

**THURSDAY, MAY 19, 2022**  
**LEGAL, RISK AND COMPLIANCE COMMITTEE MEETING**

Elizabeth P. Kessler  
Alan A. Stockmeister  
Jeff M.S. Kaplan  
Elizabeth A. Harsh  
Michael F. Kiggin  
Tom B. Mitevski  
Tanner R. Hunt  
Gary R. Heminger (ex officio)

Location: WOSU Livestream or  
Sanders Grand Lounge, Longaberger Alumni House

Time: 1:30-3:00pm

**Public Session**

ITEMS FOR ACTION

1. Approval of February 2022 Committee Meeting Minutes – Ms. Elizabeth Kessler
2. Outside Activities and Conflicts Policy Review and Revision – Mr. Chris Glaros,  
Ms. Jessica Tobias

1:30-1:50pm

**Executive Session**

1:50-3:00pm



## **SUMMARY OF ACTIONS TAKEN**

*February 10, 2022 – Legal, Risk & Compliance Committee Meeting*

### **Voting Members Present:**

Elizabeth P. Kessler  
Alan A. Stockmeister  
Jeff M.S. Kaplan

Elizabeth A. Harsh  
Tom B. Mitevski  
Tanner R. Hunt

Gary R. Heminger (ex officio)

### **Members Present via Zoom:**

N/A

### **Members Absent:**

Michael Kiggin

## **PUBLIC SESSION**

The Legal, Risk & Compliance Committee of The Ohio State University Board of Trustees convened on Thursday, February 10, 2022, in person at Longaberger Alumni House on the Columbus campus and virtually over Zoom. Committee Chair Elizabeth Kessler called the meeting to order at 8:00 a.m.

### ***Items for Discussion***

1. **Name, Image & Likeness:** Athletics Director Gene Smith gave a report on the recent changes to the Name, Image and Likeness (NIL) landscape and how Ohio State Athletics has embraced NIL as a way to educate student-athletes on a variety of issues. Because there has not been consistent national oversight of restrictions on the use of NIL deals or federal legislation in this area as of this point, individual institutions and states have been left to establish their own NIL legislation and guidelines. According to state law in Ohio, universities are allowed to restrict certain categories (e.g., distilled alcohol, gambling, marijuana, tobacco, vapor products, adult entertainment, etc.) and to require that students disclose their deals prior to performing any NIL activity. Around 225 student-athletes have disclosed 620 NIL deals at Ohio State to date; most are small, around \$25 to \$500, with a handful of six-figure deals, for a total transaction value of nearly \$3 million. Men's football is the top sport for NIL deals at Ohio State, followed by women's volleyball. Ohio State developed an institutional SWAT Team, led by Senior Associate Athletics Director Carey Hoyt, that reviews student-athletes' NIL deals and verifies intellectual property rights. The team does not approve deals or give legal advice to the student-athletes, but it does offer educational insights on how to avoid pitfalls and how to take advantage of NIL opportunities appropriately. Ohio State also established the EDGE Team, which is an internal advisory working group of senior staff from Business Advancement and Athletics that is focused on creating and coordinating best-in-class NIL opportunities for student-athletes. This team includes certain NIL designated staff who are permitted to engage with brands and companies to assist in making connections with Ohio State's student-athletes. Three student-athletes – Mitchell Pehlke, men's lacrosse; Sarah Morbitzer, women's volleyball; and Treveyan Henderson, men's football – also joined the meeting to share their experiences with utilizing NIL deals as platforms for monetizing their personas.

(See Attachment X for background information, page XX)



***Items for Action:***

1. Approval of Minutes: No changes were requested to the November 18, 2021, meeting minutes; therefore, a formal vote was not required, and the minutes were considered approved.

**EXECUTIVE SESSION**

It was moved by Ms. Kessler, and seconded by Mr. Kaplan, that the committee recess into executive session to consult with legal counsel regarding pending or imminent litigation, to consider business-sensitive trade secrets that are required to be kept confidential by federal and state statutes, and to discuss personnel matters regarding the appointment, employment and compensation of public employees.

A roll call vote was taken, and the committee voted to go into executive session, with the following members present and voting: Ms. Kessler, Mr. Stockmeister, Mr. Kaplan, Mrs. Harsh, Mr. Mitevski, Mr. Hunt and Mr. Heminger.

The committee entered executive session at 8:31 a.m. and the meeting adjourned at 9:41 a.m.

DRAFT

## APPROVAL OF THE OUTSIDE ACTIVITIES AND CONFLICTS POLICY

Synopsis: Approval of a comprehensive university policy on outside activities and conflicts is proposed.

