

Introduction

To address situations when outside interests may overlap or conflict with someone's activities at Indiana University, the University has adopted policies regarding financial conflicts of interest. One such policy applies to researchers at IU Bloomington: the [Indiana University Policy on Financial Conflicts of Interest in Research](#). This Policy recognizes the importance of the research mission to the University and acknowledges that the research mission is enhanced when members of the University community interact with other groups and organizations, including business, government, not-for-profit groups, professional societies, and other academic institutions. In these interactions, there is the potential for a conflict of interest when external activities, income, or other interests may affect or appear to affect the research activity pursued within the University.

Real or even apparent conflicts of interest, when not appropriately disclosed and addressed, can undermine confidence in the integrity of University research and sponsored programs. Additionally, federal law and regulations require Indiana University to have a process in place to manage conflicts of interest involving federally funded research. The policies of Indiana University and the applicable federal regulations recognize that the existence of a potential conflict of interest does not necessarily mean that the outside interest or activity must be avoided or discontinued. Often, potential and actual conflicts of interest can be addressed effectively by disclosure or other steps to resolve or manage the conflict.

To administer the policies and federal regulations on the Bloomington Campus, the Bloomington Faculty Council has adopted Campus Procedures for Regulation of Financial Conflicts of Interest. These Procedures have two major elements:

1. The Procedures require annual disclosures of "significant financial interests" by all faculty and others investigators who conduct research or sponsored program activities.
2. The Procedures establish a Conflicts of Interest Committee (made up of five tenured faculty members, associate deans for research from designated schools, and a community representative) which reviews those annual disclosures that present a potential conflict of interest and has the responsibility for developing, through consultation with the affected researcher and the researcher's unit, management plans or other appropriate means for resolving actual or potential conflicts.

These elements and other components of the Policy and Procedures are described in more detail below.

What you need to know about Conflict of Interest at IU Bloomington

The Office of Research Compliance has drafted this material to be a general summary of the Indiana University policies and how they are administered on the Bloomington campus. If you have questions about this summary or the questions and answers that follow, or questions about how they apply in your specific situation, please contact the Research Compliance Advisor, Stephanie Roberts at (812)856-1706; or Victor Kinzer at

(812)855-7865

Timing of Disclosure

All full or part-time tenured or tenure-track faculty, visiting faculty, and research scientists/ scholars must complete an annual conflict of interest disclosure form whether or not they conduct research at IU. Principal investigators should also ensure that any staff, students, or other employees who participate in the design, conduct, or reporting of research, complete a conflict of interest disclosure form. Additionally, anyone engaged in any sponsored program, whether or not involving research, must complete an annual disclosure form. Forms on file must also be updated during the year whenever interests change.

Disclosing Financial Interests on Your Form

When you are completing your form, you must disclose a financial interest if it meets the following criteria or you expect an interest to meet the following criteria within the next year:

1. You, your spouse, registered domestic partner, or your dependent children (individually or collectively) expect to receive compensation in any form that exceeds \$10,000 in value from an external entity that operates in areas relating to your research. This includes revenue distributions from Indiana University Research and Technology Corporation. It does not include Indiana University salary, whether or not it is funded under a University sponsored program; income from lectures, seminars, or teaching engagements sponsored by public or non-profit entities; or income from service on advisory committees or review panels for public or non-profit entities.
2. You, your spouse, registered domestic partner, or your dependent children (individually or collectively) own or expect to own (other than "indirectly" through a mutual fund) an interest in an external (non-IU) entity that operates in areas relating to your IU research or sponsored programs and your ownership interest exceeds ten thousand dollars (\$10,000) in value or five percent (5%) ownership.
3. For persons engaged in medical clinical trial research, you, your spouse, registered domestic partner, or your dependent children expect to receive compensation in any form or amount from an external entity that operates in areas relating to your research.

Management Plans

If any follow up is necessary, the Office of Research Compliance will perform the follow up with the participation of the Conflicts of Interest Committee. Management plans may be developed between the University and the researcher to address potential conflicts of interest. These management plans are designed to protect the researcher and to comply with the applicable University policies and federal law, if any federal funding sponsors the

researcher's work. Management plans take the form of an agreement with a researcher confirming that the researcher understands the policies that govern the researcher's activity at Indiana University, and it may set out requirements that are tailored to the researcher's specific activity at the University or outside interest.

Frequently Asked Questions

OVERVIEW

Why does Indiana University have the Policy and Procedures to address Conflicts of Interest in Research?

