INDIANA UNIVERSITY BLOOMINGTON

Procedures for Regulation of Financial Conflicts of Interest

(By Action of Bloomington Faculty Council: April 2, 2002; Amended December 3, 2002)

The following campus procedures implement the University's Policy on Conflicts of Interest, including the creation of a Bloomington Campus Conflicts of Interest Committee.

A. **Adoption of Local Procedures**

1. Except as otherwise provided in the provisions of this Section A, paragraph 2, and Section C below, specific procedures for disclosure of financial conflicts of interest by faculty should be developed and implemented at the school/unit level on Bloomington Campus.
2. All procedures shall be consistent with the University's Policy on Conflicts of Interest, adopted by the Trustees of Indiana University in September 2000, and any amendments duly adopted thereto (the "COI Policy"), and shall provide for:
    a. Annual reports by all faculty of "significant financial interests," as defined in the COI Policy. Such reports shall be made at the beginning of each fall semester on uniform disclosure forms provided by the Conflicts of Interest Committee referred to in Section B below (the "COI Committee"). Such unit procedures shall also require update reports as specified in Sections 5 (b) and (c) of the COI Policy.
    b. Submission of all annual reports and any update reports to the Office of Sponsored Research for review. Such submission may be either after a first level of review at the department or school level or as the initial review.
    c. Mechanisms for recusal of any reviewer of a disclosure report who has an actual or perceived conflict of interest.
    d. Procedures to assure that all persons involved in the design, conduct or reporting of federally funded research or instructional projects (e.g., technicians, students, post-doctoral fellows) report any significant financial conflict of interest.
    e. the forwarding of all reports that, in the opinion of either the initial reviewer or the Office of Sponsored Research, raise or disclose an actual, potential or an apparent conflict of interest to the COI Committee for further review and recommendation.
    f. Procedures for written notification to any faculty member or other employee of the recommendations of any school or department reviewer and opportunity for response by the faculty member or employee. Such response shall be forwarded to the Office of Sponsored Research and made part of any further review by that Office and by the COI Committee.

g. Procedures for assuring that (i) all information disclosed will be held confidential to the extent possible under the law; (ii) information will only be disclosed to those with a need to know or as a requirement of law or regulation, and (iii) information will not be part of the collection of unrelated information, such as faculty annual reports.

h. the maintenance by the schools of records, which shall be retained for three years after the latest of: (i) the termination or completion of any contract or award to which they relate (as determined by the funding agency); (ii) termination or completion of the research or educational activity to which the disclosed conflict relates; (iii) the resolution of any action involving those records.

i. Maintenance of aggregate data, as is necessary for purposes of the University's oversight obligations under federal law.

B. **Creation of the Conflicts of Interest Committee**

1. *Membership.* The Conflicts of Interest Committee shall be composed of:

i. four tenured faculty members appointed by the Bloomington Faculty Council nominations committee;

ii. the associate deans for research of the following schools: College of Arts & Sciences, Kelley School of Business, School of Education, School of Informatics and the School of Optometry;

iii. the chair, a tenured faculty member, who shall not be one of four members referred to in clause (i) above, jointly appointed by the Bloomington Faculty Council Nomination Committee and the Vice President for Research;

iv. a community representative; and

v. University Counsel and the Assistant Vice President for Research, or their delegees, who shall be non-voting, ex-officio members.

2. *Terms.* COI Committee Members (other than those persons referred to in clauses (ii) and (v) above) shall be appointed for staggered two-year terms, with two groups of three. Such members may be reappointed to two additional terms.

3. *Jurisdiction.*

. (i) The committee shall oversee the uniform disclosure process for the faculty (and such other members of the university community as are deemed appropriate by the COI Committee), (ii) review disclosures and develop management plans or other means for resolving actual or potential conflicts; (iii) consult with appropriate administrative officials in the development of such plans; (iv) coordinate with the campus Institutional Review Board(s) to resolve and manage conflicts of interests arising in human subjects-based research; (v) review and approve unit conflicts procedures; (vi) help conduct and support education of faculty, staff, and students on conflicts issues; and (vii) collect aggregate

data for the campus regarding conflicts and provide that data to the Vice President for Research for compliance oversight purposes.

a. In the performance of its duties under Section 3(a)(ii), the COI Committee may impose conditions or restrictions to manage or resolve a conflict. Such conditions or restrictions may include, but are not limited to: public disclosure of significant financial interests; monitoring of research by independent reviewers; modification of the research plan; disqualification from participation in all or part of a project in which an actual or potential conflict exists; divestiture of significant financial interests; and severance of relationships that create actual or reasonably perceived conflicts of interest.

4. *Procedures.*

. The COI Committee shall develop, within thirty calendar days of its formation, procedures for review, disclosure and management of conflicts of interests. Those procedures shall provide for (i) written notification to the faculty member or other employee of its determinations; and (ii) opportunity for the employee to respond.

a. All efforts shall be made to resolve conflict issues informally. If the COI Committee and a faculty member or other employee, however, fail to agree as to whether there is an actual or potential conflict, or fail to agree on a plan of disclosure and management, the final determination shall be made by the Vice President for Research, upon consultation with the appropriate school dean.

b. The procedures shall provide for the maintenance of confidentiality of disclosure information consistent with the COI Policy.

c. The COI Committee's procedures shall be presented to the Bloomington Faculty Council for immediate action. Until such time as the procedures are approved by the Bloomington Faculty Council, the procedures presented shall serve as interim procedures for purposes of resolving issues that come before the Committee.

d. The COI Committee shall report annually to the Bloomington Faculty Council and to the Vice President for Research on matters within its jurisdiction.

C. **Faculty Responsibilities.**
The following provisions shall apply to all faculty on the Bloomington Campus and may not be modified by any school's procedures:

1. All faculty members shall report annually on the forms provided by the COI Committee whether or not they have any financial conflicts of interests. This reporting requirement also applies to all other persons in the design, conduct or reporting of federally funding research or instructional projects.

2. A faculty member shall disclose in a timely manner to the appropriate school dean and to the COI Committee his or her assumption of an executive position or membership on the Board of Directors of a private entity engaged in a business that (a) is related to the research activities of

such faculty member, or (b) competes with, or provides services to, the University.

3. A faculty member engaged in research shall disclose any significant financial interests he or she has that are related to such research at the time of submission of a manuscript for publication, and to any audience when presenting research results.

4. Proposed agreements with private entities (the "Sponsors") (and to which the University is not a Party) to provide consulting or collaborative research services that contain in substance one or more of the following types of provisions shall be submitted to the COI Committee for approval prior to being entered into:

    . provisions that restrict publication of research results beyond 90 days after submission to the Sponsor;

    i. Provisions that restrict or limit the faculty member's ability to do other research at the University.

    ii. Provisions that require faculty to assign students, post-doctoral fellows or other University employees to the Sponsor's research or other projects.

    iii. Provisions for commitment of future intellectual property rights to the Sponsor, to the extent such commitment conflicts with the University's Intellectual Property Policy or with the publication rights of the University with respect to research.

5. With respect to any agreement brought to the COI Committee pursuant to Section C (4) above, the COI Committee shall notify the faculty member and the appropriate school dean, in writing, within 15 working days of its receipt of the proposed agreement, of its approval or its specific objections to the agreement as drafted. A copy of the notice shall also be sent to the Vice President for Research.
   If informal negotiations fail to result in an agreement satisfactory to the parties to the contract and the COI Committee, the Vice President of Research, in consultation with the school dean and the University Research Policy Committee, shall make a final determination as to whether to approve of the contract agreement.

D. **Enforcement.**
   Instances of breach of these procedures or any school procedures adopted pursuant to this resolution of the Bloomington Faculty Council, including failure to file as required or knowingly filing an incomplete, erroneous, or misleading disclosure form; violation of the standards set forth in these procedures; or failure to comply with prescribed requirements for resolution of conflicts will be adjudicated in accordance with applicable disciplinary policies of the Bloomington campus and of Indiana University. These policies include the rights of faculty as are provided by the rules governing appeals to the Faculty Board of Review. Possible sanctions include, but are not limited to the following:

a. formal admonition;

b. inclusion in the faculty member's file of a letter from the appropriate dean indicating that the individual's good standing as a member of the academic community

(faculty member, research scientist/scholar, professional staff, student, etc.) has been called into question. Such information can be used, for example, in establishing annual salaries and for decisions on such conditions of employment as promotion and tenure, graduate student support, etc.;

c. ineligibility of the faculty member for submitting grant applications, requests for Institutional Review Board (IRB) approval, or supervision of graduate students;

d. report to the Research Integrity Officer of possible research misconduct;

e. nonrenewal of appointment;

f. Initiation of due process for dismissal from the University.