WHEREAS the university currently has multiple university policies addressing university ethical expectations, research conflicts of interest regulations, and other federal and state laws governing financial and fiduciary conflicts of interest, specifically the Faculty Conflict of Commitment and Faculty Paid External Consulting policies owned by the Office of Academic Affairs, the Faculty Financial Conflict of Interest policy owned by the Office of Research, and the Conflict of Interest and Work Outside the University policy owned by the Office of Human Resources; and

WHEREAS to promote simplicity and efficiency in these areas, the university proposes a single, comprehensive Outside Activities and Conflicts policy owned by the Office of University Compliance and Integrity to replace the four existing policies; and

WHEREAS the goal of the proposed policy is to make it easier for university community members to understand their ethical and legal responsibilities as well as the university's processes for managing and monitoring potential conflicts; and

WHEREAS the proposed policy has been approved by the University Senate, the Senior Management Council, and the President's Cabinet, and other university community members have reviewed and provided feedback on the policy in accordance with the university's standard approach to policy review; and

WHEREAS the Board of Trustees has previously approved three of the four policies being merged into the new comprehensive policy (Faculty Paid External Consulting, Faculty Conflict of Commitment, and Faculty Financial Conflict of Interest), and therefore the retirement of those three policies and the issuance of the new comprehensive Outside Activities and Conflicts policy are presented for Board approval; and

WHEREAS future changes to the Outside Activities and Conflicts policy may proceed through the university's standard policy review and approval process, and the Board of Trustees may be consulted but will not need to approve future policy changes:

NOW THEREFORE

BE IT RESOLVED, That the Board of Trustees hereby approves the attached Outside Activities and Conflicts policy, proposed to be effective September 1, 2022; and

BE IT FURTHER RESOLVED, That the Board of Trustees hereby approves the retirement of the Faculty Paid External Consulting policy, the Faculty Conflict of Commitment policy, and the Faculty Financial Conflict of Interest policy to become effective upon the issuance of the Outside Activities and Conflicts policy.



# Outside Activities and Conflicts Policy

Board of Trustees | May 19, 2022



THE OHIO STATE UNIVERSITY



## Conflicts of Interest in Higher Education: Process Improvement Strategy (2014-2022)

<b>Phase 1</b>	Align and simplify processes to improve the electronic conflict of interest (eCOI) disclosure process
<b>Phase 2</b>	<ol style="list-style-type: none"><li><b>1. Combine four COI policies</b></li><li>2. Revise UTCC Rule</li></ol>
<b>Phase 3</b>	Continue to advocate for regulatory change in higher education and Ohio State's strategic direction

<b>Laws and Regulations</b>	Ohio Ethics Law O.R.C. 102 & 2921	Federal Research	Ohio Technology Commercialization O.R.C. 3345	CMS Open Payments
<b>Purpose</b>	Ensure public employees maintain high ethical standards	Manage potential conflicts of interest in research	Allow university inventors to own interest in technology	Monitor physician/manufacturer and
<b>The Ohio State University Rules, Policies, &amp; Requirements</b>	3335-13-03 University Facilities			
	Nepotism Policy		3335-13-07 Technology Commercialization	
	Financial Code of Ethics		3335-13-06 Rights to and Interests in Intellectual	
	Medical Center Vendor Interaction Policy			
	Conflict of Interest and Work Outside the University Policy			Medical Center Conflict of Interest Protocol/Process
	Faculty Financial Conflict of Interest Policy			
	Faculty Paid External Consulting Policy			
	Faculty Conflict of Commitment Policy			
	OSU BOT Protocol		Intellectual Property Policy	
<b>Individuals covered by law/regulation</b>	~40,000	~15,000	Varies (faculty with intellectual property)	~1600 physicians and others
<b>Current disclosure process</b>	Electronic Conflict of Interest Disclosure (eCOI) Form (not all employees are required to disclose)		CEO Invention Disclosure	Open payments data reviewed against eCOI Form
<b>Manager/reviewer</b>	OUCI/Med Center Compliance	Office of Research Integrity/Dean/Chair	Corporate Engagement Office (CEO)	Med Center Compliance



# Organizational Alignment

## Institutional Strategy Map

- Improves operational efficiencies
- Accelerates decision making
- Reduces policy barriers
- Expands research infrastructure and eliminates redundancy

## Shared Values

- Creates sustainable solutions
- Facilitates openminded exploration and freedom of expression
- Advances institutional fairness
- Meets people where they are and promotes transparency





# Outside Activities and Conflicts Policy

## Incorporated Policies (to be Retired)

- **Faculty Financial Conflict of Interest (Office of Research).** Governs conflicts related to research; applies to faculty, staff, and students associated with research activities; approval process involves COIAC
- **Conflicts of Commitment (Office of Academic Affairs).** Governs conflicts related to all faculty responsibilities; conflicts reviewed by chair/dean
- **Faculty Paid External Consulting (Office of Academic Affairs).** Governs conflicts related to consulting/other paid outside activities; requires approval by chair or supervisor
- **Conflict of Interest and Work Outside the University Policy (Office of Human Resources).** Governs conflicts related to all staff responsibilities