The Indiana University Policies and Procedures have their origins in the conflicts of interest regulations of two federal agencies that provide a significant portion of the University's sponsored research funding, the National Institutes of Health and the National Science Foundation. In 1995, the NIH and NSF issued regulations providing for the disclosure and review of certain outside financial interests held by persons responsible for the design, conduct, or reporting of agency-funded research, and the resolution of any financial conflicts of interest posed by those outside interests. From 1995-2000, the Board of Trustees applied the standards and requirements of the NIH and NSF regulations to all federally funded research at IU.

In 2000, the Board passed a new policy that covered all University research, regardless of the source of funding for such activities (federal, state, private, internal), and all externally sponsored programs, whether or not the program entails research. The 2000 Policy was superseded in 2005 by the Policy of Financial Conflicts of Interest in Research. Accordingly, all University employees are required to make annual disclosures of outside financial interests that reasonably relate to their University research or sponsored programs ("IU Financial Conflicts Disclosure"). The Policy's definitions and standards parallel the NIH and NSF regulations to determine what types of outside financial interests need to be disclosed, the monetary threshold for disclosure (except for medical clinical research, when no monetary threshold applies), whether an outside financial interest poses a financial conflict of interest, and appropriate steps for resolving identified conflicts of interest.

At the heart of the concept of financial conflicts of interest is the concern that outside financial interests may cause someone to perform their University responsibilities, or use University resources, in a manner that serves their outside interest, but does not serve the best interests of the University. The University assumes that all IU faculty and staff will perform their University responsibilities with the highest degree of ethics; we recognize, however, that sponsors of faculty research, state legislators, the press, and other members of the public may suspect the integrity of IU's operations when employees involved in those operations have outside financial interests that could be substantially affected by what they do within IU. The Board of Trustees has adopted this policy to identify and resolve financial conflicts of interest in order to protect our faculty and staff from challenge and to ensure public confidence in the integrity of IU's research.

When does an interest constitute a "conflict of interest" under the Policy and Procedures?

An interest in an outside entity creates a conflict of interest when a person's significant financial interest, or the interests of the outside entity, reasonably would appear to affect or be affected by the person's research or sponsored programs.

For example, Professor Steven Stephens conducts academic research in the area of how autistic children learn. Professor Stephens also owns a company that sells educational materials based on his research for schools to use as instructional materials for autistic children. There is a connection between the interests of the company and the research Professor Stephens conducts at the University; therefore, this conflict needs to be managed.

Sorting through whether or not there is a relationship between an outside interest and someone's research or sponsored programs can be complicated. It is best to err on the side of disclosure if you believe that there may be such a connection or when others might perceive such a connection to exist. To evaluate the interest and whether a conflict exists, it is helpful to describe in detail the relationship between the interest and your University research or sponsored program activity.

Do I need to give up any significant financial interests when there is a real or apparent conflict?

It is rare when a researcher will be required to divest a significant financial interest. Any interest must be disclosed as soon as it is acquired so that it can be managed; but most significant financial interests that create a conflict can be managed effectively through disclosure or other steps that will resolve or manage the conflict. This is typically done through a "Management Plan." The exact terms of the Management Plan will vary depending on the interest and the nature of the research.

COMPLETING THE FORM

Who needs to fill out an annual IU Financial Conflicts Disclosure form?

The following people need to fill out an annual IU Financial Conflicts Disclosure form:

- Full- or part-time tenured or tenure-track faculty
- Visiting faculty
- Research scientists/scholars

Anyone else (including students, whether paid or unpaid, post-docs, research associates, and staff) engaged in the design, conduct, or reporting of University research or other sponsored programs must complete an IU Financial Conflicts Disclosure with respect to the particular research project(s) on which they are engaged. Such disclosures must be made by the time that the research proposal is submitted or, if they are not chosen to work on

the project until after submission, as soon as they are chosen. The IU Principal Investigator on the project is responsible for ensuring that all necessary disclosures have been made and reviewed by the head of the unit in which the research is being conducted.

I am a faculty member and I do not receive any federal funding for my research. Do I still need to complete the annual disclosure form?

Yes. The policies and procedures adopted by the IU Board of Trustees and the University and Bloomington Faculty Council require that all faculty, research scientists/scholars complete the annual disclosure process, whether or not someone does research. The disclosure requirement also applies to anyone who is involved in the design, conduct, or reporting of research, regardless of the source of funding for that research. Principal Investigators are responsible for ensuring that everyone on a research project has completed a Financial Disclosure.

What about conflicts for other University employees like lecturers, teaching assistants, adjuncts, and staff that do not involve research or sponsored programs?

