

# Financial Conflict of Interest Management Plan Example

## Management Plan

Investigator: \_\_\_\_\_

Entity or Entities: \_\_\_\_\_

**I. Publications and Presentations.** Your relationship with \_\_\_\_\_ (hereafter "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–Madison 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 A: Disclosing in publications.)

**II. Interactions with Students and Staff.** UW–Madison 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 COI Committee requires that individuals with potential conflicts of interest inform others who may be impacted by the potential conflicts.

You should 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 COI Committee. You must complete the following:

- Provide a written summary of the information for each student or staff member
- **Provide to the COI Program documentation that this process has occurred within 90 days of receipt of this management plan**

- Provide any individuals who subsequently join the group comparable information in a timely manner
- Provide updated documentation to the COI Committee within 90 days of receipt of communication of continuing management plan requirements every year this plan is active.

See "Appendix B: 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 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 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 (<https://research.wisc.edu/compliance-policy/outside-activities-reporting/>), 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 COI 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-Madison 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.

### **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 RAMP 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-Madison. 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-Madison 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. Links to relevant resources are provided in the [Financial Conflict of Interest Policy and Procedures: Guidance Document](#).

## **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**

- You may not serve as principal investigator (PI), co-investigator (co-PI), or key personnel on the human subjects protocol.

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 COI Committee in writing. The COI Committee only grants exceptions for specific protocols. If the COI Committee approves an exception, the COI Committee may require modifications to the human subjects protocol, such as those outlined below in subsection c. For instructions on applying for an exception, see the [Financial Conflict of Interest Policy and Procedures: Guidance Document](#).

### **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,<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.

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 above in subsection b.

<sup>1</sup> 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**

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. For guidance on what relevant changes in your outside activities are, please see: [Financial Conflict of Interest Policy and Procedures: 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.

### **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.

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

Meeting Confirmation Form

### **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](mailto: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:
  - 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 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 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–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 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 [coiprogram@research.wisc.edu](mailto:coiprogram@research.wisc.edu) and listing out each recipient. A draft Notification Letter is located on your OAR Summary page.

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 COI Committee.

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