

# Research and Other Sponsored Programs Conflict of Interest Guidance Document

## CONTENTS

PURPOSE.....	3
INTRODUCTION.....	3
OUTSIDE ACTIVITIES REPORT (OAR).....	3
Who Needs to File an Outside Activities Report.....	3
What to Report on an OAR.....	4
When to File OARs and Make Updates.....	6
How to File an OAR.....	6
Annual OAR.....	6
OAR Update.....	6
Division and/or School/College Approval of OAR.....	6
OAR Approval.....	6
RCOI Committee Review of OAR Reports Relating to Research.....	6
MANAGEMENT PLANS.....	7
Who Needs to Have a Management Plan.....	7
What is a Management Plan.....	7
When is a Management Plan Necessary.....	7
How to Complete a Management Plan and Remain in Compliance.....	7
Requesting an Exception to the Restriction on Participation in Human Subjects Research.....	7
Appealing a Management Plan.....	8
Terminating a Management Plan.....	8
ADDITIONAL REQUIREMENTS FOR INVESTIGATORS INVOLVED IN PHS-FUNDED RESEARCH.....	8
Definitions.....	8
FCOI Training.....	9
Who Needs to Complete FCOI Training.....	9
What Needs to be Completed.....	9
When FCOI Training Must Be Completed.....	9
How to Complete FCOI Training.....	9
Significant Financial Interest Disclosure.....	9
Who Needs to Fill Out an SFID.....	9
What Needs to Be Reported on an SFID.....	9
When Does an SFID Need to Be Completed.....	10
How to Complete an SFID.....	10

SFID Approval .....	11
Approver Training.....	11
RCOI Committee Review of SFID.....	11
SFI and Non-Compliance Reporting to PHS.....	11
INSTITUTIONAL CONFLICT OF INTEREST COMPLIANCE .....	12
Research Conflict of Interest Committee .....	12
Appointments.....	12
Membership.....	12
Meetings .....	12
Responsibilities .....	12
Office of Sponsored Programs.....	12
Personnel .....	12
Responsibilities .....	13
REFERENCES.....	13
EXHIBIT A: TEMPLATE MANAGEMENT PLAN .....	14

## **PURPOSE**

The purpose of this document is to clarify sections of UWM's two policies related to conflict of interest, the Conflict of Interest (COI) Policy for Individuals Engaged in Research and Other Sponsored Programs, SAAP Number 07-18 and the UWM Policy for Financial Conflicts of Interest in Public Health Service-Funded Research, Faculty Document 2879. It is intended as a guide is to identify what Investigators must do to comply with these policies.

## **INTRODUCTION**

UWM has an obligation to manage any conflicts of interest as part of ensuring the integrity of research at the university. Federal regulations, 42 CFR Part 50, Subpart F, and 45 CFR Part 94, University of Wisconsin System Board of Regents policy, and University of Wisconsin System Chapter 8 (UWS8) require disclosure of outside financial interests and inform UWM's COI policies and the operations of the COI program. The federal regulations state that a conflict of interest exists when an Investigator has a significant financial interest (SFI) 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 his or her spouse and/or dependent children. Conflicts of interest therefore require careful oversight from the University.

The Vice Provost for Research is given the responsibility and authority to conduct an ongoing conflict of interest management program for research and other sponsored programs at UWM. In this capacity, the Vice Provost for Research provides leadership support to the Research Conflict of Interest Committee (RCOI Committee) and makes final decisions on conflict management issues. The RCOI Committee reviews all annual Outside Activities Reports involving sponsored programs, evaluates their disclosures, and implements management plans when disclosures reveal significant financial interests related to Investigators' institutional responsibilities regarding research or other sponsored programs.

UWM recognizes that Conflicts of Interest:

1. Represent a state of affairs, not behavior;
2. Frequently involve perceptions; and
3. Are judged by others, not by those directly involved.

This document describes the actions Investigators and UWM are required to take in order to comply with federal, University of Wisconsin system, and UWM COI policies. The UWM COI Program in the Office of Research is responsible for carrying out the COI policies and regulations as they pertain to research and other sponsored programs.

## **OUTSIDE ACTIVITIES REPORT (OAR)**

OAR reporting is broader than just research and sponsored programs, but is also the starting point for the research and other sponsored programs COI procedures. This document includes information that is applicable more broadly than just to Investigators. For information on OAR reporting for the broader UWM community, information is available at the [OAR Toolkit](#) and [OAR FAQ](#) and questions may be directed to [OAR Support](#).

### **Who Needs to File an Outside Activities Report**

The following UWM personnel need to submit an Outside Activities Report:

- All UWM faculty, regardless of appointment level

- All UWM academic staff and limited appointees with total appointments equaling 50% or greater
- All PIs, co-Investigators, and senior/key personnel on current federal grants
- All individuals with an active management plan from the RCOI Committee

Individuals must submit an OAR even if they have no outside financial interests related to their institutional responsibilities at the University.