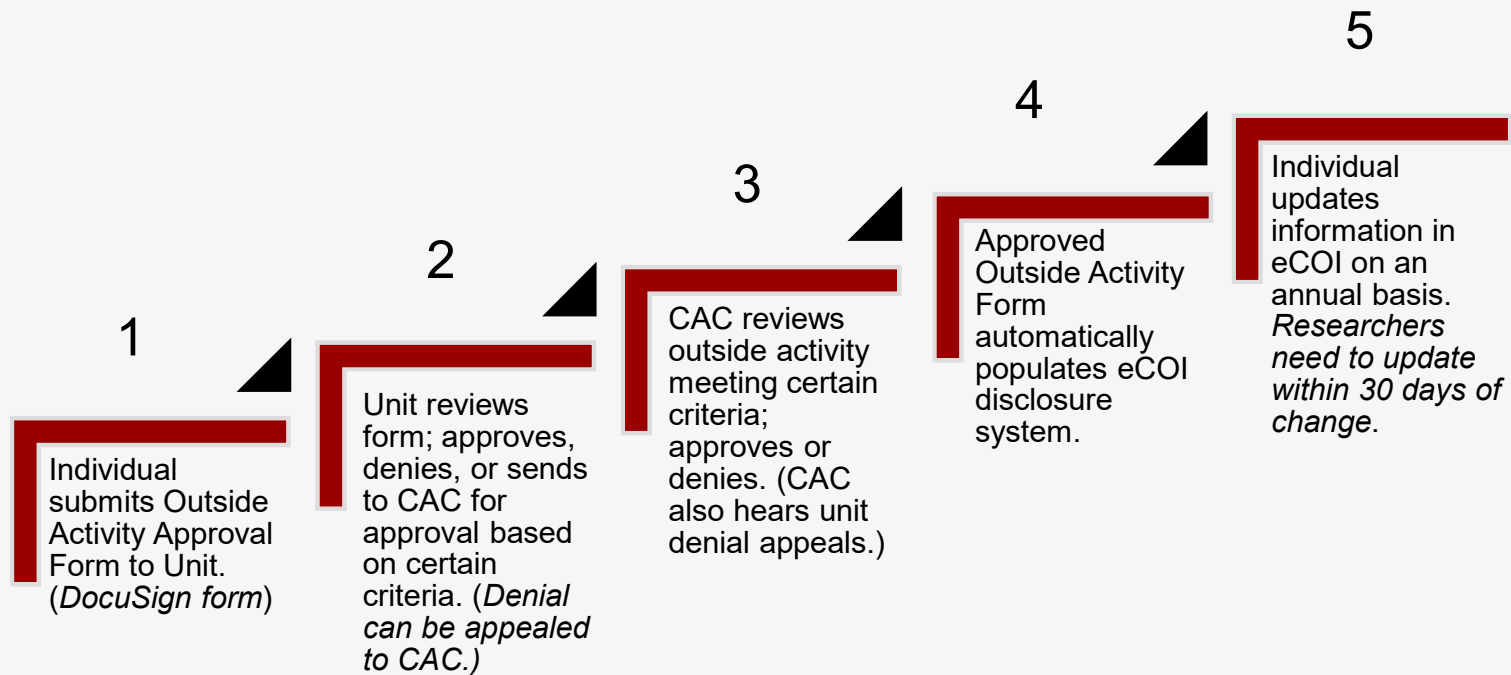
## Proposed Policy Key Elements

- **Integrates university values, four pre-existing policies, and multiple processes;** clarifies expectations and responsibilities regarding conflicts
- **Combines requirements of multiple legal areas**
- **Codifies existing university-wide eCOI disclosure process**
- **Establishes a Conflicts Approval Committee (CAC)** to review/approve outside activities for conflicts meeting certain criteria; allows college/unit participation in approvals, and allows them to set more restrictive requirements
- **Clarifies accountability for violations**



# Outside Activities Approval Process

(Consolidated steps replace 4 disparate processes)



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## Socialization and Engagement

This complex policy initiative relied on a well-established university policy process to solicit feedback and obtain buy-in.

