

Individual Financial Conflicts of Interest (X.2.1)

Volume X: Ethics

Chapter 2: Compliance

Responsible Executive: Vice President for Ethics and Compliance

Responsible Office: Office of Vice President for Ethics and Compliance

Date Issued: [University Policy Office will complete.]

Date Last Revised: N/A

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STATEMENT OF POLICY

Purdue acknowledges that Employees, and their families and Dependents, have the right to acquire, retain and accumulate personal financial assets (including personal income from the

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transfer of technology or intellectual property subject to University policy), and to establish financial relationships with outside private entities. However, each Employee also has the responsibility to manage his or her financial affairs and relationships in a manner that does not interfere with, or improperly influence the performance of, his or her duties and responsibilities as an Employee.

Purdue will exercise oversight and care in eliminating or managing Financial Conflicts of Interest that do or may arise because of an Employee's Financial Interest in University activities. The University will not accept or enter into agreements, contracts, gifts or purchases that give rise to a Financial Conflict of Interest unless the conflict can be eliminated or appropriately managed through administrative oversight to protect the interests of the University. Purdue will comply with all reporting responsibilities imposed by Indiana or federal laws or regulations with respect to Financial Interests that have been disclosed while protecting the personal privacy of Employees, except where disclosure is required by applicable law or this policy. If a federal agency sponsor requires notification of the existence of a Financial Conflict of Interest, of the existence of a Financial Conflict of Interest that is being managed or of the existence of a Financial Conflict of Interest that cannot or should not be managed that is associated with a project proposed to that agency by Purdue, the University will comply with this reporting requirement, but will maintain the specific fiscal details of the subject Financial Conflict of Interest as confidential information to the extent allowed by laws or regulations.

As part of fulfilling his or her responsibilities, and to assist the University in avoiding or managing Financial Conflicts of Interest, each Employee must disclose any known Financial Interests that he, she or a Dependent has in any of the following:

1. Any University purchase or procurement of goods or services (whether or not pursuant to a formal contract) or in any investment or loan made by the University.
2. Proposals that are submitted to external sponsors for funding.
3. Protocols for research that are submitted for review and approval by a Regulatory Committee (or to a subcommittee).
4. Any agreement relating to University technology or other intellectual property that is or will be subject to negotiations between OTC and any third person or entity.
5. A donor that contributes a monetary gift or gift-in-kind designated to be in support of the Employee's scholarly activities.
6. For an Employee who is a member of a Regulatory Committee, any Financial Interest that he or she has in any research protocol submitted to that Regulatory Committee (with the Employee also recusing himself or herself from the review process regarding such protocol).
7. For an Employee who is an Investigator, any Significant Financial Interest that he or she has not already disclosed as a Financial Interest.

Such disclosures must be made annually and whenever a new Financial Interest arises.

An Employee who fails to make disclosures required by this policy, or who otherwise violates any of the provisions in this policy, may be subject to discipline for misconduct and/or insubordination under University policies, practices and procedures, up to and including dismissal.

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An Employee or Investigator who disagrees with a decision regarding the existence of a Financial Conflict of Interest, Significant Financial Conflict of Interest or the necessary elements of a conflict management plan may submit a written appeal in accordance with Section VII of the Procedures.

Purdue encourages faculty authorship of instructional materials and does not discourage the use of such materials in courses in a faculty member's department. In order to prevent Financial Conflicts of Interest or the appearance of such in selecting instructional materials, every academic department or school must have a policy appropriate to its circumstances that ensures instructional materials are selected for their academic merit.

Situations involving Financial Interests also may involve issues addressed in the University's policy on Conflicts of Commitment and Outside Activities (**hyperlink and number to be added**), in the Regulations Governing the Use and Assignment of University Facilities (I.4.1) and in the University Policy on Nepotism (Executive Memorandum No. C-37), among others. Employees must comply with these and all other applicable policies and regulations.

REASON FOR THIS POLICY

This policy confirms Purdue's commitment to the basic values of openness, academic and scholarly integrity, integrity of business policy and procedure, independence, and safe and ethical research, as well as to its tradition and expectation that Employees will conduct their relationships with the University with candor and integrity. To ensure the integrity of all institutional activities, including review and conduct of research involving human subjects, and the associated fiscal, contractual and procurement transactions, regardless of the source of support, Purdue has elected to apply the same Individual Financial Conflicts of Interest policy to all University activities.

In addition to supporting these basic values, this policy is also designed to:

- Comply with Indiana law (IC 35-44-1-3), which provides that an Employee who knowingly or intentionally has a monetary interest in or profits from a University contract or purchase may be charged with conflict of interest, a felony punishable by fine and imprisonment, unless the Employee has made the required disclosure in advance of the contract or purchase, and the disclosure has been approved in advance by the Board of Trustees and submitted to the Indiana State Board of Accounts.
- Satisfy federal regulations requiring the University to establish and implement policies concerning Significant Financial Interests held by:
 1. Personnel engaged in research funded by certain federal agencies [e.g., Public Health Services (Title 42 CFR Part 50, Subpart F and 45 CFR Part 94) and the National Science Foundation (Award and Administration Guide)],
 2. Institutional Review Board members (Title 45 CFR Part 46.107(e)), and
 3. Certain personnel involved in research involving human subjects funded by the

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Department of Health and Human Services.

Such policies allow the University to maintain eligibility for federal funding from the Public Health Service and the National Science Foundation, and in the case of research involving human subjects, funding from any federal agency that is a signatory to the Common Rule (Title 45 CFR 46) when researchers have Significant Financial Interests in research involving human subjects.

- Protect researchers and other Employees from misplaced charges of Financial Conflicts of Interest by providing a mechanism for prior objective review and approval of Financial Interests.

INDIVIDUALS AND ENTITIES AFFECTED BY THIS POLICY

This policy affects all Purdue University Employees and any individual who meets the definition of an Investigator.

WHO SHOULD KNOW THIS POLICY

- Trustees
- President
- Chancellors
- Vice Presidents/Vice Chancellors
- Vice Provosts
- Deans/Directors
- Department Heads/Chairs
- Faculty
- All Other Employees
- Investigators

EXCLUSIONS

There are no exclusions from this policy.

WEBSITE ADDRESS FOR THIS POLICY

[University Policy Office will complete.]

CONTACTS

Subject	Contact	Telephone	E-mail/Web Address
Policy Clarification	Vice President for Ethics and Compliance	765-494-5830	vpec@purdue.edu

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Questions Regarding Non-Research Related Financial Interests	Calumet:		
	Fort Wayne:		
	North Central:		
	West Lafayette: Vice President for Ethics and Compliance	765-494-5830	vpec@purdue.edu
Questions Regarding Research Related Financial Interests	Calumet: Associate Vice Chancellor for Research and Graduate Studies	219-989-8363	research@calumet.purdue.edu
	Fort Wayne: Associate Vice Chancellor for Research and External Support	260-481-4101	ores@ipfw.edu
	North Central: Vice Chancellor for Academic Affairs	219-785-5500	
	West Lafayette: Vice President for Research	765-494-6840	fcoi@purdue.edu

DEFINITIONS

Board of Trustees

The Board of Trustees of The Trustees of Purdue University.

Conflicts Committee

The University’s Conflict of Interest Committee (including appointed subcommittees). The Executive Vice President for Academic Affairs and Provost, the Executive Vice President for Business and Finance and Treasurer (EVPT) and the Vice President for Ethics and Compliance (VPEC) will jointly appoint members of this standing committee, which will include the following membership:

- COI Officer as chairperson (ex officio)
- Responsible Official (ex officio)
- The VPEC (ex officio)
- Two faculty representatives from the West Lafayette campus, as recommended by the Faculty Affairs Committee of the University Senate
- One faculty representative from each of the regional campuses, as recommended by the

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University Senate of the corresponding campus

- One representative from the Administrative/Professional Staff Advisory Committee
- One representative from the Clerical/Service Staff Advisory Committee
- One representative from units reporting to the EVPT
- One representative from units reporting to the Provost
- One representative from each regional campus, as recommended by its Chancellor
- One representative for all other areas reporting directly to the President (one person total)
- Any additional members jointly appointed by the Provost, EVPT and VPEC

Committee members will be appointed to three-year terms with the terms of one-third of the members to expire each year.

The Provost, EVPT and VPEC may also appoint one or more subcommittees comprised of members of the Conflicts Committee to perform the functions of the Conflicts Committee when necessary or appropriate in view of the size of the membership of the Conflicts Committee.

COI Officer

The Conflict of Interest Officer, who will be the VPEC or his or her designee.

Dependent

An Employee's spouse, Domestic Partner or unemancipated child(ren), including stepchildren and adoptees, under the age of 18, or anyone who receives more than one-half of his or her financial support during a year from an Employee.

Domestic Partner

A same sex domestic partner of an Employee who is eligible for same sex domestic partner benefits under University policy.

Employee

Each employee of Purdue University, wherever located and whether full-time or part-time, including but not limited to all executive officers, faculty and staff.

Equity Interest

Any ownership interest in a company or business, including but not limited to stocks, stock options or warrants, membership or partnership interests or rights, and similar interests.

EVPT

Purdue's Executive Vice President for Business and Finance and Treasurer.

Financial Conflicts of Interest

Situations where an Employee's Financial Interest (including an Investigator's Significant Financial Interest, where applicable) compromises, or could appear to compromise, his or her judgment or ability to carry out the Institutional Responsibilities associated with his or her appointment or employment. A Financial Conflict of Interest may take many forms, but in general arises when an Employee in a relationship with an outside person or organization is in a position to influence the University's business, research or decisions in ways that could lead

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directly or indirectly to financial gain for the Employee or the Employee's Dependents, or could give an improper advantage to others to the detriment of the University.

When applied to an Investigator, Financial Conflicts of Interest occur in situations in which such Investigator's Financial Interest (including Significant Financial Interest) compromises or could appear to compromise his or her professional judgment regarding the design, conduct or reporting of research, or if such Financial Interest could directly and significantly affect the design, conduct or reporting of research. The bias such conflicts may conceivably impart not only affects collection, analysis and interpretation of data, but also the hiring of staff, procurement of materials, sharing of results, choice of protocol, involvement of human participants and the use of statistical methods.

Financial Conflicts of Interest also include the use of University facilities, personnel, equipment, confidential information or other resources for purposes that could lead directly or indirectly to financial gain for the Employee and/or his or her Dependents.

Financial Interest

Any interest that will, could or is intended to lead to a profit or an ascertainable increase in the income or net worth of an Employee and/or a Dependent. Such a profit or increase in income or net worth could be realized through the receipt of anything of monetary or potential monetary value, including but not limited to, payments of any kind (e.g., salary, consulting fees, honoraria, gifts, dividends, distributions, rent, paid authorship, etc.), Equity Interests, an increase in the value of real estate or Equity Interests, or Intellectual Property Rights.

FIS

A Financial Interest Statement.

IC 35-44-1-3

Indiana Code 35-44-1-3 relating to conflicts of interest.

Institutional Responsibilities

An Employee or Investigator's professional responsibilities on behalf of Purdue, including but not limited to activities such as research, research consultation, teaching, professional practice, institutional committee memberships and service on panels such as institutional review boards or data and safety monitoring boards.

Intellectual Property Rights

Any interest in intellectual property, including but not limited to patents, copyrights, licenses, royalties from such rights, agreements to share royalties and similar interests.

Investigator

A project director, a principal investigator of a research project and any other person, regardless of title or position, who has responsibility for the design, conduct or reporting of research or project results at or involving Purdue, including Employees, subgrantees, contractors, subcontractors, collaborators and consultants. In general, any individual specifically named in a proposal and any individual whose resume or curriculum vitae is appended to a proposal is an Investigator for the purposes of this policy.

OTC

The Office of Technology Commercialization in Purdue Research Foundation, or any successor office performing similar functions.

PI

A Principal Investigator.

President

Purdue's President.

Provost

Purdue's Executive Vice President for Academic Affairs and Provost.

Purdue University, Purdue and University

Any campus, unit, program, association or entity of Purdue University, including but not limited to Indiana University-Purdue University Fort Wayne, Purdue University Calumet, Purdue University North Central, Purdue University West Lafayette, Purdue Cooperative Extension Service and Purdue University College of Technology Statewide.

Regulatory Committee

Any University committee or board with regulatory oversight responsibilities, such as Institutional Review Boards, the Purdue Animal Care and Use Committee, the Institutional Biosafety Committee and similar boards or committees.

Responsible Official

The Responsible Official for Research-Related Financial Conflicts of Interest, who is appointed by the Vice President for Research to oversee the receipt and review of disclosures of Significant Financial Interests related to (i) proposing, conducting or reporting of Purdue research or scholarship, (ii) research regulatory compliance and (iii) commercialization of Purdue's intellectual property, and the management of real or potential Conflicts of Interest arising from these disclosed Significant Financial Interests.

Significant Financial Interest

A Financial Interest held by an Investigator and/or an Investigator's Dependent that reasonably appears to be related to the Investigator's Institutional Responsibilities, and that consists of one or more of the following:

- Remuneration (including salary, consulting fees, honoraria, paid authorship and travel reimbursement) received from a publicly traded company during the twelve-month period preceding the date on which an Investigator is making a disclosure, and/or an Equity Interest held in such publicly traded company, if the aggregate value of such remuneration, plus the value of the Equity Interest as of the date of disclosure, exceeds \$5,000;
- Remuneration (including, but not limited to, salary, consulting fees, honoraria and paid authorship) received from a non-publicly traded company during the twelve-month period preceding the date on which an Investigator is making a disclosure, if the remuneration exceeds \$5,000;

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- Any Equity Interest in a non-publicly traded company or business, regardless of value; and
- Any Intellectual Property Rights, regardless of value.

Significant Financial Interest does not include:

- An Employee's salary or royalties received from Purdue and/or the Purdue Research Foundation,
- Income from seminars, lectures or teaching engagements sponsored by a federal, state or local government agency or an institution of higher education, or
- Income from service on panels for a federal, state or local government agency or institution of higher education.

SPS

Sponsored Program Services.

VPEC

Purdue's Vice President for Ethics and Compliance.

VPR

Purdue's Vice President for Research.

RESPONSIBILITIES

Academic Schools or Departments

Establish a policy appropriate to their circumstances to ensure that instructional materials are selected for their academic merit and that there is no significant Financial Conflict of Interest or appearance of such in selecting instructional materials.

Board of Trustees

In accordance with IC 35-44-1-3, review and approve disclosures and direct those that are approved be transmitted to the Indiana State Board of Accounts.

COI Officer

Receive disclosures of Employee Financial Interest in University procurement or contractual transactions, gifts received by the University and dedicated to the Employee's research or scholarship, or any University investment or loan from the office of the VPEC ; oversee the review of these disclosures; and manage any real or potential Conflicts of Interest arising from these Financial Interests.

Chair the Conflicts Committee and any appointed subcommittee.

Coordinate the development and oversight of appropriate conflict management and mitigation plans for Financial Conflicts of Interest when appropriate.

