

INDIANA UNIVERSITY

Policy on Financial Conflicts of Interest in Research

(By Action of the University Faculty Council: September 12, 2000, March 9, 2004, April 27, 2004;

Approved by the Board of Trustees: September 15, 2000, March 3, 2006)

The trustees, administration, faculty, and staff of Indiana University all bear the responsibility of serving the research mission of the University. That mission is enhanced by the sustained, active interaction of members of the University community with business, government, not-for-profit groups, professional societies, academic institutions, and other individuals and organizations. Moreover, the University recognizes that the members of the University community participate actively in community, political, religious, and cultural activities and institutions, and other personal and economic endeavors.

These many interactions inherently create the potential for conflicts of interest in which University employees' external activities, income or other interests affect—or reasonably would appear to affect—the manner or extent to which those individuals pursue research within the University. Such real or apparent conflicts, when not appropriately disclosed and addressed, can undermine public and professional confidence in the integrity of University research and sponsored programs. The existence of a real or apparent conflict of interest does not necessarily mean that the outside activity at issue must be avoided or discontinued. Often, conflicts of interest can be dealt with effectively through disclosure or other steps to resolve or manage the conflict.

This document sets forth University policy on the avoidance, disclosure, management, and resolution of financial conflicts of interest regarding University research and sponsored programs. Recognizing the broad variety of both professional settings in which conflicts may occur and means of responding to them, this policy specifies only the basic principles that should guide the resolution of financial conflicts of interest. Specific requirements necessary to conform with federal law regarding financial conflicts of interest in federally funded research, including the conflicts of interest regulations issued by the national Institutes of Health at 42 C.F.R. Part 50.601 et seq., and the National Science Foundation in its Grant Policy Manual at Section 310, are detailed in a separate Statement of Compliance with Federal Conflicts of Interest Rules, which is at: http://www.indiana.edu/~deanfac/acadhbk/acad_handbk_2002.pdf. It is the responsibility of the Chancellors to ensure that each Campus, or all of the Schools or Departments within a Campus, adopt specific conflict of interest procedures, consistent with University policy and Federal and State law.

This document only addresses financial conflicts of interest in research, whether externally sponsored or internally funded, and sponsored programs. There are other areas in which financial conflicts may arise, such as the assignment to Indiana University students of textbooks or materials for which a faculty member received royalties, and other types of conflicts, such as conflicts of commitment, when outside activities interfere with someone's fulfillment of his or

her University responsibilities. These matters are addressed in other University policies, which are listed in Appendix A to this policy [Appendix A and the Statement of Compliance may be updated or revised from time to time.]

1. Applicability

This Policy applies to all persons at IU who are “Investigators” on University research projects or sponsored programs, as defined in Section 2 below. An “Investigator” is anyone who participates in designing research, collecting research data or performing other substantive research activities, or reporting research; and anyone who participates in designing, conducting, or reporting with respect to a sponsored program. Investigators may include: (1) academic appointees; (2) staff or students who are involved in the design, conduct, or reporting of research or sponsored programs; and (3) emeritus faculty to the extent that they still actively perform research or sponsored programs under the auspices of the University.

2. Definitions

- a. “Activities outside of the University” and “outside activities” are defined as activities not directly undertaken to fulfill the research, teaching, and service mission of the University.
- b. “University activities,” by contrast, are defined as activities that are undertaken directly to fulfill one’s research, teaching, or service responsibilities within the University.
- c. “University responsibilities” are defined as the responsibilities of a University employee to perform University activities as defined by University or unit policy, contract, or collective bargaining agreement.
- d. A “Conflict of Interest” exists when a Covered Person’s Significant Financial Interests, or the interests of outside entities in which a Covered Person holds a Significant Financial Interest, reasonably would appear to affect or be affected by the Covered Person’s research or sponsored programs.
- e. “Covered Persons” means persons to whom this Policy applies, as specified in Section 1.
- f. “Dependent” is defined as any person who receives more than one-half of his or her annual support from an employee, whether or not related to that employee.
- g. “Disclosure Period” means the one-year period immediately following the date on which the Covered Person completes a disclosure of outside significant financial interests.
- h. “Family Members” are defined as the member’s spouse or domestic partner under Indiana University procedures and dependent children.
- i. “Financial Interest” is defined as anything of monetary value, including, but not limited to, salary, commissions, consulting fees, honoraria, equity interests, interests in real or personal

property, dividends, royalties, rent, capital gains, intellectual property rights, and forgiveness of debt, other than:

