

Case Study: Streamlining Policies, and Processes

Conflicts of Interest, Conflicts of Commitment and Nepotism

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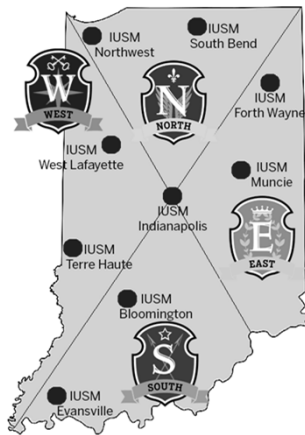
INDIANA UNIVERSITY

Background

- 7 Campuses
- Faculty Fulltime/Part time = 9,005
- Exec Admin & Professional Staff = 6,549
- Health schools include:
 - Medicine
 - Dentistry
 - Nursing
 - Optometry
 - Speech & Hearing
 - Physical & Rehab Sciences
 - Public Health
- 200 Research Centers



IU School of Medicine Campuses



IU Health Hospital Locations



Goals

A Singular Approach (sort of)

- Single online disclosure process and source of data
- Single COI/COC policy
- Single **initial** point of contact, other contacts
 - Research
 - Non Research
 - Health System
- Single set of FAQs
- Comprehensive reports
- Central Authentication – prepopulated fields

Key considerations

- Applicable Authorities
 - Laws/Regulations
 - Existing Policies
- Scope
- Current Processes
- Management Plans
 - Research
 - Nepotism
- Points of contact
 - University contacts
 - Local liaisons
- Centralized versus local adjudication
- Routing and Approval Processes
- Training
- Reporting
- Access to System/Data
- Communication Plan
- Enforcement
- Consistency

Applicable Authorities

Public Health Service (PHS)

- **42 CFR Part 50 Subpart F (Grants):**
Promoting Objectivity in Research

- **45 CFR Part 94 (Contracts):**
Responsible Prospective Contractors

National Science Foundation (NSF)

- Section 510, Conflict of Interest

Indiana Code - Indiana Code 35-44.1-1-4

Public Servants – Statutory Conflict of Interest

Applicable Authorities

Principles of Ethical Conduct:

Section 8 – Refrain from Conflicts of Interest and Commitment

University Policies:

- Appropriate Duties of Academic Employees (Ghost Employees) (ACA-42)
- Conflicts of Interest (HR 07-40)
- Conflicts of Commitment (HR 07-30)
- Financial Conflicts of Interest in Research (ACA-74)
- Gifts and Gratuities (FIN-PUR-3.4)
- Nepotism (UA-10)
- Purchasing Ethics (FIN-PUR-3.0) – Conflicts of Interest Disclosure Statements
- State Conflict of Interest for Procurement Transactions (FIN-PUR-3.3)

Proposed Scope

- IU Leadership
- All Fulltime Faculty
- Individuals with the following HR Position Levels or higher:
4AD, RS4, AX4, DV4, FC4, HP3, IT4, PR4, SS4, SA4, Health Care Provider and Clinical Diagnostician
- University employees with Signature Authority
- Office of the VP & General Counsel
- Human Resources
- Fiscal Officers
- Purchasing/Procurement
- Discretionary

IU Classification Level Guide
Administrative Job Family – Administrative

Positions in this job family primarily provide and / or manage administrative functions of an organization. To accurately classify a position, specific supporting examples of a position's primary duties and responsibilities in terms of scope, impact and complexity should be provided.

Level	1AD	2AD	3AD	4AD
Level Overview	<ul style="list-style-type: none"> Grandfathered positions may be reclassified to CLTESS support positions when the position becomes vacant. No new positions in this job family will be slotted at this level/grade. These professional positions are all classified as PAO (Professional Overtime Non-Example). 	<ul style="list-style-type: none"> A professional contributor to administrative matters of an organization without full authority to deviate from established protocols. Has good grasp of professional principles and skills. Knows and effectively uses fundamental concepts, practices, and procedures. Work is of limited scope, typically on smaller, less complex projects / assignments or providing support for larger projects/ assignments. Assists in fact finding. Errors generally are limited to unit operations. May be first line supervisors, often of support staff. 	<ul style="list-style-type: none"> Fully competent and productive professional working independently on progressively more complex projects/assignments. The work may involve program ownership. <p><i>This is intended by design to cover an extensive span of professional work.</i></p> <ul style="list-style-type: none"> Responsibilities are of a professional or highly analytical nature. Jobs may have significant technical requirements with a high level of accountability. Errors may have impact beyond operations but normally are caught and / or corrected prior to signification impact. May train and direct work of junior staff. 	<ul style="list-style-type: none"> Generally responsible for managing a department or major function within a department with staff responsibility. —OR— Will manage highly complex processes or have diverse and complex responsibilities such as: people or financial management, external relationship development, project / process leadership. <p><i>This must be the primary purpose of the position, not a sporadic assignment. Focus of management is more frequently operational than strategic. The depth of the organizational structure may impact this.</i></p> <ul style="list-style-type: none"> Frequently contributes to management strategy. Establishes priorities; assigns functions; maintains quality control. Provides total management and expert guidance to lower level staff.
Decision Making		<ul style="list-style-type: none"> Works in compliance with established procedures. Identifies and resolves readily identifiable problems. Makes decisions within established guidelines and policies. Refers the most difficult situations to supervisor for guidance. Nature of work requires supervision, exercises limited judgment. Work typically involves regular process checks or review of output by a coworker and/or supervisor. 	<ul style="list-style-type: none"> Performs full range of professional level work that typically requires more complex and less clearly-defined issues. Identifies problems then solutions then takes appropriate action to resolve. Nature of work requires significant independence. Requires guidance only on unusual, complex problems / issues. Typically involves periodic review of output by supervisor / manager. 	<ul style="list-style-type: none"> Has latitude to make operational/procedural decisions within broadly defined parameters. Decisions require a high level of judgment. Guidance from higher management limited to expected outcomes. Generally requires higher managerial approval for policy and/or fiscal variances.

August 2, 2007 1

Current COI/COC Processes

- Centralized Process
 - Research COI Committees at Bloomington (Main) and Indianapolis (Med Center) campuses – approximately 10,000 disclosures are completed annually
 - State Conflict of Interest – managed by General Counsel's Office for contract or purchase connected with government entity
- Decentralized Process
 - COI/COC are addressed at School level – disclosure and adjudication process varies with each school
 - School of Medicine – Industry Relations Committee
 - School of Nursing
 - Kelley School of Business

Research COI Process

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.

Below are the basic steps of the Conflict of Interest process:



Research COI

COI Committee Review of Management Strategies

http://researchcompliance.iu.edu/coi/coi_manage_res.html

Please note: Each disclosure is reviewed based upon the individual situation. The techniques mentioned above for the noted situations have been used in the past but are not a guarantee that the COI Committee will choose the particular management strategy in all cases.

Type of outside relationship	Company also sponsors research in individual's lab	Management Strategy typically put in place
Family member employed at company related to individual's university research	No	Best Practices Memo
Family member employed at company unrelated to individual's university research	No	No action required
Family member employed at company related to individual's university research	Yes	Best Practices Memo/Management Plan
Equity ownership in company related to individual's university research	No	Best Practices Memo
Equity ownership in company unrelated to individual's university research	No	No action required
Equity ownership in company related to individual's university research	Yes	Best Practices Memo
Employer compensation	Yes	No Action
Employer compensation	No	No Action
Compensation from a non-profit organization	No	No Action/Best Practices Memo
Compensation from a non-profit organization	Yes	No Action/Best Practices Memo
Compensation from outpatient surgery center	No	No Action
Speaking engagement – content controlled by sponsor	No	Management Plan
Speaking engagement – content controlled by sponsor	Yes	Prohibition
Speaking engagement – speaker controlled content	Yes	Best Practices Memo/ Management Plan
Speaking engagement – speaker controlled content	No	No Action/Best Practices Memo
Speaking engagement – CME event, speaker controlled content	No	No Action
Speaking engagement – CME event, speaker controlled content	Yes	No Action
Consulting	No	Best Practice Memo/Management Plan
Consulting	Yes	Management Plan
Patent royalties	Do not use item patented in individual's lab	Case-by-case assessment
Patent royalties	Use patented item in individual's lab	Management Plan
Licensing Fees	Yes	Management Plan
Licensing Fees	No	Best Practices Memo
Start-up Company	No	Management Plan
Start-up Company	Yes	Management Plan

Management Techniques: Last Update 08-05-2015

IU State Conflicts of Interest Form

**IU Vice President &
General Counsel**

<https://vpgc.iu.edu/our-services/conflict-interest.html>

Approval Process:

1. Dean/Chair, Director
2. Campus Executive Officer (Chancellor or Provost)
3. If > \$5,000 Trustees

Routing

Public Servant

Dean/Dpt Chair

Campus Exec or VP

General Counsel

Trustees' Office

CONFLICT OF INTEREST DISCLOSURE STATEMENT

Pursuant to and in compliance with Indiana Code 35-44-1-1-4
(Form adapted for use by Indiana University)

1. Name of public servant submitting statement: _____
2. Title or position with Indiana University: _____
3. Home campus: _____
4. This statement is submitted (check one):
 - As an annual disclosure statement of my financial interest connected with any contracts or purchases of Indiana University, which are made on a regular basis with or from particular contractors or vendors; or
 - As a single-transaction disclosure statement of my financial interest in a specific contract or purchase connected with Indiana University proposed to be made by Indiana University with or from a particular contractor or vendor.

The phrase "my financial interest," as used in this disclosure statement includes any interest of myself, my spouse, or my dependent(s).

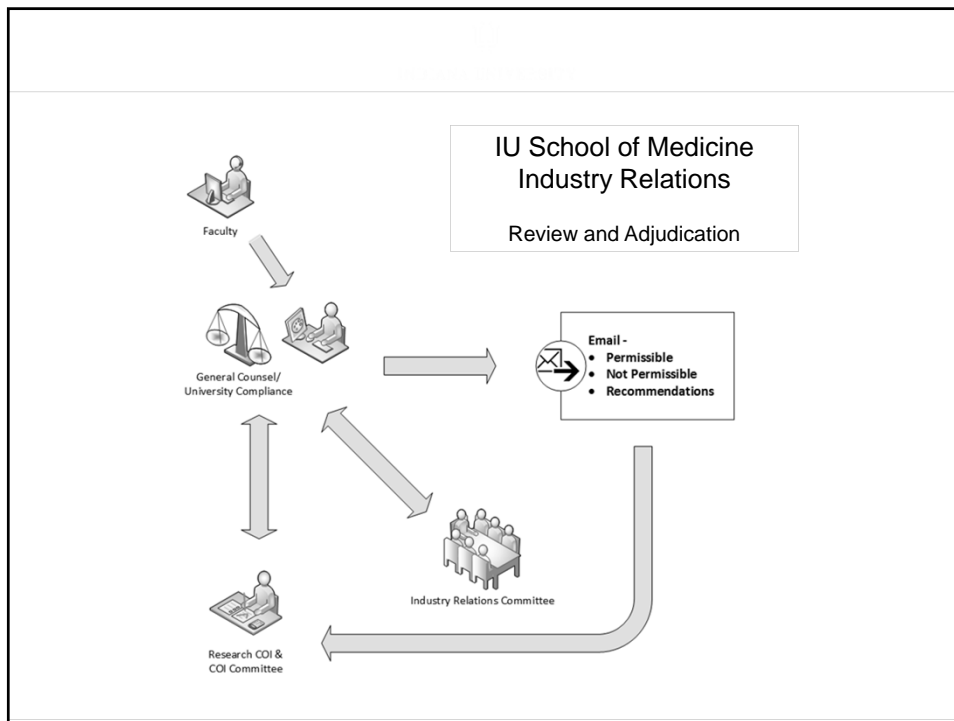
5. Name(s) of contractor(s) or vendor(s): _____
6. Description of contract(s) or purchase(s) to be made by Indiana University: (Describe the kind of contract involved, names of parties involved [other than those disclosed above], the effective date and term of contract or transaction date of purchase if reasonably determinable. [Dates required if this is a single-transaction disclosure.]) _____
7. Description of my financial interest: (Describe in what manner you or your family expects to derive a profit or financial benefit from, or otherwise has a pecuniary interest in, the above contract(s) or purchase(s). **State the approximate dollar value of such profit or benefit.**) _____
8. Affirmation of Public Servant: I affirm, under penalty of perjury, the truth and completeness of the statements made above, and that I am the public servant named above.

Signed: _____ Date: _____
(Signature of Public Servant)

Reviewed: _____ Date: _____
(Dean or Department Chair)

Reviewed: _____ Date: _____
(Campus Executive Officer or Vice President)

Reviewed: _____ Date: _____
(Vice President & General Counsel)



IU School of Medicine Industry Relations Policy

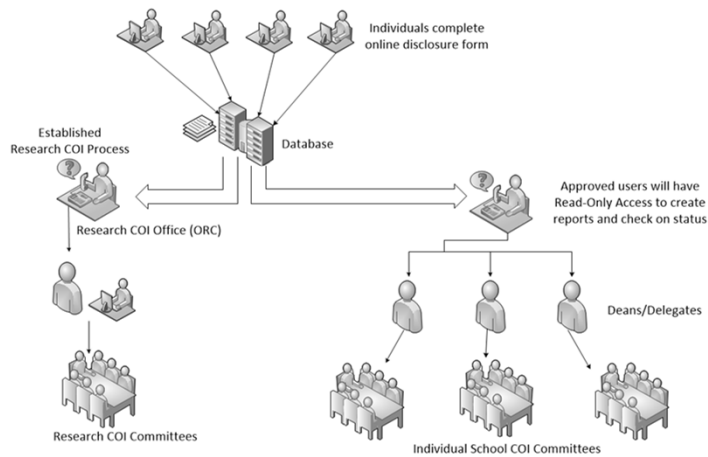
IUSM Industry Relations resources:
<https://medicine.iu.edu/about/policies-guidelines/industry-relations/>

Executive Summary – IUSM Industry Relations Policy 11-3-2014

Domain	Summary Description of Policies
Disclosure	Mandatory disclosure of potential, perceived, or real conflicts of interest; annual acknowledgement of policy required.
Industry-funded Speaking	Speaker's Bureaus and other industry promotional, sales, or marketing prohibited.
Industry Support of Accredited Continuing Medical Education (CME)	Unrestricted educational grants permitted. Exhibitors prohibited on campus but allowed off campus. Mandatory compliance with ACCME Standards.
Attendance at Industry-Sponsored Lectures and Meetings	Attendance discouraged.
Pharmaceutical Sales Representative Presence	No sales access to IUSM personnel. Collaborative meetings between faculty and industry scientists permissible.
Medical Device Representative Presence	Access limited to in-service training and technical assistance.
COI Curriculum and Extension to Community Educational Settings	COI education required for all trainees and faculty. Faculty should model professional behavior for trainees. Focus on critical thinking, evidence-based practice, avoidance of influence, and commitment to lifelong learning.
Gifts and Meals	Industry gifts and/or direct funding of meals prohibited. Reference to Sunshine Act.
Consulting for Marketing	Marketing relationships prohibited.
Consulting/Advising for Scientific Activities	Research consultation encouraged; must be governed by written contract or agreement and compensated at fair market value.
Financial/Hedge Fund Consulting	Prohibited.
Pharmaceutical Samples	Personnel must follow the rules of facility where work occurs.
Pharmacy and Therapeutics Committees	Voting membership prohibited for personnel with industry relationships. Prior disclosure of industry relationships required for requests to change or add to formulary.
Ghostwriting and Honorary Authorship	Strictly prohibited.
Industry-Supported Fellowships	Funds must be routed through IU Foundation. No involvement from industry in selection of fellows or of fellowship curricular material.
Proctoring	Faculty may proctor other faculty. Proctoring requests may not come from industry.

This executive summary is intended for quick reference and must not be applied in place of the specific policy language.

Proposed Review Process



INDIANA UNIVERSITY
University Policies

Policy Feedback Contact Us

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Categories

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Board of Trustees Approved Policies

Policies

Conflicts of Commitment
HR-07-30

Scope

Policy Statement

Reasons for Policy

Procedures

Definitions

Sanctions

Scope

This policy applies to all Staff and Temporary employees of Indiana University, whether part-time or full-time.

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Policy Statement

- It is the policy of Indiana University that its employees conduct the affairs of the university in accordance with the highest legal, ethical and moral standards.
- It is the policy of Indiana University that employees are expected to devote their university work activities to official functions of the university, and to use university resources only in the interest of the university. An employee may not commit university resources to activities not in the interest of the university.
- It is the policy of Indiana University that employees should not allow external activities to impede the fulfillment of university responsibilities.
- Nothing in this policy shall be construed to permit any activity that is prohibited by law.
- There are federal and state laws regarding the reporting of suspected illegal activity, including federal whistleblower laws.
 - Indiana state law
 - Indiana Code (IC 35-44-1-3, Ghost Employment) indicates that ghost employment can result in civil and criminal action against the supervisor and employee, as a Class B felony. Examples of when ghost employment occurs under state law:

About This Policy

Effective date: 06-01-2004

Last updated:

Responsible University Office:
University Human Resources
Responsible University administrator:
Vice President and Chief Financial Officer

Policy Contact:
University Human Resources
hrpolicy@iu.edu

Print or View PDF

Related Information

- IU Policy on Financial Conflicts of Interest in Research**
Employees engaged in research programs may also be subject to the university's policy regarding financial conflicts of interest. Employees should consult the campus Sponsored Research office or campus Academic Affairs office with any questions.
- Policy on Conflicts of Interest**
Employees should avoid potential conflicts of interest, or otherwise disclose them for review and resolution by their unit head in accordance with the university's policy on Conflicts of Interest for Staff and Temporary employees.
- IU Purchasing Policies**
Employees shall not use their purchasing authority for personal gain.
- Brochure: Managing Interests and Commitments**

Policy Feedback

If you have comments or questions about this policy, let us know with the policy feedback form.

Streamlining Policy Content

- Responsible Office
- Responsible University Administrator
- Policy Contact
- Scope
- Policy Statement
- Reason for Policy
- Procedures
- Definitions
- Sanctions
- Forms

Responsible Offices

- Financial Management Services
- Human Resources
- General Counsel
- Office of Research Compliance
- Procurement Services
- University Compliance

Primary Areas Addressed

- Research
- Outside professional activities
- Start-ups
- Outside teaching
- Nepotism
- Intellectual property
- External positions of authority
- Interest in transactions to which IU was or is a party
- COI disclosure requirement for IU Health/IU Health Physicians (as applicable)

QUESTIONS?