Notify the University's Purchasing Services and contracting officers upon receipt of a [Form C-1] disclosing a Financial Interest that involves their respective activities and for which it is

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determined that a Financial Conflict of Interest that cannot or should not be managed exists.

If a Financial Interest disclosed by an Employee is governed by IC 35-44-1-3, submit the disclosure for approval by the Board of Trustees and transmittal to the Indiana State Board of Accounts.

Report annually to the Conflicts Committee on identified real or potential Conflicts of Interest associated with University procurement, contracts, investments or loans; the status of formal plans implemented to manage or reduce these Conflicts of Interest; and compliance with applicable state requirements and University policies.

College/School/Departmental Business Offices

Obtain positive verification from the COI Officer that Financial Conflicts of Interest have been managed or eliminated prior to accepting a gift for which a Financial Interest has been disclosed.

Conflicts Committee

Review and comment on University procedures (including design of disclosure forms and questionnaires for gathering information) proposed by the COI Officer for the disclosure of Financial Interests by Employees, and proposed by the Responsible Official for disclosure of Significant Financial Interests by Investigators.

Review and comment on the design of management plans for real or potential Conflicts of Interest arising from disclosed Financial Interests and Significant Financial Interests and on procedures for monitoring these management plans, with a focus on compliance with applicable state and federal laws and other sponsor requirements relating to Conflicts of Interest and preserving objectivity in research.

Advise the COI Officer and Responsible Official as requested.

Receive and evaluate appeals from Employees and Investigators regarding management of real or potential Conflicts of Interest arising from disclosed Financial Interests and Significant Financial Interests.

Employee

Disclose, as required by this policy, any and all Financial Interests that he, she or a Dependent has in University activities or transactions. Such disclosures must be made as far in advance of the contract, purchase, procurement, investment or loan as possible, and may be made on an annual basis with respect to particular types of contracts or purchases of goods or services that the University makes on a repetitive basis from a particular vendor.

Upon request by the COI Officer, confirm the accuracy of and sign each [Form C-1] prepared by the COI Officer for transmittal to the Board of Trustees and the Indiana State Board of Accounts.

Comply with the requirements of any management or mitigation plan approved by the Conflicts Committee.

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EVPT

Forward disclosures received from the COI Officer to the Board of Trustees for review and approval.

Transmit all disclosures approved by the Board of Trustees to the Indiana State Board of Accounts.

Investigator

Disclose, as required by this policy, any and all Significant Financial Interests that he, she or a Dependent has, and update such disclosures within thirty days when necessary to maintain accuracy due to changed circumstances.

Comply with the requirements of any management or mitigation plan approved by the Conflicts Committee.

PI

Notify SPS of all Investigators on a project.

Provost, EVPT and VPEC

Jointly appoint the Conflicts Committee.

Purchasing Services

Obtain positive verification from the COI Officer that Financial Conflicts of Interest have been managed or eliminated prior to procuring goods or services for which a Financial Interest has been disclosed.

Regulatory Committees

Obtain positive verification from the COI Officer that Financial Conflicts of Interest have been managed or eliminated prior to approving a protocol for which a Financial Interest has been disclosed.

Obtain positive verification that committee members with Financial Interests in the sponsor or outcome of a proposed protocol have recused themselves from participation in the review of the protocol.

Responsible Official

Design and implement disclosure, review and Conflict of Interest management procedures to satisfy federal and other sponsor requirements and regulations to ensure objectivity in research and research regulatory compliance.

Oversee the review disclosures of Significant Financial Interest to identify real or potential Conflicts of Interest arising from these Significant Financial Interests.

If a Significant Financial Interest disclosed by an Employee is governed by IC 35-44-1-3, inform the COI Officer.

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Satisfy all federal regulatory requirements relevant to the subject matter of this policy and applicable to Purdue including, but not limited to, requirements related to (i) reporting, (ii) record keeping, (iii) causing required clauses to be included in agreements with subgrantees, subrecipients, contractors, subcontractors and collaborators in federally sponsored research projects, (iv) making any required public disclosures of Significant Financial Interests and (v) training Investigators.

Develop, implement and monitor management plans for real or potential Conflicts of Interest arising from disclosed Significant Financial Interests.

Serve as an ex officio member of the Conflicts Committee.

Report annually to the COI Officer and Conflicts Committee on real or potential Conflicts of Interest that may impact objectivity in research, the status of formal plans implemented to manage or reduce these Conflicts of Interest and compliance with applicable state and federal requirements and University policies.

Provide a report annually to each dean and to the executive director of Discovery Park identifying Investigators with appointments in their respective units with active Conflict of Interest management plans.

SPS

Receive FISs from PIs and Investigators when a proposal is submitted to an external sponsor.

Obtain positive verification from the COI Officer that Financial Conflicts of Interest have been managed or eliminated prior to awarding or expending any funds for a sponsored project for which a Financial Interest or a Significant Financial Interest has been disclosed.

University Development Office

Obtain positive verification from the COI Officer that Financial Conflicts of Interest have been managed or eliminated prior to accepting a gift for which a Financial Interest has been disclosed.

VPEC

Administer this policy.

Receive disclosures of Employee Financial Interest and distribute copies to the COI Officer (if someone other than the VPEC is designated as such) and others as appropriate.