- compensation from Indiana University, except that royal income distributed under the University Intellectual Property Policy *shall* be considered a “Financial Interest”;
- income from seminars, lectures, or other educational activities sponsored by not-for-profit entities;
- income from service on advisory committees, or review panels for public or not-for-profit entities; or
- any financial interest arising solely by means of investment in a mutual, pension, or other institutional investment fund where the Covered Person does not exercise control over the management and investments of such fund;
- any ownership interests in an entity that is an applicant under Phase I of the SBIR or STTR Programs. Ownership interests in entities that apply for funding under later phases of the SBIR or STTR Programs, however, are included in the definition of “financial interest.”

j. “Indiana University” or the “University” shall refer to Indiana University and to any foundation associated with Indiana University.

k. “Investigator” means the principal investigator and any other person who participates in the design, conduct, or reporting of research.

l. A financial interest is “significant” if:

- it is an equity interest the value of which exceeds \$10,000 from one enterprise or entity, or represents more than a 5 percent ownership interest in any one enterprise or entity, when aggregated for the member and his or her Family Members for the Disclosure Period; or
- it is salary, royalties, or similar payments which exceed, or are expected to exceed, \$10,000 within any one-year period, when aggregated for the member and his or her Family Members.

However, Covered Persons engaged in medical or clinical trial research shall disclose all financial interests of themselves, or of outside entities in which they hold significant financial interests, that reasonably would appear to affect or be affected that research, without regard to any monetary threshold.

m. “Research” means a systematic investigation designed to develop or contribute to generalizable knowledge. The term encompasses basic and applied research and product

development. As used in this Policy, “research” includes both externally and internally funded activities.

n. “Sponsored Programs” means projects or activities, other than research, undertaken within the University pursuant to funding from an external source.

o. “SBIR Program” means the Small Business Innovation Research Program, an extramural research program for small business that is established under federal law.

p. “STTR Program” means the Small Business Technology Transfer Program, which is a part of the SBIR Program.

3. Responsibility of Covered Persons

a. University personnel and students who are covered by this Policy share an obligation to conduct their professional affairs in a manner consistent with the University’s mission and to conduct their relationships with each other and with the University with candor and integrity.

b. Pursuant to that obligation, covered persons share an obligation to identify and, when possible, avoid financial conflicts of interest. When conflicts cannot be avoided, covered persons must disclose outside financial relationships that create, or reasonably appear to create, conflicts of interest, and work with University officials to manage or resolve those conflicts.

c. Accordingly, covered persons must disclose any significant financial interest of themselves or their Family Members that reasonably would appear to affect, or be affected by, the University research activities or sponsored programs in which they are engaged, and any financial interest of themselves or their Family Members in external companies or other organizations whose financial interests reasonably would appear to affect, or be affected by, their University research and sponsored program activities.

d. Disclosures under this Policy shall be made as soon as possible after a significant financial interest that meets the disclosure standard of (c) arises. Disclosure shall be made to the official designated by the applicable policies and procedures on conflicts of interest.

e. If any application for external funding is involved, covered persons shall ensure that they have disclosed all significant financial interests related to the proposed research or sponsored program, prior to submitting the application to the applicable University sponsored research office, and as soon as possible thereafter if a new significant financial interest meeting the disclosure standard of (c) arises. Disclosures shall also be updated as soon as possible when an existing significant financial interest ends or materially alters.

4. Federally Funded Research

Federal regulations require institutions receiving federal funding to have in place a written, enforced policy and process to identify and manage, reduce, or eliminate conflicts of interest of persons engaged in the design, conduct, or reporting of federally funded research. The purpose

and specific requirements of Federal law are detailed in the Statement of Compliance, [URL]. This policy, the Statement of Compliance (which is incorporated into this Policy by reference), and the procedures adopted by campuses to implement this Policy and the Statement of Compliance, are intended to meet the requirements of federal law.

5. Disclosure Policies and Procedures

- a. Disclosure shall be made pursuant to the applicable Campus, School, or Department procedures on conflicts of interest. These procedures shall be designed to facilitate the local resolution or management of any conflict, and minimize administrative burden.
- b. All such procedures shall be consistent with the following:
 - i. It is the obligation of each covered person to disclose real or apparent conflicts of interest.
 - ii. Covered persons shall disclose annually all significant financial interests that meet the standards of Section 3(c) above, and they shall update these disclosures within the annual period as soon as possible whenever (a) they acquire a new significant financial interest that reasonably would appear to affect or be affected by their University activities, or (b) an existing significant financial interest ends or materially alters.
 - iii. Covered persons shall not be subject to burdensome or random disclosure requirements; however, this shall not restrict the use of disclosure as a tool for avoiding, resolving, or managing an on-going conflict of interest.
 - iv. Disclosure shall be made to the official designated by the applicable procedures on conflicts of interest. Disclosure policies should require no more information than is necessary.
 - v. Disclosure should not be part of the collection of unrelated data (*e.g.*, annual reports). Disclosure documents shall be destroyed as soon as appropriate and in accordance with applicable legal requirements.

