

Management Plan for Human Subjects Research

Investigator:

Entity or Entities:

1. **Publications and Presentations.** Your relationship with _____ (hereafter “the entity or entities”) 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 or entities in publications and academic presentations where disclosure is possible and appropriate. 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.)

2. **Interaction with Students and Staff.** The 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 or entities, and b) the right of students and staff to bring concerns about the effect of your relationship with the entity or entities on their work, studies, or progress towards degree to your dean, director, his or her designee, or the COI 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 documentation that this process has occurred to the COI Committee within 60 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 COI Committee at least once a year

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 or entities 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 or entities, if the terms and conditions of participation would prevent or inhibit them from meeting applicable UW-Madison degree requirements, such as completion and public defense of a thesis or dissertation.

Annually, you must notify the COI Committee and your dean or director in writing of any students and staff involved in the activities of the entity or entities. Such involvement may require modification of this management plan.

The COI Committee recommends that all involvement of students and staff with the entity or entities 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 significant financial interests in the entity or entities to make an annual report of outside activities using the on-line process (<https://www.gradsch.wisc.edu/disclose>), 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 reportable significant financial interest in the entity or entities will be reviewed by the COI Committee and may be issued their own management plans.

3. **Human Subjects Research.** Absent written approval from the COI Committee, you cannot serve as principal investigator (PI), co-investigator (co-PI), or key personnel for a human subjects protocol reviewed by a UW-Madison IRB if the entity or entities: a) sponsors the study, or b) owns or licenses a technology tested in the study.

Likewise, you cannot recruit potential subjects for a human subjects protocol, if the entity or entities: a) sponsors the study, or b) owns or licenses a technology tested in the study.

You may refer potential subjects to an independent third party for study information and possible enrollment in human subjects protocols.

The COI Committee may grant you an exception to restrictions on participation in human subjects research. The COI Committee only grants exceptions for specific protocols.

The exception process depends on the risk level of the proposed research. If a UW-Madison IRB determines that a study poses no greater than minimal risks to subjects, investigators will normally be granted an exception to this prohibition without COI Committee review, unless a UW-Madison IRB determines that the investigator must apply to the COI Committee for an exception. For all other protocols, individuals must apply to the COI Committee for exceptions in writing. For instructions on applying for an exception, see the Graduate School's COI Web pages (<http://info.gradsch.wisc.edu/research/compliance/coi>).

The COI Committee only grants exceptions for protocols that pose greater than minimal risks to subjects in very rare circumstances. For example, the COI Committee might grant an exception if an individual is uniquely qualified by virtue of expertise or experience to participate in the research and the research could not be conducted as safely or effectively without the individual.

If the COI Committee approves an exception, the COI Committee may require modifications to the human subjects protocol or this management plan. Required modifications could include disclosure of financial interests to participants, disclosure of financial interests to research collaborators, additional protocol monitoring, restriction of your roles in the study, or other management, as determined by the committee.

You may not receive payments from University accounts or directly or indirectly from the entity or entities for particular research results or for research outcomes related to human subject protocols conducted at or through the 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. The 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:

1. The payment reasonably relates to costs incurred, as specified in research agreements between the sponsor and the UW-Madison.
2. The payment reflects the fair market value of services performed.
3. The payment is commensurate with the efforts of the investigator(s) performing the research.

For your reference, UW-Madison's "Policies and Procedures for Conflicts of Interest in Human Subjects Research" are posted on the Web (<http://info.gradsch.wisc.edu/research/compliance/coi/4.coipolicy.html>).

- 4 Research Support from the Entity or Entities. Before accepting any research support (e.g. grants, contracts, unrestricted gifts, or materials) from the entity or entities, you must specifically disclose details of the award, including the scope of the work and any award conditions, to your dean's office for approval. The written disclosure details must accompany an Extramural Support Transmittal Form and be routed from the department chair to the dean or director's office for approval. You must notify the COI Committee of any award approved by the dean's office, so that it may be noted in the committee's records.

If support from the entity or entities is expected to be \$15,000 or more per year, additional clearance may be required. You should contact your dean or director's office regarding this possibility well in advance of the award.

5. Reporting of Outside Activities. As a reminder, you are required to submit an annual report of outside activities each spring using the on-line process. In addition, if you have major changes in your outside activities between annual reports, you must update your report. Instructions on how to update an annual disclosure are available on the Graduate School's Conflict of Interest Web Site (<http://info.gradsch.wisc.edu/research/compliance/coi/2.updating.html>).
6. Outside Activities Agreement. A departmental agreement on the appropriate level of outside activities in light of your faculty appointment needs to be established.
7. Use of University Facilities and Services. Any activity involving the use of University facilities or services for the benefit of the entity or entities must be conducted in accordance with all relevant University policies pertaining to the use of University facilities. If you wish to use University facilities for the benefit of the entity or entities, you must make arrangements through your department chair and your dean. The COI Committee recommends that you have a written facilities use agreement before the activity begins. Links to relevant resources are provided on the Graduate School's Conflict of Interest Web Site (<http://info.gradsch.wisc.edu/research/compliance/coi/2.facilitiesuse.html>).
8. Purchases. You may not be directly involved in making decisions involving the purchase of items from the entity or entities using funding under your control. Any such contractual arrangements are to be delegated to 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.
9. 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. The assessment will then be forwarded to the COI Committee and utilized in its annual review of the relationship between your University research and the entity or entities.

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.

One effective way to communicate the details of conflict of interest management plans is to hold a meeting to explain the conflict situation, review the provisions of the management plans, and allow participants to ask questions. 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 provide the COI Committee a single copy of the written summary and a list of all individuals who received and signed the summary. After an initial meeting, the investigator would speak individually with anyone new who should receive information. The list of individuals who have received information must be updated annually for the COI Committee.

The written summary would be printed on department letterhead and include the following (See example letter below.):

1. Date
2. Description of the investigator's involvement with the company
3. Description of the purpose of the company
4. Description of the relationship between the investigator's professional work (research) at the UW-Madison and the company
5. Description of any relationships between the UW-Madison and the company, 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 company
7. Description of the ownership of any intellectual property resulting from research connected to the company
8. Impartial contacts for students and staff (the investigator's dean or director's designee AND a representative of the COI Committee. See list below.)
9. Investigator's signature
10. Statement of acknowledgement to be signed and dated by the recipient

Student and staff contacts

Conflict of Interest Committee: Chris Buth Furness (890-1613 or chrisb@bascom.wisc.edu)

College or School	Dean or Director's Designee	Email Address
Agricultural and Life Sciences	Irwin Goldman	ilgoldma@wisc.edu
Education	Mariamne Whatley	whatley@education.wisc.edu
Engineering	Deanna Dietrich	dietrich@engr.wisc.edu
Graduate School	Petra Schroeder	pschroeder@bascom.wisc.edu
Letters and Science	Bill Barker	barker@geology.wisc.edu
Medical School	Steve Harsy	harsy@facstaff.wisc.edu
Veterinary Medicine	Rachel Rothschild	rothschr@svm.vetmed.wisc.edu

Example letter

[Letterhead]

[Date]

To All Personnel in the Laboratory of [PI Name],

This letter is to inform you that I am [List position in company.] of a company called [Name of Company], devoted to research in the areas of [Add text explaining the purpose of the company, your involvement with it, and any connections to the lab.]. My relationship does not carry with it any restrictions on publication, and any associated intellectual property will be disclosed and processed according to UW-Madison policy.

The purpose of this letter is to inform you of this potential conflict of interest, and, if you feel that at any time your academic pursuits and freedoms are compromised by this relationship, that you may contact [Provide contact information for the appropriate dean or director's designee listed above.] or the Conflict of Interest Committee via Chris Buth Furness (890-1613 or chrisb@bascom.wisc.edu).

Sincerely yours,

[Signature]

I acknowledge receipt of the above information on a potential conflict of interest. I understand that I may address questions about this matter to my dean or director's designee or to the Conflict of Interest Committee.

Name: [of recipient]

Date: