

# Financial Conflicts of Interest in Research

ACA-74



## About This Policy

Effective Date:

08-24-2012

Last Updated:

10-30-2012

Responsible University Office:

Office of the Vice President for Research

Responsible University Administrator:

Board of Trustees, Indiana University University Faculty Council

Policy Contact:

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## Related Forms

\* [Research-Related Financial Interest Disclosure Form](#)

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## Scope

This Policy applies to all persons at IU who are “Investigators” on University research projects or sponsored programs, as defined below (*see Definitions*).

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## Policy Statement

### 1. Responsibilities of Investigators

- A. Investigators 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, Investigators share an obligation to identify and, when possible, avoid financial conflicts of interest. When conflicts cannot be avoided, Investigators must disclose outside financial relationships that are related to the Investigator’s University Responsibilities and work with University officials to manage or resolve those conflicts.
- C. Accordingly, Investigators must disclose any Significant Financial Interest of themselves or their Family Members that are related to the Investigator’s University Responsibilities, and any Significant Financial Interest of themselves or their Family Members in external companies or other organizations whose financial interests could appear to affect, or be affected by, their University Responsibilities.

- 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 according to the processes established by the University Official.
- E. If any application for external funding is involved, Investigators shall ensure that they have disclosed all Significant Financial Interests related to their University Responsibilities 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 arises. Disclosures shall also be updated as soon as possible when an existing Significant Financial Interest ends or materially alters.

## 2. Federally Funded Research

This policy fulfills federal regulations requiring 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.

In addition, to satisfying applicable requirements of federal law, Investigators must complete training prior to engaging in any Research related to any PHS-funded grant or contract in accordance with 42 C.F.R. Part 50.601 et seq.

## 3. Disclosure Policies and Procedures

- A. Disclosure shall be made to the University Official pursuant to the applicable 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 Investigator to disclose all Significant Financial Interests related to their University Responsibilities.
  - ii. Investigators 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 and within thirty days of (a) acquiring a new Significant Financial Interest that reasonably would appear to affect or be affected by their University Responsibilities, or (b) the end or material alteration of an existing Significant Financial Interest.
  - iii. Investigators 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 or the compliance with annual monitoring by the University Official or designee.
  - iv. Disclosure shall be made to the University 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.
- C. The University Official will determine whether an Investigator's Significant Financial Interest is related to his or her Research or Sponsored Programs activities and, if so, whether the Significant Financial Interest is a Conflict of Interest.
- D. A Significant Financial Interest is related to Research or Sponsored Programs activities when the University, through its University Official, reasonably determines that the Significant Financial Interest:
  - i. Could be affected by the Research or Sponsored Program activity; or,
  - ii. Is in an entity whose financial interest could be affected by the Research or Sponsored Program activity.

## 4. 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 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 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.
- D. In the event it is not possible to resolve a Conflict of Interest successfully at the Campus level, the matter shall be referred to the University Official, advised by the relevant campus conflicts of interest committee or other office or entity given relevant authority under local policies and procedures. The University Official will then determine if the Conflict of Interest must be reduced, eliminated or managed through the development and implementation of a management plan.
- 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.

#### 5. Training

University shall provide Conflict of Interest training to all Investigators receiving funding from the Public Health Service in accordance with C.F.R. Part 50.601 et seq.

#### 6. Public Accessibility

This Policy and disclosure of Investigators' Conflicts of Interest shall be available to the public to the extent required by C.F.R. Part 50.601 et seq.

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## Reason For Policy

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. This Policy includes the requirements necessary to conform to federal law regarding financial conflicts of interest in federally funded research, including the conflicts of interest regulations issued by the U.S. Department of Health and Human Services Public Health Service (“PHS”) and the National Science Foundation.

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.

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## Definitions

1. A “Conflict of Interest” means a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of Research or a Sponsored Program.
2. “Dependent” is defined as any person who receives more than one-half of his or her annual support from an Investigator, whether or not related to that Investigator.
3. “Family Members” are defined as the Investigator's spouse or domestic partner under Indiana University procedures and Dependents.

4. “Financial Interest” is defined as anything of monetary value, whether or not the value is readily ascertainable, 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;
  - income from seminars, lectures, or other educational activities sponsored by a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education;
  - income from service on advisory committees, or review panels for a public federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or
  - an interest arising solely by means of investment in a mutual, pension, or other institutional investment fund where the Investigator does not exercise control over the management and investments of such fund.
5. “Indiana University” or the “University” shall refer to Indiana University.
6. “Investigator” means University faculty and staff who have responsibility for designing research, collecting research data, performing other substantive research activities, or reporting research. Investigator also includes the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of Research funded by the PHS or other federal agencies, or proposed for such funding which may include, for example, collaborators or consultants.
7. “Research” means a systematic investigation designed to develop or contribute to generalizable knowledge. The term encompasses basic and applied research and product development and any activity for which research funding is available from a PHS Awarding Component.
8. “Significant Financial Interest” means one or more of the following Financial Interests of the Investigator (and those of the Investigator’s Family Members) that reasonably appear to be related to the Investigator’s University Responsibilities:
  - With regard to any publicly traded entity, it is the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, the value of which exceeds \$5,000 from one enterprise or entity;
  - With regard to any non-publicly traded entity, it is the value of remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator holds any equity interest;
  - Intellectual property rights and interests, upon receipt of income related to such rights and interests subject to the de minimis thresholds set forth by the federal regulations and guidance;
  - Salary, remuneration, or similar payments which exceed, or are expected to exceed, \$5,000 within any one-year period, when aggregated for the member and his or her Family Members; or,
  - Any reimbursed or sponsored travel, related to an Investigator’s University Responsibilities subject to the de minimis thresholds set by the federal regulations and guidance; provided, however, that Investigators need not disclose travel that is reimbursed or sponsored by a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C 1001(a), an academic teaching hospital, a medical center, or a research institution that is affiliated with an Institution of higher education.
9. “Sponsored Program” means projects or activities, other than Research, undertaken within the University pursuant to funding from an external source.
10. “University Responsibilities” are defined as the responsibilities of an Investigator to perform University activities as defined by University or unit policy, contract, or collective bargaining agreement and, are defined as activities that are undertaken directly to fulfill one’s research, teaching, or service responsibilities within the University.
11. “University Official” is the Vice President for Research who provides oversight in the solicitation and review of disclosures of Significant Financial Interests from Investigators and is the institutional official for purposes of administering the duties outlined in applicable federal regulations.

1. 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 Official, advised by the relevant campus conflicts of interest committees or other campus officials with authority for conflicts matters.
2. 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.
3. Appeals from administrative decisions concerning Conflicts of Interest are subject to applicable University policies and procedures concerning review of administrative decisions.

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## History

This policy was updated in October 2012 to comply with federal regulations and guidance regarding "significant financial interest" (see [Definitions](#)). These changes were approved by the University Faculty Council on October 30, 2012 and went into effect, by approval of the Board of Trustees, on December 6, 2012.

University Faculty Council previously approved this policy on the following dates: 9/12/00, 3/9/04, 4/24/04, 11/24/09, 4/24/2012

The Indiana University Board of Trustees previously approved this policy on the following dates: 9/15/00, 3/3/06, 5/4/2012, 8/17/2012