### **What to Report on an OAR**

Individuals who are subject to UWM COI policies and who are required to file an OAR must report all outside financial interests that are related to their institutional responsibilities. The federal regulations consider "institutional responsibilities" to include all professional responsibilities done on behalf of UWM, including research, research consultation, teaching, professional practice, outreach, administration, and institutional committee memberships.

Individuals should report all outside financial interests that are related to their institutional responsibilities, including those of their spouses and dependent children. Outside financial interests include any activity or relationship that has monetary value, unless the interest is exempt from reporting.

Additionally, regardless of compensation, service in positions with fiduciary responsibilities must be reported. This includes executive positions, senior management positions, or membership on boards of directors.

An individual should report ownership in any privately held entity, including consulting businesses, and the total compensation received from the entity. An individual should also disclose each client of the consulting business separately with the total compensation received from that client if the compensation is greater than \$5,000 in a reporting year.

Examples of Reportable and Non-Reportable Outside Financial Activities:

#### **COMPENSATION**

<b>REPORTABLE</b>	<b>NON-REPORTABLE</b>
Salary, unless it falls into one of the non-reportable categories	Compensation from activities not related to your institutional responsibilities at UW-Milwaukee
Spousal salary, if your spouse is employed in a field related to your institutional responsibilities	Compensation for employment previous to UW-Milwaukee
Consulting fees	Salary or other compensation from UW-Milwaukee
Gifts or other awards, including gifts-in-kind, honoraria, and participation in promotional activities	Royalty income from intellectual property that arose from University employment and that was assigned to UWM Research Foundation
Income from editorial work (e.g. journal editorships)	Payments under grant or gift agreements between the sponsor and UW-Milwaukee or UWM Foundation
Payments connect to research but not governed by a research agreement between the sponsor and UW-Milwaukee	
Payments for service on advisory boards	
Royalty and copyright income not managed by the UWM Research Foundation	

<b>REPORTABLE</b>	<b>NON-REPORTABLE</b>
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	

### **OWNERSHIP**

<b>REPORTABLE</b>	<b>NON-REPORTABLE</b>
Stock	Ownership interests NOT related to your institutional responsibilities
Stock options	Income from investment vehicles such as mutual funds and retirement funds as long as you, your spouse, or dependent children do not directly control the vehicle or fund's investment decisions
Sole proprietorships	Interests in businesses or organizations that are unrelated to your institutional responsibilities
Partnerships	
Limited liability corporations	

### **LEADERSHIP**

<b>REPORTABLE</b>	<b>NON-REPORTABLE</b>
Service in positions with fiduciary responsibilities, which may include: <ul style="list-style-type: none"> <li>• Executive positions such as president, CEO, CIO, etc.</li> <li>• Senior management positions such as president, treasurer, etc.</li> <li>• Service on boards of directors</li> <li>• Trusteeships</li> <li>• Professional societies</li> </ul>	Positions that do not relate to your institutional responsibilities or do not have fiduciary responsibilities, commonly including religious and political organizations

### **FOREIGN SUPPORT AND APPOINTMENTS**

<b>REPORTABLE</b>	<b>NON-REPORTABLE</b>
Investigators with relationships with foreign entities must report resources made available to them in support of their research endeavors but which are not managed or expended through UW-Milwaukee, which may include: <ul style="list-style-type: none"> <li>• Grants</li> <li>• Contracts</li> <li>• Unrestricted gifts</li> <li>• Materials and equipment</li> <li>• Laboratory space or personnel</li> </ul>	Research support managed or expended through UW-Milwaukee
Foreign academic appointments (paid or unpaid)	
Involvement with Foreign talent programs	

## When to File OARs and Make Updates

Annual report: an annual report must be submitted by April 30th. An email with instructions on how to complete the OAR is sent early in the year.

After changes to outside activities occur: An updated OAR must be filed any time there is a relevant change to outside activities. This must be done within 30 days of acquiring a new outside activity or within 30 days of experiencing a change in an existing outside activity.

Examples of relevant and non-relevant changes:

<b>RELEVANT</b>	<b>NON-RELEVANT</b>
A new relationship with an outside organization	Receipt of paychecks if the salary has been reported in toto on an OAR
New roles or positions within organizations such as board of directors membership or executive positions	If greater than \$5000 for a particular relationship has already been reported, additional compensation does not need to be reported until the next annual OAR
New or changed forms of ownership such as intellectual property rights, stock, stock options, or equity interest	
Increases or decreases in the amount or kind of compensation or remuneration received from an entity	

## How to File an OAR

### Annual OAR

An annual notification is sent to most UWM employees in the spring, to be completed by April 30 each year. The original OAR filing can be accessed by logging in to UWM [Streamline \(BP Logix\)](#) using the regular UWM login and open the Task List to complete. If assistance is needed, contact [OAR Support](#).

### OAR Update

To submit an updated OAR, log in to UWM [Streamline \(BP Logix\)](#). Make the Request Type *Updated Request*, enter appointment details, appropriate disclosures, and reviewers. Include any other pertinent information or documents in the Additional Comments and Supporting Documentation area and click the Submit Form button. If assistance is needed to enter the information, contact [OAR Support](#).

## Division and/or School/College Approval of OAR

### OAR Approval

The OAR is routed to staff member's Chair and/or Dean for approval.

## RCOI Committee Review of OAR Reports Relating to Research

The RCOI Committee administrator will review the *OAR Report Status – OSP Review* report on a monthly basis, comparing the results against the population of researchers, and determining if there is a nexus between an Investigator's research and the reported interest and if so, if it is or appears to be a conflict of interest. If there is or appears to be a conflict, the RCOI Committee works with the Researcher to implement a management plan that specifies actions that have been, or will be, taken to manage the financial conflict of interest.

## **MANAGEMENT PLANS**

### **Who Needs to Have a Management Plan**

Researchers who have or appear to have conflicts of interest or commitment between their outside activities and their research are required to have a management plan in order to eliminate or mitigate these conflicts or appearances of conflict.

### **What is a Management Plan**

A [template management plan](#) can be seen at the link. It describes the actions that must be taken to eliminate or mitigate any conflict of interest or commitment or the appearance of such. If a management plan is required, a notification will be sent from the RCOI Committee and they will work with the researcher to implement and report as necessary.

### **When is a Management Plan Necessary**

A management plan is necessary when there is or appears to be a conflict of interest or commitment between a researcher's outside activities and their UWM research as determined by review of disclosed activities by the RCOI Committee. If it is required, the RCOI Committee will contact the researcher to complete the form and work with them to explain any elements and complete all the necessary approvals.

### **How to Complete a Management Plan and Remain in Compliance**

A template management plan can be found on the [Office of Research Forms and Documents download page](#). The upper portion is information specific to the Investigator and the Investigator's research and possible conflicts, and the remainder of the documents are the requirements to eliminate and/or mitigate any potential types of conflicts. If there are any issues not covered in the management plan, please include them in an additional document when the completed form is sent to the RCOI Committee. Please include any questions or a request to review the management plan with the committee when returning the form.

Once the plan has been agreed upon and reviewed, the Investigator is responsible for all its terms and conditions and must cooperate with UWM's efforts to monitor compliance with the management plan.

Sponsored funding that is related to the management plan will not be available for spending until the management plan is fully completed and approved.

Management plans prohibit participation in human subjects research when a managed entity sponsors the study, or own or license a technology used in the study.

### **Requesting an Exception to the Restriction on Participation in Human Subjects Research**

Researchers may apply for an exception to the restriction on participation in human subjects research. Exception requests are only granted for specific protocols; therefore, every protocol requires a separate, explicit exception.

Protocols that have been determined to be of no greater than minimal risk do not require an exception and may proceed without one according to the limitations listed on the Management Plan.

For all protocols that are greater than minimal risk, or where the researcher must appeal a limitation for a minimal risk study, the research must work with their Dean's Office to request an exception. If the Dean's Office agrees to support the exception request, they will prepare a memorandum outlining the basis for the exception, and their willingness to participate in additional management actions.

Additional management actions include: disclosure of financial interests to participants, disclosure of financial interests to research collaborators, additional protocol monitoring, restriction of roles in the study, and other management, as determined by the committee.

The Dean's representative will share this memorandum with the RCOI Committee at the next RCOI Committee meeting. After the meeting, the Investigator will be notified of whether or not the exception has been granted.

The IRB has authority to require disclosure of the conflict of interest in the consent form as well as restrict participation in the recruitment of study participants for any study if the IRB determines either is necessary to protect research participants.

### **Appealing a Management Plan**

Faculty members may appeal the VPR's determination to the Faculty Appeals and Grievances Committee. Academic staff members may appeal the determination to the Academic Staff Hearing and Appeals Committee. These committees may then make recommendations concerning the management plan in question to the Provost. The decision of the Provost regarding conflict of interest matters shall be final. Please note that the appeal process may delay spending on sponsored awards.

### **Terminating a Management Plan**

If the circumstances of a managed outside activity change so that they meet one of the criteria listed below, please contact the [RCOI Committee](#) to request termination of a management plan. Termination of an existing management plan requires explicit action from the UWM RCOI Committee.

Situations that may be cause for termination of a management plan:

- The Investigator is no longer employed by UWM
- The managed entity has dissolved
- The Investigator's relationship with the managed entity has ended
- The Investigator's compensation from the managed entity has fallen below the PHS management threshold

## **ADDITIONAL REQUIREMENTS FOR INVESTIGATORS INVOLVED IN PHS-FUNDED RESEARCH**

Federal regulations, 42 CFR Part 50, Subpart F, and 45 CFR Part 94 requires disclosure of outside financial interests and inform UWM's COI policies and the operations of the COI program. The federal regulations state that a conflict of interest exists when an Investigator has a significant financial interest (SFI) 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 his or her spouse and/or dependent children..

### **Definitions**

**Financial Conflict(s) of Interest (FCOI):** A Significant Financial Interest that could directly and significantly affect the design, conduct or reporting of PHS Research Activity.

