

CONFLICTS OF INTEREST

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|---|------------|---|--|------------------------|----------------|-----------------------------|------------|
| SOP #: | 106 | VERSION #: | 1 | EFFECTIVE DATE: | 11/1/06 | SUPERSEDES DOCUMENT: | / / |
| THIS POLICY PERTAINS TO: | | | IRB STAFF, IRB MEMBERS, CONSULTANTS | | | | |
| RESPONSIBILITY FOR EXECUTING POLICY: | | ASSOCIATE VICE PRESIDENT FOR RESEARCH, IRB STAFF, IRB CHAIRPERSON, INSTITUTIONAL OFFICIALS | | | | | |
| LAST REVIEWED ON: | | / / | | RESULTS: | REVISED | | |
| APPROVAL AUTHORITY: | | Associate Vice President for Research | | | | | |
| APPROVED BY: | | | | | | DATE: | / / |

1. POLICY

In the environment of research, openness and honesty are indicators of integrity and responsibility, characteristics that promote quality research and can only strengthen the research process. Therefore, conflicts of interest should be eliminated when possible, and effectively disclosed and managed when they cannot be eliminated.

2. SPECIFIC POLICIES**2.1 Definitions**

Conflict of Interest: A conflict of interest occurs when an employee is involved in an activity, commitment, or interest that could adversely affect, compromise, or be incompatible with the obligations of the employee to the University of North Dakota. A conflict can involve commitment of time, research integrity, or financial gain.

A **conflict of time commitment** means employee involvement in and commitment to unauthorized non-university activities that interfere with obligations to students, colleagues, and the primary mission of the University.

A **conflict of research integrity** means any obligation between an employee and an external entity that is in conflict with the employee's obligations to the University, or that restricts or impairs the employee's ability to perform research or other activities at the University.

A **conflict of financial interest** means influencing the University in such a way as to lead to unauthorized direct or indirect financial gain for the employee or any member of the employee's close family (spouse and/or dependent children). Conflicts of financial interest may arise when a person who has a significant financial interest in a non-university entity a) can also influence or approve purchase of goods or services worth more than \$10,000 per year in their university role, or b) is responsible for the design, conduct, or reporting of research supported by federal agencies.

The term **significant financial interest** means anything of monetary value, including, but not limited to: salary or other payments for services (e.g., consulting fees, honoraria); equity interests (e.g., stocks, stock options, patents, copyrights, other ownership interests); and non-University royalties from intellectual property rights

(e.g., patents, copyrights, trade secrets, and trademarks). Any of these conflicts of interests of any IRB member, Consultants to the IRB, or staff, or his or her immediate family, in aggregate. (The thresholds described apply to the aggregate ownership of IRB members or staff and his or her immediate family. For example, if an IRB member or staff, his/her spouse, and dependent children own together \$10,000 or 5% worth of equities in the sponsor).

The term does **not** include:

1. remuneration from the University of North Dakota including such things as salary and royalties derived from copyrights or patents arising from University-related work;
2. income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
3. income from service on advisory committees or review panels for public or nonprofit entities;
4. an equity interest that when aggregated for the employee and the employee's spouse and/or dependent children meets both of the following criteria: does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than a five percent ownership interest in any single entity;
5. salary, royalties or other payments that when aggregated for the employee and the employee's spouse and/or dependent children over the next twelve months, are not expected to exceed \$10,000.

2.2 Financial and Non-Financial Criteria

The criteria for financial and non-financial potential conflicts include but are not limited to, when a member of the research team:

- Has a financial interest in the research with the value that cannot be readily determined;
- Has a financial interest in the research with the value that exceeds a specified monetary threshold (\$10,000);
- Has received or will receive compensation with value that may be affected by the outcome of the study;
- Has a proprietary interest in the research, such as a patent, trademark, copyright, or licensing agreement;
- Has received payments from the sponsor that exceed a specified monetary threshold in the past year;
- Is an executive, serves on the board (Advisory, Trustee, committee member) or is a Director of the agency or company sponsoring the research;
- Has an interest that the IRB members believe conflicts with his or her ability to objectively review a protocol; or
- Has an interest that the IRB member or others perceive may conflict with his or her ability to objectively review a protocol.