Serve as the COI Officer, or designate another Employee to do so.

Respond to requests for interpretation or clarification of this policy.

Serve as ex officio member of the Conflicts Committee.

VPR

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Designate an individual to serve as Responsible Official.

PROCEDURES

- I. Disclosures of Employee Financial Interests in University Purchases or Procurement of Goods or Services, Contracts, Investments and/or Loans**
 - A. Prior to the beginning of each fiscal year, the VPEC will remind all Employees of the obligation to disclose any and all Financial Interests held by the Employee and/or their Dependents in University purchases or procurement of goods or services, contracts, investments and/or loans. The reminder notice will also:
 1. Describe the necessity of updating financial disclosures or submitting new financial disclosures during the year if new or altered Financial Interests develop.
 2. Remind Employees that a disclosure related to a Financial Interest in any University purchase or procurement of goods or services, or in any investment or loan made by the University, must be made as far in advance of the purchase, procurement, investment or loan as possible to provide sufficient time for the COI Officer to obtain approval of the disclosure in a public meeting of the Board of Trustees before final action is taken on the purchase, contract, investment or loan, as required by state law.
 - B. The COI Officer, in consultation with appropriate University human resources staff and other officials, will develop a process whereby each new Employee either (i) completes a disclosure form for each of his or her then existing and known Financial Interests in accordance with this policy or (ii) certifies that he or she has no known Financial Interests to disclose at that time.
 - C. Employees who have a known Financial Interest, held either by themselves or by their Dependents, in any University purchase or procurement of goods or services, or in any investment or loan by the University, whether the Financial Interest is held directly or through an interest in a vendor or other entity that may benefit financially from a University purchase or procurement, must disclose the Financial Interest on a [Form C-1] in advance of the purchase or procurement. Forms are to be submitted to the office of the VPEC.
 - D. [Form C-1]s received by the office of the VPEC will be forwarded to the COI Officer (if someone other than the VPEC) who will first determine if the financial disclosure is necessary under this policy. Disclosures found to be unnecessary will be returned to the Employee. If necessary, the disclosure will be reviewed by the COI Officer for completeness and clarity. When judged to be complete, the COI Officer will determine if the disclosure is new or a renewal of a previous disclosure.
 - E. New disclosures will be reviewed to determine whether there is a Financial Conflict of Interest. If no Financial Conflict of Interest is identified, the COI Officer will forward all necessary documentation to the EVPT for review and approval at the next scheduled public meeting of the Board of Trustees. Once approved, the EVPT will transmit the

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information to the Indiana State Board of Accounts. Each identified Financial Conflict of Interest will be considered to determine whether it can and should be managed by the University.

1. If the Financial Conflict of Interest is judged to be unmanageable or inappropriate to manage, steps will be taken to eliminate the Financial Conflict of Interest, which may include blocking execution of the University transaction that is the subject of the Financial Interest or changing the Employee's role and/or responsibilities. If, after the Financial Conflict of Interest has been eliminated, it is still possible and desirable to complete the University transaction, the COI Officer will forward all necessary documentation to the EVPT for review and approval at the next scheduled public meeting of the Board of Trustees. Once approved, the EVPT will transmit the information to the Indiana State Board of Accounts.
 2. If the Financial Conflict of Interest is judged to be manageable, a written conflict management plan will be developed with the Employee and the appropriate oversight manager(s). Once a management plan has been established and accepted, the COI Officer will forward all necessary documentation to the EVPT for review and approval at the next scheduled public meeting of the Board of Trustees. Once approved, the EVPT will transmit the information to the Indiana State Board of Accounts.
- F. Renewal disclosures will be reviewed by the COI Officer to determine if elements of the disclosure or associated University transaction have changed such that the original disposition of the disclosure should be reconsidered.
1. If there is no significant change, the COI Officer will forward all necessary documentation to the EVPT for review and approval at the next scheduled public meeting of the Board of Trustees. Once approved, the EVPT will transmit the information to the Indiana State Board of Accounts.
 2. If a significant change is identified, the disclosed Financial Interest will be re-reviewed as a new disclosure under Section I.E of these Procedures.

II. Disclosures of Financial Interests Related to a Gift Designated for the Benefit of a Named Investigator's Scholarship or Research

- A. Purdue University's Gift Acceptance policy (IX.2.1) specifies the procedures related to determining whether any business or pecuniary ties exist between a donor and the Investigator named as the beneficiary of a gift. Supplementing those procedures, the following steps will be taken.
- B. Once any business or pecuniary ties are identified by the responsible business manager, the nature of these ties will be communicated to the COI Officer. Upon receipt of this communication, the COI Officer will develop, with the Investigator and the proposed oversight manager, a management plan specifying how the gift will be managed and how the implementation of said management plan will be monitored.

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- C. The management plan will be forwarded for additional approval by all administrative levels specified in Policy IX.2.1.
 - 1. If approved at all administrative levels, the gift will be accepted and the management plan implemented.
 - 2. If the management plan is not approved at all administrative levels, the concerns of the official not approving will be identified and an alternative approach addressing these concerns will be developed. Once the revised management plan has been accepted by the Investigator and oversight manager and approved at all administrative levels specified by Policy IX.2.1, the gift will be accepted and the management plan implemented.