**Investigator:** The Principal Investigator or project director and any other person regardless of title or position who is responsible for the design, conduct or reporting of research proposed for funding or funded by PHS. This includes, but is not limited to, Key Personnel named on a proposal budget.



**PHS-Funded Research:** Research funded by Public Health Service entities (which include the National Institutes of Health (NIH), the Centers for Disease Control (CDC), and others, [listed here](#)), as well as non-federal agencies which also follow PHS FCOI regulations (such as those [listed here](#)).

**Significant Financial Interest (SFI):** Anything of monetary value that meets the PHS thresholds (see [Significant Financial Interest Disclosure](#) below) for reporting received by the Investigator and, except for travel, received by the Investigator's spouse and dependent children for the following categories and reasonably appears to be related to or is in the same field of expertise as the Investigator's Institutional Responsibilities.

**Significant Financial Interest Disclosure (SFID):** The required form to indicate whether or not there is an SFI. If the form is positive, this includes review and approval by Department, School/College, and Office of Research approvers as necessary.

## **FCOI Training**

### **Who Needs to Complete FCOI Training**

UWM requires all Investigators engaged in PHS-funded research to receive training in financial conflicts of interest.

### **What Needs to be Completed**

The FCOI course is a three-module course addressing Financial Conflicts of Interest, Conflicts of Commitment and Conscience, and Institutional Responsibilities As They Affect Investigators.

### **When FCOI Training Must Be Completed**

FCOI Training must be completed every four years or, per federal guidelines, when changes to the UWM's FCOI policies change in a manner that affects Investigator requirements. The UWM Office of Sponsored Programs (OSP) will check an Investigator's FCOI training status each time they begin the setup of an award account with PHS-funded research on which an Investigator is PI or senior/key personnel. Notification will be sent via email to ensure FCOI training is up-to-date. Spending on new and non-competing PHS funded award accounts will not be permitted until FCOI training of all senior/key personnel is complete.

### **How to Complete FCOI Training**

The course is available at [the CITI website](#). Select University of Wisconsin – Milwaukee from the dropdown menu. Then go to Choose Courses, Add a Course, and select Financial Conflicts of Interest (FCOI).

For questions about FCOI training, please contact the [RCOI Committee Administrator](#).

## **Significant Financial Interest Disclosure**

### **Who Needs to Fill Out an SFID**

Anyone who is an Investigator on a PHS-Funded Research application must complete an SFID prior to submission of the proposal. Anyone who is an Investigator on PHS-Funded Research must complete an SFID prior to award set-up, and every year thereafter that they are on PHS-Funded Research.

### **What Needs to Be Reported on an SFID**

According to federal regulations and UWM policy, the following interests of an Investigator, or an Investigator's spouse or dependent children, constitute an SFI:

### ***PUBLICLY TRADED ENTITIES***

<b><i>REPORTABLE</i></b>	<b><i>NON-REPORTABLE</i></b>
The value of remuneration received from an entity in the twelve months preceding disclosure, in combination with the value of any equity interest in the company as of the date of disclosure, <b>exceeds \$5,000</b>	Remuneration received in the twelve months preceding disclosure, in combination with the value of any equity interest in the company as of the date of disclosure <b>does not</b> exceed \$5000

### ***NON-PUBLICLY TRADED ENTITIES***

<b><i>REPORTABLE</i></b>	<b><i>NON-REPORTABLE</i></b>
The value of any remuneration received from an entity in the twelve months preceding disclosure <b>exceeds \$5,000</b>	Remuneration received in the twelve months preceding disclosure <b>does not</b> exceed \$5000

### ***EQUITY INTEREST IN A COMPANY***

<b><i>REPORTABLE</i></b>	<b><i>NON-REPORTABLE</i></b>
Income from intellectual property rights received during the previous twelve months that <b>exceeds \$5,000</b>	Royalty income from intellectual property that arose from University employment and that was assigned to UWM Research Foundation
Service in positions with fiduciary responsibility, including executive positions, senior management positions, or memberships on boards of directors	Service in positions with no fiduciary responsibility or remuneration

### ***TRAVEL***

<b><i>REPORTABLE</i></b>	<b><i>NON-REPORTABLE</i></b>
All reimbursed and sponsored travel over the last twelve-month period	Non-reimbursed travel (i.e. personal travel)
New travel within 30 days of the start of the travel event reimbursed made by an outside entity to cover expenses paid by a PHS funded Investigator as part of a travel event	Travel reimbursed by a federal, state, or local U.S. government agency, a U.S. institution of higher education, a U.S. academic teaching hospital, a U. S. medical center, a research institute affiliated with a U.S. institution of higher education, or travel covered through UWM's e-Reimbursement system

### **When Does an SFID Need to Be Completed**

Anyone who is an Investigator on a PHS-Funded Research application must complete an SFID prior to submission of the proposal. Anyone who is an Investigator on PHS-Funded Research must complete an SFID prior to award set-up, and every year thereafter that they are on PHS-Funded Research.

