

# **GUIDELINES AND PROCEDURES ON CONFLICTS OF INTEREST FOR ACADEMIC APPOINTEES**

## **INDIANA UNIVERSITY-PURDUE UNIVERSITY INDIANAPOLIS**

### **INTRODUCTION**

These guidelines and procedures detail the IUPUI campus' implementation of the Indiana University Policy on Conflict of Interest for handling conflicts of interest related to research activities <http://www.research.indiana.edu/rschcomp/coi/policy.html>. Recognizing the scope of IUPUI Academic Appointees responsibilities these guidelines and procedures are also applied to teaching and service activities and administration.

IUPUI encourages interactions and the establishment of relationships between Academic Appointees with governmental entities (federal, state, and local), business and industry, and non-profit organizations as an important part of the university mission of teaching, research and professional service. The Academic Appointees at IUPUI have a major responsibility to discover and transmit new knowledge through scholarly activities. Financial support for such activities comes both from public and private entities external to the University. Increasingly, alliances between Academic Appointees and external entities have become a significant feature of academic research and educational activities. As these relationships become more common and complex, possibilities for conflicts of interest increase.

A basic principle of these Guidelines and Procedures is the assurance of objectivity in research, teaching, professional service and administration to preserve the credibility of the University and the individuals engaged in these endeavors. While broader in scope, these guidelines are intended specifically to ensure that individual financial interests do not influence our commitment to uphold ethical standards for the protection of human subjects. Interactions with the private sector carry with them an increased potential for financial conflicts of interest, or at least the perception thereof. Just as integrity in teaching, research, and professional service is a personal responsibility of each individual, integrity in decision-making associated with financial and other business relationships with the private sector is a critical responsibility of those individuals and the administrators engaged in these relationships. As a steward of public funds, the university assumes the responsibility to assist the Academic Appointees in identifying activities that present potential for conflicts and in reducing or managing the conflicts to ensure they do not threaten the credibility of the University's Academic Appointees' core activities.

The IUPUI Guidelines and Procedures on Conflicts of Interest are designed: (1) to help identify conflicts of interest arising from relationships between Academic Appointees and external entities; (2) to assist Academic Appointees to either manage or avoid conflicts of interest; and (3) to establish a system for disclosure and review of relationships with external entities in order to identify and resolve actual and perceived conflicts of interest.

### **Application of this policy**

These guidelines and procedures apply to: (1) all Academic Appointees, including part-time and visiting faculty, faculty who are neither tenured nor on tenure-track appointments, lecturers, and academic specialists; (2) students, and anyone else with an appointment at IU who is involved in the design, conduct, or reporting of research, teaching, or service; and (3) retired faculty to the extent that they are still actively performing research, teaching, or providing service under the auspices of the University.

There is a separate University policy on conflicts of interest that applies to staff who are not involved in the design, conduct, or reporting of research, the financial administration of research funds, or teaching activities. That policy can be found at [<http://www.indiana.edu/~uhrs/policies/uwide/coi.htm>]

## DEFINITIONS

**An Academic Appointee** is any person, including but not limited to anyone holding an academic at IUPUI, whether full or part-time, who is engaged in the design, conduct or reporting of research or Educational Activities.

**Activities Outside of the University** and **Outside Activities** are defined as activities not directly related to the research, teaching, and service mission of the University.

**Covered Persons** means persons to whom these guidelines and procedures apply, as specified in Section 1.

**Dependent** is defined as any person who receives more than one-half of his or her annual support from an employee, whether or not he or she is related to that employee.

An **Educational Activity** may include the dissemination and application of knowledge through teaching, executive education, consulting, service, and publication (except those publications reserved to individuals through the Indiana University policies on copyright and intellectual property). The specific definition of "Educational Activity" may be further developed by each school or administrative unit to reflect the diverse missions of units and the varied work of Academic Appointees.

**Eligible Domestic Partner** is defined as being the same sex as the employee; at least 18 years of age and competent to enter into a contract; not legally married or the domestic partner of another individual; has lived with the employee as a couple for at least six consecutive months; and has submitted documentation to verify an interdependent relationship with the employee that is the functional equivalent of a marriage.

**Employee** is defined as any person employed by Indiana University, whether full or part-time (hourly employees are not included).

An **External Entity** includes any individual, corporation, company, trust, organization, enterprise, or other entity (including government agencies) that is not an entity under the control of or under common control with the University.

**Family Members** are defined as the member's spouse, Dependent and Eligible Domestic Partner.

A **Financial Interest** is "significant" if:

it is an equity or similar interest (e.g., stocks, stock options, or other ownership interests), allowance, forbearance, forgiveness of debt, interest in real or personal property, dividends, rent, capital gain which exceed \$10,000, 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;

or it is salary, commissions, consulting fees, honoraria, 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;

or intellectual property rights that exceed \$10,000 in value (e.g. patents, copyrights, and royalties from such rights).

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 by their University responsibilities, without regard to any monetary threshold.

Exclusions:

- i. Receipt of royalties from licensed University technology when no further related research, teaching or service activities will be pursued within the University by the individual;
- ii. Salary or other remuneration from Indiana University.
- iii. Income from seminars, lectures, or other educational activities sponsored by not-for-profit entities;
- iv. Income from service on advisory committees or review panels for governmental or not-for-profit entities;
- v. Any financial interest arising solely by means of investment in a mutual, pension, or other institutional investment fund over the management and investments of which the member of the University community does not exercise control;
- vi. Receipt of royalties or honoraria for published scholarly works, commissioned papers, and occasional lectures as long as they are not required for purchase for the author's classes;
- vii. Serving as a consultant to a domestic government agency;
- viii. Income received from a private practice plan recognized and approved by the IU School of Medicine (or other schools that may establish practice plans).

It should be noted, however, that the state law on conflict of interest establishes \$250 as the threshold at which a Financial Interest is *de minimus*, or insignificant; accordingly, the facts of each situation must be considered carefully.

A **Human Subject** is a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information, or an individual who is or becomes a participant in research, either as a recipient of an FDA-regulated test article or as a control.

**Professional Activities** are defined as activities related to the research, teaching, or service missions of the University, or an employee's discipline, profession, or craft, irrespective of whether those activities are compensated or constitute University activities.

**Research** means a systematic investigation designed to develop or contribute to generalizable knowledge. The term encompasses basic and applied research and product development. For biomedical research, this includes any experiment that involves an FDA-regulated test article on one or more human subjects that either is subject to requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act: or is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for research or marketing.

**Royalty Income from Licensed Technology** means the receipt of or the entitlement to receive future royalty income derived from the licensing of technology or other processes or products. Not included is income derived from the sale of books, journals, or artistic works.

**Sponsored Programs** is Research and Educational Activities involving funds, materials, gifts, or other compensation from External Entities under agreements with the University.

**Statement of Compliance** is defined as “A Statement of Compliance with State Law on Conflicts of Interest and Federal Law on Financial Conflicts of Interest in Research,” published in the *Academic Handbook*, and any amendments thereto.

**University** means Indiana University and the Indiana University - Purdue University Indianapolis (IUPUI) campus specifically, including the Academic Appointee of Purdue missions schools located at IUPUI.

**University Activities** are defined as activities directly relating to the research, teaching, and the service mission of the University.

**University Responsibilities** are defined as the responsibilities of a University employee to perform University activities as defined by the University or unit policy, contract, or collective bargaining agreement.

## State Law

### Interests in University Purchases or Contracts

According to Indiana state law, it is a criminal offense for University employees and their dependents to have an aggregate financial interest of \$250 or more per year in, or deriving an aggregate profit of \$250 or more per year from, any contract(s) or purchase(s) connected with the University, unless certain exceptions apply. The terms of the state conflicts law are set forth in the Statement of Compliance with State Law on Conflicts of Interest (<http://www.in.gov/legislative/ic/code/title35/ar44/ch1.html>).

## Required Disclosures

- a. All Academic Appointees must disclose any significant financial interest of themselves or their Family Members that would reasonably appear to affect, or be affected by the research, teaching, service, or other professional activities in which they are engaged as part of their University responsibilities. However, Academic Appointee 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 by that research, without regard to any monetary threshold. The following must be disclosed unless listed as an exclusion:

Disclosures required by the IU COI Policy:

- An equity interest that exceeds \$10,000 or represents more than a 5% ownership interest in any one enterprise or entity (equity in a privately held entity for which the value is not known will be treated as above the 5% threshold), when aggregated for the Academic Appointee or Family Members;
- Salary, royalties, or other payments expected to exceed \$10,000, when aggregated for the Academic Appointee or Family Members over the twelve month period.

Other Required Disclosures:

- Compensation to the Academic Appointee or Family Members of any amount that could be higher for a favorable outcome than for an unfavorable outcome, such as compensation that is explicitly greater for a favorable result or compensation to the investigator in the form of an equity interest in the sponsor of a covered study or in the form of compensation tied to sales of the product, such as a royalty interest;
- Proprietary or other financial interest by the Academic Appointee or Family Members in the product to be used in clinical trials including, but not limited to, a patent, trademark, copyright or licensing agreement. Fiduciary, director, board, or executive position of the Academic Appointee or Family Members in any enterprise or entity regardless of whether the position is compensated.

Disclosure is not required for any of the Exclusions listed with the Financial Interest definition:

- b. Disclosures under these guidelines and procedures shall be made annually at a time and in the form specified by the school in which the Academic Appointee's appointment is held. The disclosure form will be submitted separately from the annual summary report of activities, but it may be required at the same time.

Updates are to be submitted within 30 days after any significant change in Financial Interest occurs.

- c. At the time of filing an application for external funding or to conduct research on Human Subjects, the applicant must affirm that relevant disclosures under these guidelines and procedures are up to date.

### **Federally Funded Research**

- a. The required disclosures above ("Required Disclosures") must be made prior to the application for federal funding or as soon as possible after a change occurs with a required disclosure.
- b. The specific requirements of federal law are detailed in the Statement of Compliance.
- c. When a federal agency requires a notification of management plans, the Chancellor or the Chancellor's designee is responsible for transmitting the required information to the agency.

### **Other Research, Teaching, Service, or Professional Activities**

- a. Academic Appointees must disclose any significant Financial Interest of themselves or their Family Members that would reasonably appear to affect, or be affected by, the research, teaching, service, administration, or other professional activities in which they are engaged.
- b. Disclosures under these guidelines and procedures shall be made as described above.

### **Activities Outside of the University (Conflicts of Commitment)**

These guidelines and procedures do not attempt to address conflicts of commitment, i.e., outside activities that interfere with an employee's performance of their University responsibilities; conflicts of commitment are addressed in the University Policy on Conflicts of Commitment [<http://www.indiana.edu/~ufc/docs/AY04/circulars/U13-2004.approved.htm>].

### **Disclosure Procedures**

- a. Disclosure shall be made annually. The disclosure form will be submitted separately from the summary report of activities.
- b. All Academic Appointees are obliged to do the following:
  - i. Make all required disclosures.
  - ii. Disclose as soon as possible after he or she is aware of the required disclosure. Employees shall not be subject to burdensome or random disclosure requirements. This shall not restrict the use of disclosure as a means of avoiding, resolving, or managing an on-going conflict of interest.
  - iii. Submit disclosures annually as specified by the appointing school and provide updates whenever significant Financial Interest occurs.

### **GUIDELINES FOR IDENTIFYING CONFLICTS OF INTEREST**

The *Academic Handbook* of Indiana University references state statutes and federal guidelines regarding conflicts of interest, and the Code of Academic Ethics addresses ethical conduct generally. The IUPUI

guidelines and procedures on Conflicts of Interest specifically address conflicts of interest arising from relationships between Academic Appointees and External Entities. These guidelines and procedures call for disclosure and review of relationships with External Entities and avoidance or resolution of conflicts of interest.

Relationships with External Entities arise from a variety of academic and external activities. Activities with External Entities are organized in five broad categories listed below. A representative list of activities subject to these guidelines and procedures on Conflicts of Interest is set forth below. The first category does not require disclosure while those in Category II-IV must be disclosed by Academic Appointees before any definitive action by them takes place. The responsible department head and dean shall promptly review the disclosures represented in Category II and determine the appropriate course of action. Disclosures represented in Category III-IV shall be promptly reviewed by the responsible dean and then reviewed by the appropriate campus conflict of interest review sub-committee (Health Science or General Academic). The respective conflict review sub-committee will forward their recommendations to the Chancellor (or Chancellor's designee) for a final determination. Such activities may be permitted after disclosure, review and agreement to proposed management plans. If in doubt about whether an Activity falls in Category I through V, an Academic Appointee should confer with the dean or other person designated in school or unit procedures.

1. **Category I - Activities Normally Acceptable – No Disclosure is required.** The following are examples:
  - 1.1. Receipt of royalties from licensed University technology when no further related research, teaching or service activities will be pursued within the University by the individual.
  - 1.2. Receipt of royalties or honoraria for published scholarly works, commissioned papers, and occasional lectures.
  - 1.3. Serving as a consultant to a domestic government agency.
  - 1.4. Isolated, nonrecurring consulting activities that result in payments which do not exceed an income of \$10,000 annually from a single source.
2. **Category II - Activities Unlikely To Lead To Conflicts of Interest –These activities will be reviewed by the dean or the dean's designee of the school in which the Academic Appointee is appointed. If an individual wishes to appeal the administrative decision, the individual may request a review by the Campus Conflict of Interest Committee.**
  - 2.1. Receipt of income from multiple sources (with no single source providing more than \$10,000 of annual income) for lectures or consulting activities that result in an annual income equal to or greater than \$10,000.
  - 2.2. Receipt of annual income equal to or greater than \$10,000 for lectures or consulting activities that are not related to current university responsibilities.
3. **Category III - Activities with Potential for Conflicts of Interest –These disclosures will be reviewed by the dean or the dean's designee of the school in which the Academic Appointee is appointed and then referred to the appropriate campus Conflict of Interest Advisory Committee for recommendations to the individual's dean or the dean's designee. The following are examples:**
  - 3.1. Receipt of income from a single source for lectures or consulting activities that result in an annual income equal to or greater than \$10,000.
  - 3.2. Activities (independent of compensation) that use University personnel to further external professional activities, especially when the individual or immediate Family Members has a Financial Interest related to the activities

- 3.3. Assigning or permitting the participation of University personnel in activities sponsored by an external entity in which the individual or immediate Family Member has a Financial Interest.
  - 3.4. Support for research, except for clinical studies (see 4.1), from a business in which the Academic Appointee or Family Members have a Financial Interest.
  - 3.5. Research evaluating technology, except for clinical studies (see 4.2), that is owned by a business in which the Academic Appointee or their immediate Family Members have a Financial Interest.
  - 3.6. Conducting or reporting on research activities related to technology for which the individual or their Family Members has Royalty Income from Licensed Technology.
4. **Category IV** - Activities that Present a High Potential for Conflicts of Interest. These activities must be reviewed by the dean or the dean's designee of the school in which the Academic Appointee is appointed and then referred to the appropriate campus Conflict of Interest Advisory Subcommittee for recommendations to the individual's dean or the dean's designee. The following are examples:
- 4.1. Clinical research <sup>[1]</sup> in which the Academic Appointee or member of his/her Family Member has a Financial Interest or Royalty Income from Licensed Technology.
  - 4.2. Evaluating technology in clinical studies that is owned by a business in which the Academic Appointee or his/her Family Member has a Financial Interest.
  - 4.3. Commitment of University space or other resource by an entity for which the Academic Appointee working in that laboratory's department or section is a consultant and/or he or she or a member of his/her Family Member has a Financial Interest.
  - 4.4. Agreements with any entity or entities which provide exclusive access to information, developed with University resources or supported by independent sponsors, to an entity in which the Academic Appointee or Family Member has a Financial Interest.
  - 4.5. Acceptance for personal benefit of compensation from an entity for serving on the governing or advisory body when the Academic Appointee has been appointed to that position by the University or is representing the University in that position.
  - 4.6. Applying for, receiving, and conducting any sponsored research activities for another organization that ordinarily would be conducted under the auspices of the University.
  - 4.7. An Academic Appointee or Family Member assuming a board, director, fiduciary, or executive position in an External Entity engaged in activities related to the Academic Appointee's University research.
5. **Category V** - Activities that are Not Allowable - - The following are examples:
- 5.1. Acceptance of payments, consideration, or honoraria that substantially exceed the value of services provided.
  - 5.2. Agreements with any entity or entities contracted through the University that prohibit or unduly limit publication, or evaluation of project data by bona fide internal or external reviewers, or which link payment to favorable research results.

- 5.3. Compensation to the Academic Appointee or Family Members of any amount that could be higher for a favorable outcome than for an unfavorable outcome, such as compensation that is explicitly greater for a favorable result or compensation to the investigator in the form of an equity interest in the sponsor of a covered study or in the form of compensation tied to sales of the product, such as a royalty interest.
- 5.4. Responsibility for making or influencing administrative decisions on behalf of the University regarding activities that may benefit the individual's Financial Interests. Persons (Academic Appointee, and administrators) who have this type of conflict of interest must excuse themselves from participation in the decision making process and also must make sure that subordinates do not participate in the decision making.

## IMPLEMENTATION

All IUPUI employees and others to whom this policy applies on the IUPUI campus must annually file a disclosure statement of financial interests. Academic Appointees and others <sup>[2]</sup>[2] who serve as principal investigators will submit the names of all individuals under their supervision who are involved with the design, conduct or reporting of research. These individuals must also annually file disclosure statements of financial interests to the dean of the school in which they are appointed.

All disclosure statements are to be submitted to the dean's office of the individual submitting the disclosure statement. The dean or the dean's designee will review submitted disclosure statements within 30 days. For those activities that require management by the University, the dean or the dean's designee will determine whether the decisions can be administered within the school (typically Category II activities), or the activities need to be referred to the Campus Conflict of Interest Committee (typically for Category III and IV activities). The dean or the dean's designee should work with the individual to develop a management plan to minimize the potential conflict of interest issues. Management plans should seek to ensure the objectivity of the University activity and that the Financial Interest does not affect the protection of Human Subjects.

**Deans** shall annually submit financial disclosure statements to the Chancellor or the Chancellor's designee. The review of these disclosure statements will be handled in a manner similar to the procedures described above for academic employees.

The disclosure statement and proposed management plan will be reviewed by the appropriate subcommittee (Health Science or General Academic) of the campus Conflict of Interest Committee. The Committee recommendations are transmitted back to the individual and dean or the dean's designee for implementation. Examples of management plans may include one or more of the following:

- a) Disclosure - Disclosure is required in every case approved by the dean or Chancellor, including: (i) public disclosure of the financial interests of the Academic Appointee in all relevant publications, presentations (whether or not academic presentations), and (ii) disclosure to the appropriate co-investigators, members of the laboratory or research group, and students or trainees, and (iii) disclosure on Human Subject consent forms;
- b) Limiting the role of the Academic Appointee with a Financial Interest - requiring that the role of the investigator with the financial interest be limited in some way (e.g., the Academic Appointee may not be allowed to i) serve as principal investigator, (ii) analyze data, (iii) determine whether potential subjects are eligible for enrollment, iv) solicit consent, or v) determine whether an adverse event report is required);



c) Oversight - appointment of a disinterested individual or group to monitor the relevant research activity. An oversight committee might be charged, at a minimum, with reviewing abstracts and manuscripts before they are submitted for publication to ensure that the research is conducted and reported according to scientific and ethical standards and that conflict of interest management measures are observed. In other cases, an oversight committee might meet quarterly and review protocols, subject accrual, complications, and other issues as appropriate;

d) Restriction on Equity - i) placement of stock in escrow until a trigger date specified by the Committee, or ii) requirement that options, warrants, and similar instruments not be exercised without the prior permission of the Committee;

e) Divestiture - allow arrangements to go forward contingent upon the sale or disposal of specified financial interests to eliminate or reduce the financial conflict of interest by a date certain;

f) Severance of relationships that heighten or create actual or potential conflicts - for example, relinquishing a seat on a board of directors or terminating a consulting arrangement with an outside entity in order to reduce the Financial Interest.

The Committee may recommend other conditions or restrictions on the proposed arrangements if, in its view, such conditions or restrictions will contribute to the elimination, reduction, or management of the conflict of interest.

If an individual wishes to appeal the decisions made regarding managing a conflict of interest, then they may appeal to the appropriate subcommittee of the campus Conflict of Interest Committee for those decisions made by deans or their designees. Decisions made by the campus Conflict of Interest Committee may be appealed to the campus Chancellor.

The Chancellor of IUPUI shall be responsible for implementation of this policy and shall appoint an IUPUI Committee on Conflicts of Interest. The Chancellor may delegate responsibility for administering this policy to another campus administrative officer.

### **Schools**

The Academic Appointees of each school (and appropriate campus administrative units) in cooperation with the dean (or administrative unit head) may directly implement these guidelines and procedures or shall establish their own procedures as long as they are consistent with the University Conflict of Interest Policy and these guidelines and procedures. School procedures must be submitted to the IUPUI Chancellor or designee within 30 days of their adoption. The dean (or equivalent administrative officer) is to ensure that the school or unit's responsibilities are met in accord with approved procedures. Specifically, the dean (or equivalent administrative officer) or designee shall:

1. Assist in establishing school procedures and in revising established procedures as required;
2. Assist Academic Appointees in interpreting the campus Guidelines and Procedures and school procedures;
3. Implement school procedures for disclosure and review of Categories II-IV activities;
4. In consultation with individual Academic Appointees, seek avoidance or resolution of conflicts of interest; and
5. Promptly transmit recommendations concerning unresolved conflicts to the IUPUI Campus Committee on Conflicts of Interest.

### **IUPUI Campus Committee on Conflicts of Interest**

The IUPUI Committee on Conflicts of Interest shall:

1. Review school recommendations concerning unresolved conflicts;
2. Review all school recommendations for management plans for activities that fit with Categories III and IV (described above) and provide recommendations to the school dean;
3. Review appeals from Academic Appointees regarding school (or unit) decisions; and
4. Promptly transmit its recommendations to the appropriate dean or designee.

The majority of the committee members shall be IUPUI faculty members. Associate Deans and committee department heads may also serve on the committee but they must recuse themselves from cases involving Academic Appointees appointed within their unit.

## **General Provisions**

Academic Appointee shall be entitled to respond to recommendations at every stage of the review process.

Administrative actions taken to address conflicts of interest shall follow the same procedures outlined in the *Academic Handbook* for enforcement of the Code of Academic Ethics, except that Academic Appointee may appeal to the IUPUI Committee on Conflicts of Interest. Academic Appointee may appeal administrative actions taken by the Chancellor or designee through the procedure for Faculty Boards of Review.

Confidentiality must be assured; disclosures should be available only to those charged with responsibility for review, subject to any restrictions on confidentiality imposed by Indiana State Law on Access to Public Records (IC 5-14-3).

In the case of Academic Appointees who hold administrative positions (e.g. Chancellor, Vice Chancellor, Dean, Department Chair, Director), disclosure of activities reportable under this Policy will be made to the academic unit in which the officer has his or her appointment and will be reviewed according to the procedures applicable to that unit. Academic Appointees with appointments in two or more units shall follow the procedures of the school in which the primary or tenure-related appointment is held. Disclosure and review of reportable activities by persons who do not also hold an academic appointment shall be addressed through approved procedures for their administrative unit or, when none exists, through ad hoc procedures approved by the Chancellor and reported to the IUPUI Committee on Conflict of Interest.

## **Timing of Disclosure**

Financial Interests and other activities reportable under this policy must be disclosed at least annually, and at other times when there is a significant change in the circumstances giving rise to a discloseable Financial Interest or eliminating a conflict previously identified. All disclosures of Financial Interests must be made prior to submission of proposals for funding from External Entities.

## **Appeals**

**Academic Employees** may appeal a dean's decision on how a conflict of interest is to be managed. The appeal should be submitted in writing to the Conflict of Interest Committee. A final appeal may be submitted to the Board of Review. Until the appeal process is resolved, an Academic Employee must minimize the conflict of interest by implementing the proposed management plan, or suspending the external activity, or suspending the proposed University activity.

## **Retention of Records**

Records relating to conflicts of interest are to be retained by the University for at least three years after the final financial report was submitted to the sponsor.

1. The termination or completion of the contract or award to which they relate; or
2. The resolution of any action involving those records.

## **Non-compliance**

Non-compliance with this policy, including failure to file or knowingly filing incomplete, erroneous, or misleading disclosures, or failure to comply with prescribed review procedures, shall be evaluated in accordance with applicable policies of Indiana University and IUPUI. If a conflict of interest involves government-sponsored research, the University may be obligated under federal, state, or local law to report any corrective action taken.

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[\[1\]](#)<sup>[1]</sup> Conflicts of interests related to research on **Human Subjects** require special considerations. When the research is considered to have more than nominal risks, investigators must document the special circumstances that should be considered to justify they should be permitted to participate in the research. They must also propose an appropriate management plan to explain how the conflict of interest will be minimized. Review of potential conflicts of Interests that involves research on Human Subjects must be coordinated with the IUPUI IRB. The IRB must be informed of decisions of the Conflict of Interest Committee. The IRB has the responsibility, as they deem appropriate, to define additional management requirements or disapprove proposed research studies involving Human Subjects to assure that protection of research subjects is not compromised by Financial Interests.

[\[2\]](#)<sup>[2]</sup> Individuals working under the auspices of the University such as post doctoral fellows, graduate students, research fellows, visiting scientists, clinical nurses and technical staff who are involved with the design of the research, conducting the research when they have an opportunity to influence the outcome of the research, interpreting the results, or writing reports on the research. Individuals who play an incidental role in the research, such as a clerical staff, technicians, and financial administrators who do general support functions are not required to file financial disclosure statements under these guidelines and procedures. Financial administrators may have to file a financial disclosure statement to fulfill the requirements of the Conflict of Interest Policy related to Administrative Responsibilities.