III. Disclosures of Investigator Significant Financial Interest in a Sponsored Project

- A. When a PI submits a project proposal to SPS for submission to an external sponsor, the PI must:
 - 1. Identify to the cognizant SPS pre-award specialist the names of all individuals who are Investigators for the proposed project.
 - 2. Complete an FIS reporting whether he or she (the PI) and/or his or her Dependent(s) has a Significant Financial Interest relating to the proposed project and submit the FIS to the cognizant SPS pre-award specialist.
- B. Upon receipt from the PI of the list of Investigators, the cognizant SPS pre-award specialist will contact each Investigator identified and alert them of the need to complete an FIS for the relevant proposed sponsored project.
- C. Upon notification by SPS of the need to complete an FIS for the relevant proposed project, all identified Investigators must:
 - 1. Complete an FIS reporting whether they (the Investigator) and/or their Dependent(s) have a Significant Financial Interest relating to the proposed project.
 - 2. Submit the completed FIS to the cognizant SPS pre-award specialist.
- D. Upon receipt of FISs from the PI and Investigators for a proposed project, the cognizant SPS pre-award specialist reviews each FIS for completeness. An incomplete FIS will be returned to the Investigator who submitted it and the deficiency noted. If the FIS is complete, the cognizant SPS pre-award specialist will do one of the following:
 - 1. If the Investigator indicated they do not have a Significant Financial Interest, the proposal record will be updated to indicate that an FIS has been submitted and the FIS will be filed in the proposal file.
 - 2. If the Investigator indicated they do have a Significant Financial Interest, the proposal record will be updated to indicate that an FIS has been submitted and the FIS will be forwarded to the Responsible Official.

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- E. When the Responsible Official receives an FIS indicating the existence of a Significant Financial Interest related to a proposed sponsored project, the Responsible Official will contact the Investigator submitting the FIS and request that the Investigator complete a [Form TBD] and return it to the office of the Responsible Official.
- F. [Form TBD]s received by the office of the Responsible Official will be reviewed first to determine if the disclosure of Significant Financial Interest is necessary under this policy. Disclosures found to be unnecessary will be returned to the Investigator. If necessary, the disclosure will be reviewed by the Responsible Official for completeness and clarity. When judged to be complete, the Responsible Official will determine if the disclosure is new or a further application of a previous disclosure.
- G. New disclosures will be reviewed first to determine if a disclosure of Financial Interest is also required under IC 35-44-1-3. If yes and the proposed project is to be initiated, the Responsible Official will notify the COI Officer (who will follow the necessary steps outlined in Section I.D of these Procedures). The Responsible Official will next determine whether the disclosed Significant Financial Interest will create a Financial Conflict of Interest if the proposed project is initiated. If no Financial Conflict of Interest is identified, the disclosure will be recorded in the Responsible Official's database, the basis for the determination of no Financial Conflict of Interest documented and the disclosure form stored in a secure location. If a Financial Conflict of Interest is identified, it will be considered to determine whether it can and should be managed by the University.
 - 1. If the Financial Conflict of Interest is judged to be unmanageable or inappropriate to manage, steps will be taken to eliminate the Financial Conflict of Interest, which may include withdrawing the project proposal that is the subject of the Financial Interest or changing the Investigator's role and/or responsibilities in the proposed project. If, after the Financial Conflict of Interest has been eliminated, it is still possible and desirable to conduct the proposed project, the Responsible Official will record the disclosure in the Responsible Official's database, document the actions taken to eliminate the Financial Conflict of Interest and file the disclosure and all documentation in a secure location until such time as the project is either cancelled or initiated.
 - 2. If the Financial Conflict of Interest is judged to be manageable, a written conflict management plan will be developed with the Investigator and appropriate oversight manager(s). Once a management plan has been established and accepted, the Responsible Official will record the disclosure in the Responsible Official's database, document the determination of a Financial Conflict of Interest and management plan, and file the disclosure and all documentation in a secure location until such time as the project is either cancelled or initiated. When the project is initiated, the management plan will be implemented.
- H. Disclosures with further application of a previous disclosure will be reviewed by the Responsible Official to determine if elements of the disclosure or the determination of a Financial Conflict of Interest have changed such that the original disposition of the

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disclosure should be reconsidered.

1. If there is no significant change, the Responsible Official will record the disclosure in the Responsible Official's database, document the conclusion that nothing has changed and any previous actions taken, and file the disclosure and all documentation in a secure location until such time as the project is either cancelled or initiated. When the project is initiated, any necessary management plans previously developed will be implemented.
2. If a significant change is identified, the disclosure will be re-reviewed as a new disclosure under Section III.G of these Procedures.

- I. Proposed projects funded by an external sponsor or initiated using Purdue internal funds that require a management plan for recognized Financial Conflicts of Interest will be implemented and monitored no less than annually by the office of the Responsible Official.
- J. If a proposed project is funded by an external sponsor, the Responsible Official will execute whatever notifications of the sponsor and/or public disclosure are required based on the sponsor's terms and conditions for award.
- K. Annually, the Responsible Official will provide a written notice to all Investigators who have filed FISs, whether they initially indicated a Significant Financial Interest or not, of the need to update their FIS and, if a [Form TBD] was also filed, of the need to update their [Form TBD].