### **How to Complete an SFID**

Investigators who are submitting an application for or have received an award for PHS-Funded Research and do not have a completed SFID within the last 12 months should complete one in the [SFID portal](#). If any assistance with the portal is needed, Investigators should contact the [RCOI Committee Administrator](#).

## **SFID Approval**

Investigators who do not have an SFI to report will have their SFID forwarded to the RCOI Committee for review. Investigators who do have an SFI to report will have the SFID routed to their Chair, Dean, and the Vice Provost of Research to approve and to give insight into whether or not it might be a conflict of interest. Once signed by all of the approvers, the SFID is forwarded to the RCOI Committee administrator for review.

## **Approver Training**

Chairs and Deans who approve SFID Forms are required to complete the FCOI Approvers course in CITI. The FCOI approver course is a four-module course addressing Financial Conflicts of Interest, Conflicts of Commitment and Conscience, and Institutional Responsibilities As They Affect Investigators, and Institutional Conflicts of Interest.

## **RCOI Committee Review of SFID**

The RCOI Committee administrator will review all SFID forms as they are completed, determining if there is a nexus between an Investigator's research and the reported interest and if so, if it is or appears to be a conflict of interest.

If there is not or does not appear to be a conflict, the RCOI Committee administrator will complete the review in the SFID system as No SFI.

If there is or appears to be a conflict, the RCOI Committee works with the Researcher to implement a management plan that specifies actions that have been, or will be, taken to manage the financial conflict of interest and report the management plan to the PHS agency affected.

## **SFI and Non-Compliance Reporting to PHS**

UWM is required to monitor Investigator compliance with management plans and provide reports on FCOIs and instances of bias to PHS. If the RCOI Committee finds noncompliance because an Investigator has failed to disclose a reportable outside financial interest or failed to comply with a management plan, the RCOI Committee may impose the following sanctions:

- Require the Investigator to complete additional training
- Withhold research funding
- Conduct a retrospective review
- Report the noncompliance to the PHS awarding component and Dean or other supervisor

If an Investigator with PHS-Funded Research does not report a Significant Financial Interest in a timely manner, UWM needs to review the SFI to determine if there is an conflict of interest, and if a conflict of interest is found, complete a retrospective review. The retrospective review must determine whether any PHS-funded research conducted during the period of noncompliance was biased in its design, conduct, or reporting.

If the retrospective review committee makes a determination of bias, UWM will notify the PHS of its findings, along with a mitigation report that includes:

- The key elements documented in the retrospective review
- A description of the impact of the bias on the research project
- UWM's plan of action for eliminating and mitigating the effects of the bias.

# **INSTITUTIONAL CONFLICT OF INTEREST COMPLIANCE**

## **Research Conflict of Interest Committee**

The Vice Provost for Research is given the responsibility and authority to conduct a conflict of interest management program at UWM. In this capacity, the Vice Provost for Research provides leadership to the Research Conflict of Interest Committee and makes final decisions on Conflict management issues.

The UWM Research Conflict of Interest Committee is responsible for managing training, reporting, and managing of all real or potential conflicts of interest or commitment between Investigators' sponsored research and their outside activities, as described above.

## **Appointments**

The Chancellor appoints the voting membership and ex officio participants to the RCOI Committee based on the recommendations of the Vice Provost for Research.

## **Membership**

The committee is made up of a minimum of 5 voting members. Members represent a range of disciplines and colleges on campus as well as members from areas of research administration and compliance. Research leadership seeks to maintain a balance of researchers from the schools and colleges, of individuals engaging in entrepreneurial activities, of representatives from larger and smaller colleges and schools, and individuals with diverse backgrounds on the Research Conflict of Interest Committee. The minimum RCOI Committee membership includes:

- IRB Representative
- OSP Representative (RCOI Committee administrator)
- At least one Investigator
- At least one Administrator

## **Meetings**

The RCOI Committee will meet monthly to review the administrator's reporting from the OAR and SFID forms as necessary as well as any current management plans.

Ad hoc meetings will be held as necessary in order to facilitate management plans or other reviews for PHS or other sponsored award set-up.

## **Responsibilities**

- OAR/Research and SFID reporting overview
- Management plan review and approval prior to signatures
- OAR/Research monthly reporting review and preliminary determination (Administrator)
- SFID form review and preliminary determination (Administrator)
- Management plan tracking (Administrator)

## **Office of Sponsored Programs**

### **Personnel**

The [pre-award team](#) is in charge of verification of any conflict of interest compliance activities necessary prior to submission of proposals or new award set-up. The [post-award team](#) is in charge of verification of some conflict of interest compliance activities necessary prior to continuation or no-cost extensions of existing awards.

## **Responsibilities**

OSP ensures COI and FCOI compliance by completing the following steps at the time of application or award set-up, as indicated:

- Verification of OAR completion at time of award set-up or award modification
- Verification of FCOI training at time of award set-up or award modification of PHS-Funded Research
- Verification of SFID submission at time of application submission, award set-up, or award modification of PHS-Funded Research
- SFID preliminary review (RCOI Committee Administrator)
- PHS reporting of SFI (OSP Director or Associate Director)
- Retrospective review (OSP Director or Associate Director)

## **REFERENCES**

[UW Regent Policy Document 20-22](#), Code of Ethics

[UW System Administrative Policy 1290](#), Code of Ethics

[University of Wisconsin System Chapter 8](#), Unclassified Staff Code of Ethics

[UWM Faculty Policies and Procedures](#), Section 5.30 – 5.39

[UWM Academic Staff Personnel Policies and Procedures](#), Chapter 113

[UWM Faculty Document No. 2229](#), Statement on Professional Ethics

[UWM Faculty Document 2879](#), Policy for FCOI in PHS-Funded Research

[Department of Health and Human Services, Code of Federal Regulations](#), Title 42, Part 50, Subpart F, Section 50.604 Department of Health and Human Services

[National Science Foundation Grant Policy Manual](#), Chapter V, Section 510

[UW System Regent Policy Document 13-6](#), Contracts with Research Companies

[Wisconsin Statute 946.13](#), private Interest in a Public Contract Prohibited

**EXHIBIT A: TEMPLATE MANAGEMENT PLAN**

## Conflict of Interest and/or Commitment Management Plan

<b>Researcher Name</b>			
<b>School or College</b>			
<b>Business, corporation, or institution with potential conflict (hereafter “Entity”)</b>			
<b>Brief Description of Entity’s Product or Service</b>			
<b>Brief Description of Interest or Commitment</b>			
<b>Areas of Concern</b>	<b>N</b>	<b>Y</b>	<b>If yes, area of guidance</b>
Other staff			Section I, Appendix A
Students			Section I, Appendix A
Potential for publication or presentation			Section II, Appendix B
Contracts between Entity and UW-Milwaukee			Section III
Purchase of items from Entity			Section IV
Use of UW-Milwaukee space or facilities			Section V
Human Subjects Research			Section VI
Guidance and Requirements for ALL MANAGEMENT PLANS		Y	Sections VII, VIII, IX, X
<b>Approval of Conflict of Interest and/or Commitment Management Plan</b>			
<b>Role</b>	<b>Name</b>	<b>Signature</b>	
<b>Researcher</b>		[WILL BE SENT VIA DOCUSIGN]	
<b>Dean or designee</b>		[WILL BE SENT VIA DOCUSIGN]	
<b>Vice Provost of Research</b>	Mark Harris	[WILL BE SENT VIA DOCUSIGN]	

**I. Interactions with Students and Staff.** UW–Milwaukee has a duty to ensure that the entrepreneurial activities of its faculty and staff do not have a negative impact on students or research staff, especially on the academic progress of students. To fulfill this obligation, the Research Conflict of Interest (RCOI) Committee requires that individuals with potential conflicts of interest inform others who may be impacted by the potential conflicts.

You must provide information on potential conflicts of interest to all students, fellows, trainees, and other research workers whom you supervise in the course of your research (hereafter students and staff). The information should include explanations of: a) your relationship with the entity, and b) the right of students and staff to bring concerns about the effect of your relationship with the entity on their work, studies, or progress towards degree

to your dean, director, his or her designee, or the RCOI Committee. The process for providing information should meet the following criteria:

- Includes a written summary of the information for each student or staff member
- Provides to the COI Program documentation that this process has occurred within 90 days of receipt of this management plan
- Provides any individuals who subsequently join the group comparable information in a timely manner
- Updates documentation to the RCOI Committee at least once a year

See "Appendix A: Informing students and staff of potential conflicts of interest" for additional guidance.

You must also notify all your co-Investigators on federal grants of potential conflicts of interest.

Your relationship with the entity may not place restrictions on the ability of your students and staff to receive, analyze, or interpret data. In addition, students may not participate in research sponsored by the entity without permission from your dean's office.

The RCOI Committee recommends that all involvement of students and staff with the entity be conducted under formal University agreements, such as sponsored research agreements or appointments approved by your dean or director's office.

You must direct any of your students and staff with financial interests in the entity to make an [annual report of outside activities using the online process](#), if they have not already done so and regardless of whether they would normally be required to make such a report. Any of your students and staff who independently have a significant financial interest in the entity will be reviewed by the RCOI Committee and may be issued their own management plans.

You must notify your Dean or Director's office if you wish for the university to hire an individual who you know has a financial interest in the entity into a position over which you have a supervisory role, or if a current employee or graduate student under your supervision obtains a financial interest in the entity. You may not be directly involved in any final institutional decision-making regarding UW-Milwaukee employment of any individual who you know has a significant financial interest in the entity. Any such decisions must be made by an impartial party who is not under your supervision or control.

**II. Publications and Presentations.** Your relationship with the entity may not restrict publication or presentation, although publication may be delayed for the purpose of pre-publication review for a period consistent with UW–Milwaukee policies.

You, your students, fellows, trainees, and other research workers whom you supervise in the course of your research must disclose the relationship with the entity in publications and academic presentations, if a) the entity supports research reported in the publication; or b) the

publication or presentation is related to the entity's commercial interests or intellectual property. For researchers in the biomedical sciences, disclosure in publications should conform to recent uniform disclosure guidelines published by a group of editors of major medical journals (Davidoff et al. JAMA 286: 1232-1234, 2001). (See Appendix B: Disclosing in publications.)

### **III. Contracts between University and Entity**

#### **A. Research Support from Entity**

Before accepting any research support (e.g., grants, contracts, unrestricted gifts, or materials) from the entity, you must specifically disclose details of the award to your dean or director's office for approval, including the scope of the work and any award conditions. The written disclosure details must accompany a WISPER record and be routed from the department chair to the dean or director's office for approval. You must update your outside activities report and indicate that you have sponsored research.

#### **B. Subagreements with Entity**

If you anticipate engaging in a project for which the entity will be a subawardee or subcontractor, you must contact your dean or director's office for approval prior to submitting a proposal.

#### **C. Contract Negotiation, Approval, and Signature**

You may not negotiate or sign any contract with the entity on behalf of UW-Milwaukee. In addition, any such contract's terms and budget must be approved by your Dean, Director, Division Head or their designee.

#### **D. Invoicing, Billing, and Issue Resolution**

If UW-Milwaukee has a contractual relationship with the entity, you may not be responsible for invoicing or billing the entity, or for institutional decision-making should any issue regarding the entity's performance under the contract arise. Any such decisions must be made by an impartial party who is not under your supervision or control.

### **IV. Purchasing**

You may not be directly involved in making decisions involving the purchase of items from the entity. Any such decisions must be made by an impartial party who is not under your supervision or control, such as your department chair or someone designated by your chair. If you are a department chair, your dean should be asked to designate someone on your behalf.

### **V. Use of University Facilities and Services**



Any activity involving the use of University facilities or services for the benefit of the entity must be conducted in accordance with all relevant University and system policies and state and federal laws pertaining to the use of University facilities and services. Except with respect to use of facilities and services made available for general public use in accordance with established rates and conditions applicable to all users, any such activity must be approved by your Dean, Director, Division Head or their designee, and a written and approved contract is required before the activity begins.

## **VI. Human Subjects Research**

For any human subjects protocol in which the entity a) sponsors the study, or b) owns or licenses a technology used in the study, the following rules apply.

### **A. All studies**

- You must report the conflict of interest and provide this management plan to the Institutional Review Board (IRB) reviewing the study within 30 days of this management plan's assignment.

### **B. Minimal Risk Studies**

- If a reviewing IRB determines that a study in which you are engaged is minimal risk, you may participate in the study, however, the following limitations apply:
  - i. You must disclose the conflict to participants in the study, unless the IRB determines that such disclosure would not be appropriate;
  - ii. You may not participate in the recruitment, enrollment or consent of participants in the study;
  - iii. If your study meets the definition of a clinical trial,<sup>1</sup> you must designate a non-conflicted co-Investigator or other key personnel on the study with responsibility for acting as an independent reviewer of the data analysis.

### **C. More than Minimal Risk Studies**

- You may not serve as principal Investigator (PI) on the human subjects protocol.

### **D. Exceptions**

- The reviewing IRB may impose additional requirements with respect to your participation in the study. If you wish to request an exception to any of the above stated limitations, you must follow the exception request process outlined below.
- If you wish to apply for an exception to the restriction on participation in human subjects research, you must work with your Dean's office to apply for the exception.

- This exception must be addressed to the RCOI Committee in writing and must include a statement of the Dean's Office to participate in additional management actions. The RCOI Committee only grants exceptions for specific protocols.
- Additional management actions include:
  - Disclosure of financial interests to participants
  - Disclosure of financial interests to research collaborators
  - Additional protocol monitoring
  - Restriction of roles in the study
  - Other management as determined by the committee
- If the RCOI Committee approves an exception, the RCOI Committee may require modifications to the human subjects protocol.

## **VII. Reporting of Outside Activities**

You are required to submit an annual report of outside activities each spring using the online process. In addition, if you have relevant changes in your outside activities between annual reports, you must [update your report](#) within 30 days of the change. You may access your [Outside Activities Report](#) at any time during the year.

## **VIII. Outside Activities Agreement**

A departmental agreement on the appropriate balance between your outside activities and your faculty appointment needs to be established.

## **IX. Annual Review**

You must meet annually with your department chair, center director, or, if you are the department chair or center director, with your dean or director, or his or her designee, to review information related to your relationship with the entity or entities, its influence on your University activities and compliance with the terms of this management plan. Meeting Confirmation Form is included as Appendix C.

## **X. Amendments.**

UW–Milwaukee reserves the right to modify this management plan and to impose new or additional conditions. Such modifications, conditions, and additional terms will be effective immediately and incorporated into this management plan. UW–Milwaukee will notify you of these changes in advance by sending an email message to the email account used for your annual Outside Activities Report notifications. You will be deemed to have accepted these terms and conditions unless you appeal your management plan, which must be done in writing and sent to UW–Milwaukee's Conflict of Interest Committee via [or-fcoi@uwm.edu](mailto:or-fcoi@uwm.edu).

