

**INSTITUTIONAL REVIEW BOARD  
THE UNIVERSITY OF MONTANA-MISSOULA**

**FINANCIAL CONFLICT OF INTEREST**

**POLICY:** Information from investigators, IRB staff, Chair, and all members on their financial interests with commercial sponsors shall be collected and reviewed at least annually.

**PROCEDURES:**

1. At the beginning of a UM IRB term, usually in September, all UM IRB staff, its Chair, and all IRB members will complete the attached form for review by the UM official for reviewing Conflict of Interest matters. Investigators will disclose potential conflicts of interest with their proposals.
2. The UM Conflict of Interest official will inform the IRB Chair of any potential financial conflicts of interest of the people reviewed.
3. Prior to convening an IRB meeting for review of proposals, the IRB Chair will determine if a potential conflict of interest exists with himself/herself, staff, or IRB members.
4. Even if a potential Conflict of Interest only presents the “appearance” of a conflict of interest, that individual will be excluded from reviewing that proposal.
5. The IRB Chair will also determine if anyone involved in the review process is aware of University investments, which may present potential future conflicts of interest. If so, those individuals will be excluded from reviewing that proposal.
6. In addition, the IRB will consider the following questions in its deliberations:
  - A) Who is the sponsor?
  - B) Who designed the protocol? Why?
  - C) Who will analyze the safety and efficacy of data?
  - D) Is there a Data Safety Monitoring Board?
  - E) What are the financial relationships between the Project Director and the commercial sponsor?
  - F) Is there any compensation that is affected by the study outcome?  
To whom?

- G) Does the investigator have any proprietary interests in the product including patents, trademarks, copyrights, and licensing agreements?
- H) Does the investigator have any equity interest in the company?
- I) Does the investigator receive significant payments of other sorts? (Grants, consultantships, etc.)
- J) What are specific arrangements for payments?
- K) Where does the payment go? To UM? To the investigator?
- L) What is the payment per participant? Are there other arrangements?

- 7. If apparent conflicts exist in any of the items in #6 (above), the IRB shall require changes in the arrangements to prevent Conflicts of Interest.
- 8. The Informed Consent Form shall disclose to potential subjects any sources of funding.
- 9. If a financial Conflict of Interest on the part of UM and/or the Project Director has not been or cannot be eliminated, what the financial arrangement is and how that potential conflict is being managed shall be disclosed in the Informed Consent Form.

APPROVED: Janice Reelbach  
Chair, UM IRB

DATE: 5/27/03

**DISCLOSURE OF FINANCIAL INTERESTS BY IRB MEMBERS AND STAFF**

Name: \_\_\_\_\_

IRB relationship: \_\_\_\_\_

Please list below current ownership by you and your immediate family in commercial entities that might sponsor proposals presented to the UM IRB. For example, pharmaceutical companies, biotechnology companies, other research entities, etc.

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Are you aware of any financial investments or other relationships by The University of Montana that could present a potential Conflict of Interest with a proposal submitted to the IRB?

Yes \_\_\_ No \_\_\_ If "Yes", please describe. \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

If any information requested on this form changes, please provide an up-date to the UM IRB Chair.

\_\_\_\_\_  
/s/

\_\_\_\_\_  
Date