6. Conflict Resolution and Management

- a. Conflicts of interest shall be avoided, resolved, or managed, as needed, pursuant to applicable policies and procedures on conflicts of interest. These policies and procedures shall be designed to meet applicable legal requirements, facilitate the local resolution or management of any conflict, minimize administrative burden, and protect the privacy of University employees and their Family Members.
- b. Any University employee may request advice about a potential conflict of interest from the relevant campus faculty council's conflicts of interest committee, or other office or entity given this authority under local policies and procedures, without being required to disclose his or her

name or identifying details of the potential conflict. Any unit of the University may request advice about a potential conflict of interest from the university designated official or a campus conflicts of interest committee, provided that no more identifying information than necessary should be disclosed unless required by law or University policy.

c. Real or apparent conflicts of interest shall be avoided, resolved, or managed, as needed, locally whenever possible. Each Campus shall determine at what level (Department, School, or Campus) “local” responsibility for conflicts of interests shall reside. Should any unit at a level responsible for managing or resolving conflicts of interest fail to enact appropriate procedures, employees within that unit shall be subject to the conflict of interest procedures of the next highest level (*e.g.*, a School without procedures would follow the procedures of the Campus on which it is located). If a Campus has not enacted conflicts of interest procedures, employees on that Campus shall be subject directly to this Policy and to those procedures applicable to the Bloomington campus.

d. In the event it is not possible to resolve a conflicts issue successfully at the Campus level, the matter shall be referred to the university designated official, advised by the relevant campus conflicts of interest committee or other office or entity given relevant authority under local policies and procedures.

e. The campus Conflicts of Interest Committees or other offices or entities given relevant authority under local policies and procedures, shall be charged with monitoring and recommending changes, as necessary, to the University Policy on Financial Conflicts of Interest; advising units of the University on the development of local conflict of interest procedures; facilitating discussion within the University about, and awareness of, conflict of interest issues; and recommending measures for resolving or managing specific conflict of interest cases.

7. Enforcement

a. Enforcement of this Policy on Financial Conflicts of Interest is the ultimate responsibility of the President and the Board of Trustees, who may delegate that responsibility to other University officials pursuant to this Policy and procedures enacted by individual Campuses, Schools, or Departments. Principal responsibility for implementation and enforcement of this Policy shall reside with the university designated official, advised by the relevant campus conflicts of interest committees or other campus officials with authority for conflicts matters.

b. Violations of this Policy and implementing procedures, including the failure to file timely disclosures; filing incomplete, erroneous, or inaccurate disclosures; or failure to comply with prescribed procedures for managing or resolving conflicts of interest, will be dealt with in accordance with applicable University policies and procedures.

c. Appeals from administrative decisions concerning conflicts of interest are subject to applicable University policies and procedures concerning review of administrative decisions.

Appendix A

Policy on faculty conflicts of commitment in teaching and service: [URL] [*see http://www.indiana.edu/~deanfac/acadhbk/acad_handbk_2002.pdf page 110*, Section 6 of the University Conflict of Interest Policy for the text on conflicts of commitment; this text will be converted to a separate conflicts of commitment policy]

Policy on Outside Activities and Extra Compensation:
http://www.indiana.edu/~deanfac/acadhbk/acad_handbk_2002.pdf

State Law on Conflicts of Interest, Indiana Code 35-44-1-3:
<http://www.in.gov/legislative/ic/code/title35/ar44/ch1.html>

Code of Academic Ethics:
http://www.indiana.edu/~deanfac/acadhbk/acad_handbk_2002.pdf

Policy on Conflict of Commitment (Staff and Hourly Employees): [URL] [*for the most recent version of this policy, contact Dan Rives*]

Policy on Conflicts of Interest (Staff and Hourly Employees): [URL] [*for the most recent version of this policy, contact Dan Rives*]

Purchasing Department Policies on Ethics, including Conflicts of Interest:
<http://www.indiana.edu/~purchase/policies/polindex.shtml>