2.3 Disclosure and Documentation of Financial Interest and COI

No regular or alternate IRB member may participate in the initial or continuing review of any expedited or full Board research project in which the member has a conflict of interest, except to provide information as requested. It is the responsibility of each voting member or alternate

member of the IRB to identify and disclose any potential COI in a study submitted to the IRB and recuse himself or herself from deliberations and voting. An IRB member is said to have a conflicting interest whenever that IRB member or the spouse or dependent child of the member:

- Is an investigator, sub-investigator, or any other member of the research staff on the protocol.
- Is involved in the design, conduct, or reporting of the research.
- Has entered into a financial arrangement with the sponsor or agent of the sponsor, whereby the outcome of the study could influence the value of the economic interest.
- Acts as an officer or a director of the sponsor or an agent of the sponsor.
- Has any equity interest in the sponsor exceeding \$ 10,000 (aggregated from PI and immediate family) or 5% of the equity of the sponsor.
- Has received any payments of other sorts from the sponsor that total \$10,000 or more within one calendar year (as the benchmark for “significant financial interest”)
- Has identified themselves for any other reason as having a conflicting interest.

At the discretion of the IRB, the IRB member may be in the room to provide information requested, but must leave during deliberations and voting. When an IRB member leaves the room for a conflicting interest, the minutes will state the name of the IRB member, the time they left the room and returned, and the reason they were absent for discussion and voting was due to a conflict of interest.

2.4 Consultants

Consultants will be required to complete the Financial Interests Disclosure Document, and to declare if they or a member of their immediate family is a member of the research team designing, conducting, or reporting the research presented in the protocol. The Associate Vice President for Research and the IRB Chairperson will review the form for potential COI. Consultants with a declared conflict of interest may provide information as requested, although they must declare the conflict to the board before providing the information.

2.5 Employees

The University of North Dakota staff whose job status or compensation is impacted by research that is reviewed by the IRB must recuse themselves from that portion of a meeting at which such a protocol is reviewed. Questions regarding COI for Investigators may be referred to the Conflict of Interest Committee.

The Vice President for Research has the authority to determine when a potential COI exists as defined by institutional policy and to impose and enforce disciplinary action in the event that COI is not disclosed.

3. RESPONSIBILITY

The Vice President for Research is responsible for articulating and enforcing the conflict of interest policy (COI) at the University of North Dakota.

The Associate Vice President for Research is responsible for enforcing the COI policy at the University of North Dakota.

The Associate Vice President for Research is responsible for monitoring the COI status and disclosures of IRB members.

The IRB Chairperson or IRB Vice Chairperson is responsible for identifying COI disclosures before beginning every IRB meeting.

The IRB Secretary is responsible for documenting all COI disclosures in IRB meeting minutes.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.103, 107

21 CFR 56.107

[FDA Information Sheets, FAQ's, Section II, question 12](#)
[University of North Dakota Conflict of Interest Policy](#)

5. ATTACHMENTS

GA 106-A Conflict of Interest Forms

6. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

| Who | Task |
|---|---|
| <i>IRB Members</i> | Disclose all financial and professional COI to the Associate Vice President for Research when joining the IRB, and periodically update that information. Recuse self from IRB deliberations where a COI exists or may appear to exist. |
| <i>IRB Secretary</i> | Document COI disclosures in IRB meeting minutes. |
| <i>Associate Vice President for Research, IRB Coordinator</i> | Maintain documentation of IRB member COI via disclosure forms and meeting minutes. |
| <i>IRB Chairperson, IRB Secretary, IRB Members</i> | Ensure that IRB members with a COI do not participate in the IRB deliberations subject to their COI disclosures. |