## **Appendix A: Informing students and staff of potential conflicts of interest**

The RCOI Committee provides the following guidance to help Investigators communicate the details of conflict of interest management plans. Investigators may use alternative approaches, if they meet the requirements laid out in the body of this management plan.

Students, fellows, trainees, and other research workers whom you supervise in the course of your research a written summary should receive a written summary of your relationship with your managed entities. The following information may be included:

The written summary would be printed on department letterhead and include the following:

1. Date;
2. Description of the Investigator's involvement with the entity;
3. Description of the purpose of the entity;
4. Description of the relationship between the Investigator's professional work (research) at the UW–Milwaukee and the entity;
5. Description of any relationships between the UW–Milwaukee and the entity, such as sponsored research agreements, facilities use agreements, etc.;
6. Description of any restrictions placed on the design, conduct, and reporting of research by the entity;
7. Description of the ownership of any intellectual property resulting from research connected to the entity;
8. Impartial contacts for students and staff;
9. Information regarding requirement that the student/staff member complete outside activities report if they also have an interest in the entity;
10. Investigator's signature; and
11. Statement of acknowledgment to be signed and dated by the recipient.

You may provide a copy of your notification letter to students and lab personnel via email, making sure to CC the COI Program at [or-fcoi@uwm.edu](mailto:or-fcoi@uwm.edu) and listing out each recipient. Template letter is included below.

Another effective way to communicate the details of your management plan is to hold a meeting to review the provisions of your plan. During this meeting, participants would receive two copies of a written summary signed by the Investigator. They would sign and date one copy and return it to the Investigator. The Investigator would then provide copies of the signed letters to the RCOI Committee.

[Template Letter to Research Collaborators]

**DATE**

Dear Researcher,

With this letter, I am informing you of my involvement with [Outside Interest] as [explanation of involvement (ownership, leadership, etc.)]. [Outside Interest] is [explanation of purpose of Outside Interest].

[Description of relationship between Investigator's work and Outside Entity]. [Description of relationships between UWM and Outside Entity (including, but not limited to, sponsored research agreements and/or space agreements)]. [Description of the ownership of any intellectual property resulting from research connected to the entity (or statement there is none)].

[Description of any restrictions placed on design, conduct, and/or reporting of research by entity (or statement there are none)].

If you have an interest in [Outside Interest] meeting the qualifications for reporting listed in the [Research Conflict of Interest Guidelines](#), you may have to create or update your Outside Activities Report (OAR). See that document for instructions.

If you have questions, please reach out to the following contacts:

Questions specific to the research/[Outside Interest]: [*Chair/Dean; your OAR approver.*]

[Name and Title]

[Email]

[Phone]

General Conflict of Interest questions:

Kate Mollen, Director of the Office of Sponsored Programs

[mollen@uwm.edu](mailto:mollen@uwm.edu)

(414) 229-4853

Sincerely yours,

Dr. XXXX

[Title], [Department]

I acknowledge the information provided to me.

---

Recipient

---

Date **October 26, 2021**

## **Appendix B: Disclosing in publications**

The RCOI Committee provides the following examples to guide Investigators disclosing their significant financial interests in publications and presentations. Investigators may use alternative approaches that meet the requirements laid out in the body of this management plan.

- Dr. A has an ownership interest in Company 1, which has licensed the technology reported in this publication.
- The research reported was supported by funding provided by Company 1, Company 2, and Company 3, with which Professor B has significant financial interests.
- Name [A member of Name's family] owns stock in [has stock options with] Company 1.
- Additional information on disclosing potential conflicts of interest in biomedical research can be found in:
  - Davidoff F, DeAngelis C, Drazen J, et al. Sponsorship, authorship, and accountability. JAMA. 2001;286:1232-1234.
  - DeAngelis CD, Fontanarosa PB, Flanagin A. Reporting financial conflicts of interest and relationships between Investigators and research sponsors. JAMA. 2001;286:89-91.

## Appendix C: Annual Meeting Confirmation Form

### Researcher Confirmation

As required by my UW-Milwaukee Conflict of Interest and/or Commitment Management Plan, I confirm that I have met with my department chair, center director, or dean's office designee to review my relationship with the entity or entities, its possible influence on my University activities and compliance with the terms of my management plan. The following items of my management plan were reviewed:

- Research Support from Managed Entities
- Interactions with Students and Staff
- Publications and Presentations
- Contracts between Entity and UW-Milwaukee
- Purchases
- Use of University Facilities and Services
- Human Subjects Research
- Reporting of Outside Activities
- Outside Activities Agreement
- Annual Review

---

Researcher Signature

---

Date

Name:

### Reviewer Confirmation

I confirm that I have met with the individual named above in compliance with the requirements of the UW-Milwaukee Conflict of Interest and/or Commitment Management Plan.

---

Chair/Center/Dean/Designee Signature

---

Date

Name: