INDIANA UNIVERSITY BLOOMINGTON

Bylaws of the Bloomington Campus Conflicts of Interest Committee

(By Action of the Bloomington Faculty Council: December 3, 2002)

Article I. NAME

The name of the committee is the Bloomington Campus Conflicts of Interest Committee (hereinafter called "COI Committee").

Article II. OBJECT

The purpose of the COI Committee is to assist with implementation of the portions of the Conflicts of Interest Policy of Indiana University, adopted by the Board of Trustees in September 2000, and any amendments thereto (the "Policy"), addressing financial conflicts of interest relating to research. Financial conflicts of interest relating to research include "real" conflicts, or conflicts that exist currently, and "apparent" conflicts, or conflicts that a reasonable person would perceive to exist. A financial conflict of interest relating to research is present when an individual's external financial interests, or the interests of external entities in which the individual participates financially, reasonably would appear to directly and significantly affect, or be directly and significantly affected by, the individual's research or teaching activities at Indiana University.

The Committee shall have no authority or responsibility for addressing conflicts of commitment, as that term is defined in the Policy.

Article III. AUTHORITY

The COI Committee is established under and pursuant to a resolution of the Bloomington Faculty Council (Circular B22-2002)(the "BFC Procedures"), and is empowered to:

(a) (i) oversee the uniform disclosure process for the faculty (and such other members of the university community as are deemed appropriate by the COI Committee) regarding financial conflicts of interest;

(ii) review disclosures in which real or apparent financial conflicts of interest have been identified by the unit, by appropriate personnel within RUGS, or by the Committee; and develop management plans or other means for resolving real or apparent conflicts;

(iii) consult with appropriate administrative officials in the affected unit(s) and RUGS, and with the affected faculty member or other member of the university community, in the development of such plans;

(iv) coordinate with the campus Institutional Review Board(s) to resolve and manage real or apparent financial conflicts of interests arising in human subjects-based research;

(v) review and approve unit procedures regarding review of financial conflicts of interest disclosures, and any management plans or other means proposed by units for resolving identified real or apparent conflicts;

(vi) help conduct and support education of faculty, staff, and students on financial conflicts of interest issues; and

(vii) collect aggregate data for the campus regarding financial conflicts of interest and provide that data to the Vice President for Research for compliance oversight purposes.

(b) In the performance of its duties under paragraph (a) above, the COI Committee may impose conditions or restrictions to manage or resolve a real or apparent conflict. Such conditions or restrictions may include, but are not limited to: disclosure to the public or to a specified person or persons of appropriate information regarding external financial interests that create a real or apparent conflict; monitoring by independent reviewers of research performed by someone with a real or apparent conflict; modification of the research plan with respect to research performed by someone with a real or apparent conflict; disqualification from participation in all or part of a project in which an actual or potential conflict exists; and divestiture of external financial interests that create a real or apparent conflict (as a condition of continuing to participate in University research or other University activities in which the conflict is presented).

(c) The COI Committee is authorized to collect sufficient information to allow it to identify the existence and extent of a real or apparent financial conflict of interest and the feasibility of options for resolving or managing such conflict. The COI Committee shall keep all such information (including information disclosed on annual disclosure forms) confidential except to the extent that disclosure is required by law or University policy or is necessary for the discharge of the Committee's responsibilities. The COI Committee may execute pledges or agreements of confidentiality or non-disclosure with regard to information collected by third parties, to the extent permitted by law and University policy and consistent with the discharge of the Committee's responsibilities.

Article IV. MEMBERSHIP

The COI Committee's membership shall consist of:

(a) four tenured faculty members appointed by the Bloomington Faculty Council nominations committee;

(b) 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;

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

(d) a community representative; and

(e) University Counsel and the Assistant Vice President for Research, or their designees, who shall be non-voting, ex-officio members.

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

Members shall receive no compensation.

Article V. OFFICERS

The Vice President for Research and the Bloomington Faculty Council Nomination Committee shall jointly appoint a chairperson of the COI Committee. The chairperson shall be a voting member of the COI Committee. The chairperson may appoint an acting chairperson to function in his or her absence.

Article VI. MEETINGS

The Committee shall meet at least monthly throughout the academic year unless a meeting is cancelled by the chairperson for good cause. Notice of time and place shall be given at least one week in advance. The chairperson may call a special meeting upon three days written, electronic or telephonic notice.

Minutes of each meeting shall be kept by the COI Committee's conflicts of interest compliance officer.

Meetings may only proceed with a quorum, which shall consist of a simple majority.

Article VII. CONFLICTS REVIEW PROCESS

No member shall participate in the discussion, management or resolution of any individual's real or apparent financial conflict if that member him- or herself has a real or apparent financial or non-financial conflict of interest related to the matter under review. A "non-financial conflict of interest" refers to a relationship between the member and the individual, or other circumstances, that reasonably appear to compromise the impartiality of the member's decision making regarding the individual. A faculty member or other individual whose real or apparent conflict is being reviewed by the COI Committee is hereinafter referred to as the "Interested Person."

In the review process, the COI Committee shall attempt to manage and resolve conflicts in as informal a manner as possible. The COI Committee shall seek for consensus. If this cannot be obtained, the appropriate course of action to be taken shall be determined by a simple majority of those attending the meeting.

Each COI Committee member, other than the two ex officio members referred to in Article IV(e), shall have one vote. Voting shall proceed openly within the Committee, after an opportunity for full discussion and debate has been afforded.

The Assistant Vice President for Research shall provide to the COI Committee disclosures of outside financial interests for review and action in the following circumstances:

(i) the Interested Person's unit or the Office of Research believes that the disclosure presents a real or apparent conflict of interest and that resolution or management of the conflict is required;

(ii) the Interested Person's unit or the Office of Research seeks the COI Committee's guidance on whether or not a disclosure presents a real or apparent conflict.

Reports of real or potential conflicts of interest will first be reviewed by the appropriate unit (department, school, or college) in accordance with the approved procedures for managing conflicts of interest within the unit. The responsible unit administrator will make a finding with regard to the report and attempt to develop a plan for resolution or management of the conflict with the involved faculty and/or staff members involved. If the unit makes a finding of "no conflict", its finding will be forwarded to the Conflict of Interest Committee for its review. If the unit makes a finding of a "conflict" and is able to formulate a plan for resolving and/or managing the conflict, its findings and plan for resolving and/or managing the conflict will be forwarded to the Conflict of Interest Committee for its review. If the unit makes a finding of a "conflict" and is unable to arrive at a plan for resolving and/or managing the conflict, its findings and recommendations for resolution will be forwarded to the Conflict of Interest Committee for its action.

The COI Committee will provide written or electronic notice to the Interested Person whose real or apparent conflict is under review, of any preliminary determinations the COI Committee makes regarding (1) the existence of a real or apparent conflict; and (2) appropriate steps for resolving or managing that conflict, within five working days of the COI Committee's meeting. Such Interested Person may respond in writing (including electronic writing) to the COI Committee's preliminary determinations within ten working days after receipt of the notice. Alternatively, the Interested Person may request to meet with the COI Committee at its next regular meeting or at a special meeting to answer questions or address issues of the COI Committee.

In the event that the COI Committee and the Interested Person cannot agree as to (i) whether a real or apparent conflict exists, or (ii) how to resolve or manage such conflict (including issues of membership on any management committee that the COI Committee proposes to appoint for oversight purposes, under Article XI below), the COI shall issue its final determination. The Interested Person may appeal to the Vice

President of Research by giving written notice to the Vice President for Research, with copies to the Chairperson of the COI Committee and the appropriate school dean within ten working days of the written notification of the final determination by the COI Committee.

The COI Committee shall use its best efforts to reach a final determination as to any real or apparent conflict referred to them within sixty calendar days of receipt of the referral of the issue from RUGS. In all cases, the COI Committee will comply with applicable deadlines under federal or state law with respect to resolving conflicts and reporting the resolution of conflicts.

Failure of an individual to cooperate with the Committee in an effort to delay or interfere with the Committee's resolution of a financial conflict of interest under its jurisdiction shall be reported to the Vice President for Research for further action consistent with Section D of the Procedures adopted by the Bloomington Faculty Council, entitled "Enforcement."

Article VIII. SUBCOMMITTEES

The chairperson shall, if necessary, appoint subcommittees from the COI Committee membership to execute various duties related to the objectives and policies of the COI Committee.

Article IX. PARTICIPATION OF NON-MEMBERS

The COI Committee, or an Interested Person, may propose that the Committee invite persons who are not Committee members to attend a meeting, to provide the Committee with information that is relevant or necessary to its review and analysis. No person outside the Committee has a right to attend Committee meetings, and no person outside the Committee shall be permitted to attend a meeting without the consent of the chairperson. Persons who may be invited by the Committee to attend a meeting ordinarily would be the Interested Persons themselves, or others with special expertise needed by the COI Committee, including but not limited to unit executives of the relevant unit(s) and personnel from the Advanced Research and Technology Institute. As specified in Article VI above, an Interested Person may request to meet with the COI Committee after such Interested Person has received notice of the COI Committee's preliminary findings. The COI Committee may also request that an Interested Person attend a meeting of the COI Committee to discuss resolution of a conflict or other matter before the COI Committee.

