FCOI Standard Management Plan Example

Management Plan

Investigator: _____

Entity or Entities: _____

All UW-Madison policies mentioned below relate to your actions as a faculty member or academic staff, and your participation in federal and external awards and projects and/or human subjects research, and in proposing research. You have agreed to these policies by virtue of your employment by the University of Wisconsin-Madison.

I. Publications and Presentations. Your relationship with _____ (hereafter "the entity") may not restrict publication or presentation.

- You must disclose the relationship with the entity in publications and academic presentations, if
  - the entity supports research reported in the publication; or
  - the publication or presentation is related to the entity's commercial interests or intellectual property.
- Follow the published uniform disclosure guidelines for researchers in the biomedical sciences according to ICMJE (See Subsec. (II)(B) of Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals, updated April 2025, pg. 3)
- See Appendix A: Disclosing in publications.

II. Interactions with Students and Staff. To prevent negative impacts your relationship may have on students or research staff, especially on the academic progress of students, you must inform them of potential conflicts of interest with the entity.

You must provide written notice about your relationship to everyone you supervise in the course of your research and co-investigators on federal grants, including those who subsequently join the group. **Provide to the COI Program documentation that this notice has occurred within 90 days of receipt of this management plan or notice of continuing management.** The notice must include:

- A summary of the nature of your relationship with the entity, and

- 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 the dean or director's office, or the COI Program.
- See "Appendix B: Informing students and staff of potential conflicts of interest" for additional guidance.

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 either your Dean, Center Director, or their designee.

You must direct students and staff under your supervision to file an outside activities report at oar.wisc.edu if they have a financial interest in the entity for individual review. You must also notify your Dean or Director's office of any individual in your reporting line that has a relationship with the entity, or of any individual you wish to hire who has a relationship with the entity.

The COI 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 either your Dean, Center Director, or their designee.

If someone under your supervision has a financial relationship with the entity, you must notify either your Dean, Center Director, or their designee. This includes current employees, students, and persons you wish to hire. Any final institutional decisions regarding UW-Madison employment of any individual who you know has a significant financial interest in the entity must be made by an impartial party who is not under your supervision or control.

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 either your Dean, Center Director, or their designee for approval, including the scope of the work and any award conditions. You must also 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 either your Dean, Center Director, or their designee 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-Madison. In addition, any such contract's terms and budget must be approved by either your Dean, Center Director, or their designee.

D. Invoicing, Billing, and Issue Resolution

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

To avoid possible violations of Faculty or Academic Staff Policies and Procedures, UWS8, or Wis. Stat. §946.13, 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, Dean, Director, or their designee.

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 either your Dean, Director, 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 IRB reviewing the study within 30 days of this management plan's assignment.

B. More than Minimal Risk Studies

i. You may not serve as principal investigator (PI), co-investigator (co-PI), or key personnel on the human subjects protocol if your conflict of interest consists of privately held equity or compensation of $25,000 or greater
ii. If the financial conflict of interest consists solely of compensation of less than $25,000, you may be allowed to participate in the study with your Dean or Director's permission, however, the following limitations apply:
    a. You must disclose the conflict to participants in the study, unless the IRB determines that such disclosure would not be appropriate
    b. You may not participate in the recruitment, enrollment or consent of participants in the study;
    c. 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.

If you wish to participate in a protocol under this section, you must ask your Dean, Center Director, or their designee for approval. They may need to apply to the COI Committee for an exception to the restriction on participation in human subjects research on a protocol-specific basis. If the COI Committee approves an exception, it may require modifications to the human subjects protocol. For instructions on applying for an exception, see the Financial Conflict of Interest Policy and Procedures: Guidance Document.

The reviewing IRB or Vice Chancellor for Research may impose additional requirements, or require additional review, for all human subjects studies.

C. 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 [1], 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.

If you wish to request an exception to any of the above stated limitations, you must follow the exception request process outlined above in subsection b.

The reviewing IRB may impose additional requirements with respect to your participation in the study.

[1] A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

D. Payments and Incentives.

You may not receive payments from University accounts or directly or indirectly from the entity for particular research results or for research outcomes related to human subject protocols conducted at or through UW–Madison. Further, you, or your immediate family, may not receive any personal incentives from University accounts or directly or indirectly from business entities, such as recruitment incentives, performance incentives, fellowships, or other research support, except through an agreement entered into by the University for a sponsored human subjects study. UW–Madison only permits payments for subject enrollment, or for the referral of potential subjects to human subjects studies, when all of the following are present:

- The payment reasonably relates to costs incurred, as specified in research agreement between the sponsor and UW–Madison.
- The payment reflects the fair market value of services performed.

The payment is commensurate with the efforts of the investigator(s) performing the research.

VII. Reporting of Outside Activities

The UW Conflict of Interest Policy requires you to submit an annual report of outside activities by April 30th of each year using the online process. In addition, you must update your report within 30 days of any relevant change. For guidance on what relevant changes in your outside activities are, please see: FCOI: Guidance Document.

VIII. Outside Activities Agreement

A departmental agreement on the appropriate balance between your outside activities and your faculty appointment needs to be established pursuant to UW-Madison's conflict of commitment policy (UW-1075).

IX. Annual Review

You must meet annually with your department chair, center director, or with your dean or director, or their 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.

You must provide to the COI Program documentation that this process has occurred within 90 days of receipt of this management plan or communication from the COI Program in subsequent years.

X. Amendments.

UW–Madison 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–Madison 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–Madison's Conflict of Interest Committee via coiprogram@research.wisc.edu.

Appendix A: Disclosing in publications

The COI 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:
    - ICMJE, Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals, § (II)(B) updated April 2025, pg. 3)

Appendix B: Informing students and staff of potential conflicts of interest

The COI 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 should receive a written summary of your relationship with your managed entities. The following information may be included:

The written summary would be written 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–Madison and the entity;
5. Description of any relationships between the UW–Madison 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 the requirement that the student/staff member complete outside activities report if they also have an interest in the entity; and
10. Investigator's signature

You may provide a copy of your notification letter to students and lab personnel via email, making sure to CC the COI Program at coiprogram@research.wisc.edu and listing out each recipient. A draft Notification Letter is located on your OAR Summary page.