IV. Disclosures of Investigator Financial Interests in a Research Project With Human or Living Vertebrate Animal Subjects

- A. At the time of submission of a protocol for review and approval of research involving human or living vertebrate animal subjects to a Purdue University Institutional Review Board or Purdue University Animal Care and Use Committee, respectively, the PI will indicate whether he or she and/or his or her Dependent(s), or any other project Investigators and/or their Dependent(s), have a Financial Interest in the outcome of the proposed research or in any entity that will be impacted by the outcome of the proposed research.
- B. If the PI or any project Investigators, or their Dependents, have such a Financial Interest, they must complete a [Form TBD] and submit it to the office of the Responsible Official.
- C. The office of the Responsible Official will first review the disclosure for completeness and clarity.
 1. If the disclosure is not complete or clear, it will be returned to the discloser and the deficiency noted.
 2. If the disclosure is complete and clear, it will be advanced to the next stage of review.

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- D. The Responsible Official will then review the disclosure to determine whether it is a new disclosure or a further application of a previous disclosure.
- E. New disclosures will be reviewed first to determine if a disclosure of Financial Interest is also required under IC 35-44-1-3. If yes and the proposed project is to be initiated, the Responsible Official will notify the COI Officer (who will follow the necessary steps outlined in Section I of these Procedures). The Responsible Official will next determine whether the disclosed Financial Interest will create a Financial Conflict of Interest if the proposed project is initiated. If no Financial Conflict of Interest is identified, the disclosure will be recorded in the Responsible Official's database, the basis for the determination of no Financial Conflict of Interest documented and the disclosure form stored in a secure location. If a Financial Conflict of Interest is identified, it will be considered to determine whether it can and should be managed by the University.
1. If the Financial Conflict of Interest is judged to be unmanageable or inappropriate to manage, appropriate steps will be taken to eliminate the Financial Conflict of Interest, which may include withdrawing the project protocol that is the subject of the Financial Interest or changing the PI's or other project Investigator's role and/or responsibilities in the proposed protocol. If, after the Financial Conflict of Interest has been eliminated, it is still possible and desirable to conduct the proposed project, the Responsible Official will record the disclosure in the Responsible Official's database, document the actions taken to eliminate the Financial Conflict of Interest and file the disclosure and all documentation in a secure location until such time as the project is either cancelled or initiated.
 2. If the Financial Conflict of Interest is judged to be manageable, a written conflict management plan will be developed with the PI or other project Investigator and appropriate oversight manager(s). Once a management plan has been established and accepted, the Responsible Official will record the disclosure in the Responsible Official's database, document the determination of a Financial Conflict of Interest and management plan, and file the disclosure and all documentation in a secure location until such time as the project is either cancelled or initiated. When the project is initiated, the management plan will be implemented and monitored no less frequently than annually by the office of the Responsible Official.
- F. Disclosures with further application of a previous disclosure will be reviewed by the Responsible Official to determine if elements of the disclosure or the determination of a Financial Conflict of Interest have changed such that the original disposition of the disclosure should be reconsidered.
1. If there is no significant change, the Responsible Official will record the disclosure in the Responsible Official's database, document the conclusion that nothing has changed and any previous actions taken, and file the disclosure and all documentation in a secure location until such time as the project is either cancelled or initiated. When the project is initiated, any necessary management plans previously developed will be implemented and monitored no less frequently than annually by the office of the Responsible Official.
 2. If a significant change is identified, the disclosure will be re-reviewed as a new

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disclosure under Section IV.E of these Procedures.

- G. If a proposed project is funded by an external sponsor, the Responsible Official will execute whatever notifications of the sponsor and/or public disclosure are required based on the sponsor's terms and conditions for award.
- H. Annually, the Responsible Official will provide a written notice to all PIs and/or other project Investigators who have filed disclosures of Financial Interests related to projects involving human or vertebrate animal subjects of the need to update their disclosure.

V. Disclosures by a Member of a Regulatory Committee of a Financial Interest in a Protocol to be Reviewed by that Committee

- A. If a member of a Regulatory Committee recognizes that he or she has a Financial Interest in a protocol to be reviewed by that Regulatory Committee, or in an entity that may be affected by the outcome of a protocol to be reviewed by the Regulatory Committee, the committee member must:
 - 1. Inform the chairperson of the Regulatory Committee that he or she has a Financial Interest in a protocol to be reviewed.
 - 2. Recuse himself or herself from participation in the review of that protocol.
 - 3. Return to the chairperson of the Regulatory Committee all materials associated with the review of the protocol.
 - 4. Leave the committee meeting room during discussion, deliberation and voting on the protocol, both during the initial meeting and any subsequent meetings of the Regulatory Committee when the protocol is considered for purposes of initial or continuing review, for discussion of unexpected or adverse events or for non-compliance associated with the protocol.

VI. Disclosures of Financial Interests Related to Commercialization of Purdue Intellectual Property

- A. Upon receipt of notification from OTC that one or more Purdue Employees holds an Equity Interest in, serves as an officer for or otherwise is involved in a management role with a third party to which OTC is considering licensing University intellectual property, the Responsible Official will contact each named Purdue Employee and determine whether:
 - 1. The Employee has received permission under the Conflicts of Commitment and Outside Activities policy (**number TBD**) to engage in an outside activity with the third party named in license negotiations with OTC.
 - 2. It is intended that the Employee will be involved in continuing research and development of the licensed Purdue intellectual property in their capacity as an Employee (for example, through sponsored research funded by the licensee to Purdue University).
 - 3. Purdue facilities will be utilized for the licensee's further commercial development of the licensed intellectual property.

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4. Any Purdue trainee (for example, graduate student or postdoctoral researcher) will be involved in further development at Purdue of the licensed intellectual property.
 5. The Employee plans to describe results from further development of the licensed intellectual property at Purdue in scholarly publications.
- B. Based on the above determinations, the Responsible Official will further determine whether a Financial Conflict of Interest management plan is required to oversee the Employee's Institutional Responsibilities concerning the licensed intellectual property.
1. If it is determined that no management plan is needed, the Responsible Official will document the basis for this decision, file the documentation in a secure location and inform OTC that negotiations regarding licensing intellectual property to the third party may be completed.
 2. If it is determined that a management plan is needed, the Responsible Official will determine whether there is an existing management plan addressing a previously disclosed Financial Interest/Significant Financial Interest related to this third party.
 - a. If no relevant management plan exists, one will be developed with the Employee and appropriate oversight manager, which will then be implemented and monitored by the office of the Responsible Official. The Responsible Official will notify the cognizant dean or unit leader of the implementation of such plan and will notify OTC that negotiations regarding licensing intellectual property to this third party may be completed.
 - i. In the event that a management plan acceptable to all parties can not be developed, the Employee, the Employee's cognizant dean or unit leader and OTC will be informed by the office of the Responsible Official that negotiations regarding licensing intellectual property to this third party may not be executed until or unless a mutually acceptable management plan is accepted.
 - b. If a relevant management plan already exists, the existing management plan will be reviewed to determine whether it addresses issues related to the potential license of University intellectual property to the third party.
 - i. If the existing management plan addresses all relevant issues, the office of the Responsible Official will notify the cognizant dean and OTC that negotiations regarding licensing intellectual property to this third party may be completed.
 - ii. If the existing management plan does not address all relevant issues, the management plan will be revised as described for a new management plan in VI.C.2.a above.

VII. Appeals

Employees or Investigators who disagree with a decision regarding the existence of a Financial Conflict of Interest or the necessary elements of a conflict management plan may submit a

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written appeal to the COI Officer. The COI Officer will submit the appeal to the Conflicts Committee for review. The decision of the Conflicts Committee on the matter will be final for all purposes.

RELATED DOCUMENTS, FORMS AND TOOLS

Policies

- Conflicts of Commitment and Outside Activities [**Policy number to be added**]:
[**Policy URL to be added**]
- Executive Memorandum No. C-37, University Policy Concerning Nepotism:
www.purdue.edu/policies/pages/human_resources/c_37.html
- Gift Acceptance (IX.2.1):
www.purdue.edu/policies/pages/advancement/ix_2_1_print.html
- Regulations Governing the Use and Assignment of University Facilities (I.4.1):
www.purdue.edu/policies/pages/facilities_lands/i_4_1.html

Forms

- [President's Office Form C-1]:
www.purdue.edu/research/vpr/rschadmin/coi/docs/FormC-1.pdf

Regulations

- Code of Federal Regulations:
www.gpoaccess.gov/ecfr/
- Department of Health and Human Services:
www.hhs.gov/ohrp
- Indiana Code:
www.in.gov/legislative/ic/code/
- National Science Foundation Award and Administration Guide:
www.nsf.gov/publications/pub_summ.jsp?ods_key=aag101&org=NSF

Other

- Flowcharts:
 1. Disclosures of Employee Financial Interests in University Purchases or Procurement of Goods or Services, Contracts, Investments and/or Loans
 2. Disclosures of Financial Interests Related to a Gift Designated for the Benefit of a Named Investigator's Scholarship or Research
 3. Disclosures of Investigator Significant Financial Interest in a Sponsored Project
 4. Disclosures of Investigator Financial Interests in a Research Project With Human or Living Vertebrate Animal Subjects
 5. Disclosures by a Member of a Regulatory Committee of a Financial Interest in a Protocol to be Reviewed by that Committee
 6. Disclosures of Financial Interests Related to Commercialization of Purdue Intellectual Property
- Frequently Asked Questions

HISTORY AND UPDATES

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This policy supersedes:

- Executive Memorandum No. C-39, University Policy on Conflicts of Interest and Commitment, dated October 25, 1995.
- Interim Faculty Policy on Conflicts of Interest and Commitment, dated December 30, 1991.
- Executive Memorandum C-1, Compliance with New “Conflicts of Interest” Disclosure Requirements, dated August 22, 1983.

APPENDIX

There are no appendices to this policy.

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