Because these employees typically do not engage in research, their conflicts disclosure and review process may be handled by other offices instead of the Office of Research Compliance. For example, University Human Resources has adopted "All Staff" Personnel Policies regarding [Conflicts of Interest](#) and [Conflicts of Commitment](#), and those will apply to other types of conflicts issues raised by staff of the University. However, any time a lecturer, adjunct, student, employee, or other person affiliated with the University is engaged in the design, conduct or reporting of University research or in sponsored programs, that person must complete an IU Financial Conflicts Disclosure pursuant to the Policy on Financial Conflicts of Interest in Research.

As described in the University Human Resources Personnel Policy regarding [Conflicts of Interest](#), all University employees are covered by the state conflicts of interest statute, and if any employee knowingly or intentionally derives a personal financial interest or profit from a contract or purchase involving the University, the employee should complete the [State Conflicts Disclosure Form](#), following the instructions on the form. Further information on the state conflicts law and state conflicts disclosures is provided in the section below describing the [State Conflict of Interest Law](#).

What do I need to disclose?

You need to disclose any "significant financial interest" (see below) that you, your spouse, registered domestic partner, or your dependent children have (a) that reasonably would appear to affect, or be affected by, your University research or sponsored programs; or (b) in entities whose financial interests reasonably would appear to affect or be affected by, your University research or sponsored programs.

What is a "significant financial interest"?

The definition of a "significant financial interest" comes from the federal conflicts regulations.

A "financial interest" is

anything of monetary value, including but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights, including those paid by Indiana University Research and Technology Corporation/ IURTC).

The term does not include:

1. Salary, royalties, or other remuneration from Indiana University (note that royalties or other payments from Indiana University Research Technology Corporation ("IURTC") must be disclosed);
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;

A "financial interest" is a "significant financial interest" if at the present time OR over the next 12 months, and when aggregated for the employee and the employee's spouse, registered domestic partner, and dependent children it meets one of the following tests:

(1) the interest exceeds a value of at least \$10,000 as determined through reference to public prices or other reasonable measures of fair market value;

(2) an interest represents at least five percent ownership in any single entity; or

(3) the interest relates to your medical/clinical research, in which case an interest in ANY amount must be considered significant.

In other words, if an ownership interest is either worth \$10,000 or constitutes at least 5% of the ownership in the entity, it is a disclosable interest; except for researchers engaged in medical/clinical research, in which case ANY amount must be disclosed when it is received from or represents ownership in an entity related to your field of research.

What are some examples of disclosable interests?

- A biology professor is paid \$20,000 a year to participate in the scientific advisory board of a for-profit biotech company that operates in areas related to the professor's University activities; the professor's duties on the board are to advise on scientific directions that the company might explore and/or to react to specific ideas the company has for new products or directions.
- A computer science professor whose research is focused on computer security owns 20% of the stock of a private company that also works to develop computer security tools.
- An optometry professor receives \$15,000 in consulting income from a contact lens company that is providing sponsored research funds for the professor to test a new lens in the University.

I'm a faculty member in the Music School. Do I need to disclose that I will earn more than \$10,000 for private concerts or performances?

No. While this activity is related to what you do within the University, it simply is not a situation in which your outside interest (compensation for giving private performances) would appear to affect or be affected by your University activity.

Why does the disclosure requirement cover financial interests of my family, and not just me?

The law and University policy assume that most employees care about and/or are financially affected by, the financial interests of their family members. Therefore, the impact of your University work on their significant financial interests raises the same potential conflicts issues as your own significant financial interests. Under the Policy, you must also include the financial interests of registered domestic partners recognized under Indiana University Human Resources policies.

Do I have to disclose all outside compensation I receive, and every share of stock in my portfolio?

You only need to disclose if the outside compensation or ownership interest (including stock holdings) from a given source if the compensation or ownership interest (a) meets the definition of "significant financial interest," above, and (b) reasonably would appear to affect, or be affected by, your University research or sponsored program activities. If your research field is nutrition, you do not have to disclose stock ownership in Ford Motor Company. If your area of academic research is software products and in your individual capacity you serve as a consultant for Microsoft and are paid at least \$10,000, you should disclose your outside consulting income.

Also, you do not have to disclose the exact value or percentage of your significant financial interests; all you need to do is to indicate that an interest meets the threshold for disclosure.

Should I disclose a related outside financial interest that meets these standards for disclosure, but when I am sure there isn't really a

conflict?

Yes. University policy adopts the federal government's two-stage process for identifying financial conflicts of interest. The first stage is for you to disclose your significant financial interests (a) that reasonably would appear to affect, or be affected by, your University research or sponsored programs, or (b) in entities whose financial interests reasonably would appear to affect or be affected by, your University research or sponsored programs.

The second stage is an evaluation of that interest to determine whether a potential or actual conflict exists. Your unit head should review the form and determine, in his or her judgment, whether your disclosed interests present a potential conflict. The details will also be reviewed by the Office of Research Compliance and possibly the Conflict of Interest Committee. Providing sufficient detail will help the Office of Research Compliance and the Conflict of Interest Committee understand the relationship and what management steps are warranted in your case.

In the first stage of this process, you should err on the side of inclusion by disclosing all outside financial interests that meet the monetary threshold and that are reasonably related to the sort of work you do at IU, or that involve compensation from or interests in companies who operate in areas relating to your IU work. For example, in most cases outside companies ask faculty to consult for them because of their academic or research expertise in areas that they are pursuing within IU; therefore such consulting income should be disclosed.

What happens to the forms or the lists after the Office of Research Compliance receives them?

- The Office of Research Compliance staff records receipt of the forms with disclosed interests and the list of those who turned in forms to the units without a disclosed interest against a list of persons in each unit who need to complete annual disclosures
- Disclosures in which the unit head has indicated that a potential conflict exists are reviewed by the Office of Research Compliance. The office will follow up with the unit head to discuss the potential conflict and the unit head's proposed resolution. Those situations that may require a management plan will be referred to the Bloomington Conflicts of Interest Committee.
- Disclosure forms on which there is a disclosable interest, but for which the unit head has indicated that there is no conflict, are also reviewed. If any additional questions arise, the unit head or the researcher will be contacted for follow up information and to discuss any questions about the disclosure. If necessary, they will work with the unit head and the individual to resolve it; any issues that are not resolved will be referred to the Bloomington Conflicts of Interest Committee.
- Any issues that cannot be resolved by the Conflicts of Interest Committee will be referred to the Vice Provost for Research, who has final authority on conflicts matters.

STATE CONFLICT OF INTEREST LAWS

What if I have a financial interest in a contract with the University in an area that doesn't relate at all to my research or work for the University?

State law makes it a felony for IU employees to knowingly or intentionally have a personal financial interest in, or derive a profit from, "a contract or purchase connected with an action by [the University]," unless certain exceptions apply.

Under state law, "employee" means not only the employee, but also the employee's spouse, children under 18 who are still at home, and any other "dependent," which means anyone for whom the employee provides more than half of their annual financial support. This means that IU employees must consider not only their own benefits from a University contract or purchase, but also any financial benefits gained by their spouse, minor children, and dependents, in determining whether or not the state conflicts law applies to their circumstances.

The law contains certain exceptions to the general prohibition against University employees having a personal financial interest in a University contract or purchase. First, there is an exception for employees whose financial interest in a University contract or purchase is de minimis. To be de minimis, the employee's financial interest in a University contract or purchase, added together with any financial benefit(s) they had in any other University contracts or purchases for the preceding 12 months, must total less than \$250.

Second, there is an exception when employees disclose in writing to the Board of Trustees their financial interest in a proposed contract or purchase, before final action is taken on the contract or purchase, and the Board approves the circumstances. Disclosures must be made on the State Conflicts Disclosure form.

Who should complete the State Conflicts Disclosure?

Any University employee who will knowingly or intentionally receive a profit or pecuniary benefit from a contract or purchase between IU and a third party, when the benefit s/he will receive, together with the benefits s/he has received on any other contracts or purchases between IU and third parties in the past 12 months, totals more than \$250.

The disclosure should include a brief description of the contract or purchase that will result in a financial benefit to you, your spouse, or your dependents; the nature of the financial benefit; the dates and term of the contract or purchase; and the names of the parties involved, including (a) the outside vendor or contractor involved in the transaction; and (b) University personnel involved in choosing the vendor or contractor and/or negotiating contract terms.

Although the law applies to anyone who knows they will receive a personal benefit from a University contract or purchase, regardless of whether or

not they are involved in the transaction as part of their University duties, it will help the Board to review and evaluate your disclosure if you briefly describe the nature and extent of your own involvement, if any, in the transaction (e.g. selecting or influencing the choice of a vendor, participating in contract negotiations, etc.). The more involvement in the contract or purchase decision by other University personnel whose authority is independent of yours (e.g., they don't report to you), the more protection there is against the perception or possibility of self-dealing.

What are some examples of outside interests that are disclosable under the state conflicts law?

- A faculty member's teenage son (who is the faculty member's financial dependent) has a freelance photography business; the IU Office of Communication and Marketing proposes to hire the son to take photographs at an upcoming campus event for inclusion in IU publicity materials. The amount of the contract will exceed \$250.
- A visiting faculty member's spouse owns a catering company that Residential Programs and Services wants to hire to cater a function in one of the residence halls. The amount of the contract will exceed \$250.
- A research scientist asks Purchasing to buy a piece of equipment for his/her lab from a vendor in which research scientist directly owns an equity interest (not through a mutual fund). While it may be difficult to predict whether the purchase would result in an increase in the research scientist's equity of more than \$250 for that year, it is better to err on the side of caution and disclose, because the burden under state law will be on the employee to show that there was not an increase in value to the equity, at some point during the year, of more than \$250. In addition, this issue tends to overlap with the conflicts concerns in research that are dealt with under the IU Financial Conflicts Disclosure, since the use of particular equipment relates directly to the design and conduct of research.

To whom do I give the disclosure once I've completed it?

Submit the form to the Provost for the Bloomington campus for review; once the Provost has reviewed and signed it, it should be sent to the University Counsel's Office, which reviews it and sends it on to the Board of Trustees. Typically the Board reviews and acts on the disclosures in its next regularly scheduled public meeting.

If either the Provost or the Counsel's Office identify a potential conflicts concern raised by the disclosure, they will follow up with you before sending the disclosure on to the Board.

When do I need to make a state conflicts disclosure?

The law requires that disclosures be made and approved by the Board before final action is taken on the contract or purchase in which the employee has a personal financial interest. However, when an employee has an ongoing financial interest in a third party with whom the University does regular,

repeated business, the employee can file an annual disclosure with the Board that covers all such contracts or purchases for the year.

When I assign textbooks or materials that I authored to my IU students, is there a potential issue under the state conflicts law?

One could read the state conflicts law to cover situations in which a professor receives more than \$250 in royalties for the year from sales of the professor's textbooks or other authored materials that are required for her IU classes. The reasoning is that in such circumstances, the professor knowingly receives a financial benefit above the \$250 threshold for "purchases in connection with an action by the University"—namely, purchases by the students resulting from the professor's action, using her authority as a University faculty member to design her courses and choose course materials. Therefore, the University has advised faculty in such circumstances that it is prudent to file a state conflicts disclosure with respect to royalties above \$250 a year obtained from materials assigned to their IU students. The faculty member should indicate on the disclosure form the pedagogical connection between the assigned materials and the course subject matter.

OTHER CONFLICT ISSUES

What happens if I do not comply with the University's financial conflicts policy?

Non-compliance with the University's financial conflicts policy would be addressed under applicable policies, such as the [Policy on Research Integrity](#) and applicable [Procedures](#), and appropriate remedies would be pursued. It is not possible to determine what remedies would be appropriate, except on a case by case basis.

Under the Policy, can I use University resources in support of my outside activities?

The University [Policy on Conflicts of Commitment](#) states that "Academic Appointees shall not use University resources in the performance of Outside Professional Activities without the written permission of their dean or unit head and without compensating the University. Where resources usage is de minimis and the cost difficult or impossible to calculate, such use of University resources shall not require reimbursement." This would include use of computers and other equipment. There is no fixed formula for compensation; this would be determined on a case-by-case basis.

Resources and Forms

INDIANA UNIVERSITY POLICY AND FORMS

[Policy on Financial Conflicts of Interest in Research](#)

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

[Policy on Conflicts of Commitment](#)

[State Conflict Form](#)

Federal Regulations and Policies on Conflict of Interest

NIH Regulations on Financial Conflicts of Interest

- [Introduction](#)

<http://grants1.nih.gov/grants/policy/emprograms/overview/ep-coi.htm>

- [Regulations](#)

<http://grants2.nih.gov/grants/guide/notice-files/not95-179.html>

- [Frequently Asked Questions](#)

<http://grants.nih.gov/grants/policy/coifaq.htm>

- [Resources](#)

<http://grants2.nih.gov/grants/policy/coi/resources.htm>

NSF Grants Policy Manual

- [Conflict of Interest Policies](#)

<http://www.nsf.gov/pubs/2002/nsf02151/gpm5.jsp#510>

Food and Drug Administration (FDA)

- [Guidance on Conflicts of Interest](#)

<http://www.fda.gov/oc/guidance/financialdis.html>

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