.
- Service on advisory committees and evaluation panels for nonprofit foundations and educational organizations.
- Leadership positions in professional or scholarly societies.



How are more days approved?

- Advance approval from department chair and dean's office for exceeding time limit allowed under the policy though the OAR system
- Dean's offices are required to response to requests within 15 calendar days
 - Determined no material conflict and activity can proceed (approved)
 - Further information is needed before a determination can be made
 - There is a conflict which must be resolved either by change in university duties or the Outside Professional Activities

Resources

- Outside Activities Report https://oar.wisc.edu/
- Conflict of Interest Policy https://policy.wisc.edu/library/UW-4001
- Conflict of Commitment Policy https://policy.wisc.edu/library/UW-1075
- COI Portal https://compliance.research.wisc.edu/COI



Closing thoughts and questions