Article X. RECORDS

The chairperson shall see that proper records are maintained, specifically: (a) minutes of each meeting with the names of those present, the issues and disclosure reports reviewed, a summary of the discussion of the issues, other COI Committee actions and discussion, (b) copies of notification of COI Committee action and any other relevant data; (c) annual disclosures and any updates thereto; and (d) correspondence.

COI Committee members will be provided with the minutes of the last meeting in advance of the next meeting. The minutes shall be kept in perpetuity.

No information relating to work performed under these bylaws, including the minutes of COI Committee meetings, shall be disclosed except as needed to resolve or manage an identified real or apparent conflict of interest or as otherwise required by law or University policy. All such reports, contracts and plans shall be kept in locked cabinets in the RUGS offices, and only the chairperson, the compliance officer, the Assistant Vice President for Research, and the Associate Dean for Research Compliance, shall have keys to such cabinets.

Article XI. ONGOING REVIEW OF CONFLICTS

Certain real or apparent financial conflicts of interest may require ongoing review and management. In such instances, the COI Committee may exercise its discretion in deciding how to structure a viable monitoring plan. It may, for example, appoint "management committees," composed of at least four members, of whom one shall be a COI Committee member, one shall be from RUGS, one shall be a person from the same discipline as the individual whose conflict is the subject of management, and one shall be the appropriate unit head, as determined by the COI Committee. All such persons shall be free of any financial or non-financial conflict of interest, as defined in Article VI hereof.

Other conflict management arrangements may be less formal.

Management committees and others providing ongoing review of financial conflicts shall report to the COI Committee as required under the terms of the relevant management plan, but at least annually. Copies of the annual report of a reviewer or management committee shall be sent to the Interested Person and to the appropriate school dean. Any monitors, including management committees, may consult with the COI Committee and other University officials and affiliates (such as Advanced Research and Technology Institute), as well as with other experts, as necessary to determine the extent of adherence to the terms of the relevant management plan, and whether or not modifications to the plan may be necessary to resolve or manage conflicts that have already been identified or are identified through the review process. The COI Committee may develop operational guidelines for management committees.

Any concerns or complaints by the Interested Person regarding any actions by a reviewer or management committee should be addressed first to the reviewer or management committee, and if the concern or complaint persists, to the COI Committee. If the COI Committee is unable to resolve the concern or complaint, it shall refer the matter to the Vice President for Research.

Article XII. SECTION C SPONSOR AGREEMENTS

Under Section C(3) of the BFC Procedures certain proposed agreements must be submitted to the COI Committee for approval prior to being entered into by a faculty member.

Upon receipt of any such agreement, the Chairperson shall determine whether or not a special meeting is necessary or appropriate to discuss the agreement, or whether the matter can be addressed at the next regular meeting of the COI Committee. If the Chair concludes that a special meeting is necessary or appropriate, the Chair will call the

meeting within ten working days after receipt of the proposed agreement from the faculty member.

The COI Committee will notify the faculty member in writing of its approval or its specific objections within fifteen working days of its receipt of the proposed agreement, with a written copy sent to the Vice President for Research and the appropriate school dean.

If the COI Committee has objections to the terms of the agreement that come within the scope of Section C(3) of the BFC Procedures, the Chairperson shall appoint a Committee member or subcommittee to meet informally with the faculty member to review the Committee's objections and to negotiate terms that would not pose a conflict of interest for the faculty member. Such terms shall be submitted to the full COI Committee for approval, within 10 working days after submission by the member or subcommittee.

In the event that (i) either no agreement can be reached pursuant to this Article XII, or (ii) the full COI Committee does not approve of the proposed revised terms, the matter shall be referred to the Vice President for Research for resolution pursuant to Section C(4) of the BFC Procedures.

In its review of Section C(3) Sponsor Agreements, the COI Committee will, to the extent possible, restrict its review and comments to the provisions of the contract specified in the BFC Procedures. Any information concerning a Sponsor Agreement and the Agreement itself will be held confidential to the extent possible under the law and University Policy and consistent with the discharge of the Committee's responsibilities. The COI Committee may execute pledges or agreements of confidentiality or non-disclosure with regard to Sponsor Agreements, to the extent permitted by law and University policy and consistent with the discharge of the Committee's responsibilities.

Article XIII. EXTENSIONS OF TIME

The COI Committee may, for good cause shown and by a simple majority vote, approve reasonable extensions of any deadlines in these bylaws; however, no extension shall be inconsistent with the fulfillment of the University's obligations under applicable law.

Article XIV. REPORTS

The COI Committee shall submit an annual report to the Vice President of Research and to the Agenda Committee of the Bloomington Faculty Council in November of each year. Such report shall contain data as to the numbers of conflicts reviewed and the nature of resolutions and data as to any trends. The report shall cover the previous academic year.

The COI Committee will assist, and coordinate with, the Vice President of Research in assuring full compliance with all federal reporting requirements with respect to conflicts of interest.