- **Sept. 20**      **University-wide Feedback**
- **Mar. 24**      **University Senate**
- **Apr. 6**        **Senior Management Council**
- **Apr. 19**      **President's Cabinet**
- **May 19**      **Board of Trustees**



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# Thank you



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## Senior Leader Support

- Office of Academic Affairs
- Enterprise, Research, Innovation, and Knowledge
- Office of Human Resources
- Office of Legal Affairs



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## Stakeholders

- University Senate
- University Integrity and Compliance Council
- Conflict of Interest Advisory Committee
- University Research Committee



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## Working Groups

- Policy/Approval Form Writing Group
- Ad-hoc Advisory Group
- OUCI Policy Team





Applies to: Faculty, staff, student researchers, student employees, graduate associates, applicants

Responsible Office

Office of University Compliance and Integrity

POLICY

Issued: target effective date in Autumn 2022

The university encourages individual participation in outside activities, such as collaborations with government, industry, and other private institutions, because such participation helps advance the university’s mission through mutually beneficial partnerships and contributes to social and economic development and increased knowledge. Participation in outside activities therefore is permitted to the extent that the activity aligns with an individual’s responsibilities to the university, and that participation does not create a conflict of commitment (COC) or conflict of interest (COI). Individuals conducting research also must avoid financial conflicts of interest (FCOI) in research.

All employees are required to devote their primary professional allegiance to the university and conduct their university responsibilities with integrity, demonstrating both honesty and transparency. Similarly, all healthcare professionals have an ethical obligation to provide safe, effective, patient-centered, timely, efficient, and high-quality care for their patients. Therefore, all employees must arrange outside obligations, financial interests, and activities so as not to conflict or interfere with this commitment to the university or the best interest of the patient. This policy will not be interpreted to interfere with any faculty member's academic freedom, including their freedom to exercise their constitutional rights as citizens without institutional censorship or discipline. See Faculty Rule 3335-5-01.

In keeping with these ethical commitments, employees engaged in research at the university, employees identified by their unit as having significant financial or fiduciary responsibilities, college and regional campus deans, and all President’s Cabinet members must complete an electronic conflict of interest disclosure (eCOI) irrespective of their engagement in outside activities.

In addition, all employees who wish to engage in outside activities (excluding professional services as defined in the policy) must submit an Outside Activities Approval Form [link to be added] and obtain approval before engaging in any outside activities.

Purpose of the Policy

To delineate expectations and requirements for conducting outside activities; establish processes for transparency and accountability through the identification, disclosure, approval, and, when possible, management of COCs, COIs, and FCOIs; facilitate compliance with federal research regulations, state ethics laws, and unit-specific requirements; and notify employees and applicants of potential consequences of noncompliance with federal regulations, state laws, and this policy.

Definitions

Table with 2 columns: Term, Definition. Rows include Conflict of commitment (COC) and Conflict of interest (COI) with detailed definitions and numbered lists of examples.



Applies to: Faculty, staff, student researchers, student employees, graduate associates, applicants

Term	Definition
Conflict management plan (CMP)	A set of written obligations, created by the Conflict Approval Committee (CAC) and agreed to by the unit and the employee, to manage conflicts.
Designated work time	Hours agreed upon by a supervisor of when an employee will perform work for the university.
eCOI disclosure process	An annual process that requires certain employees to report outside activities using an internal online program.
Employees	Faculty, staff, graduate associates, and student employees.
Financial conflict of interest (FCOI) in research	An FCOI in research exists when financial interests could affect, or be perceived to affect, the design, conduct, or reporting of research.
Outside activities	Any activity, paid or unpaid, that is related or similar to an employee's university responsibilities and is performed outside the university (excluding professional service). This includes, but is not limited to, outside employment, consulting, advising, personally reimbursed or sponsored travel, conducting research outside Ohio State, roles on outside boards, financial interests, gifts, foreign government affiliations (any academic, scientific, professional, or institutional affiliation with a foreign government entity, including participation in a Foreign Government Talent Recruitment Program), and other compensated or uncompensated activities or interests.
Professional service	Service to governmental agencies and other entities such as peer review panels and advisory bodies to other universities and professional organizations; service to academic or professional journals; presentations to either professional or public audiences in such forums as professional societies and organizations, libraries, and other universities; and peer review activities undertaken for either for-profit or nonprofit publishers, including grant reviews and consultation.
Public health service (PHS) agencies	PHS agencies include, but are not limited to, the National Institutes of Health (NIH), Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), Indian Health Service (IHS), Health Resources and Services Administration (HRSA), Substance Abuse and Mental Health Services Administration (SAMHSA), Agency for Healthcare Research and Quality (AHRQ), Centers for Medicare & Medicaid Services (CMS), Administration for Children and Families (ACF), and Administration on Aging (AOA).
Research or conducting research	Any organized program of scientific inquiry, including designing research, directing or serving as a researcher performing laboratory experiments, having a role in soliciting consent from research subjects or making decisions related to eligibility of patients to participate in research, analyzing or reporting research data, or submitting manuscripts or abstracts concerning the research for publication. This includes projects for which outside support is requested and/or projects for which approval (or exemption) of an Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), or Institutional Biosafety Committee (IBC) is required.
Researcher	Project director, principal investigator, and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of university research. This definition may include students, collaborators, or consultants. This definition does not include individuals who perform only incidental or isolated tasks related to a university research project.
Significant financial interest (SFI) (for researchers)	For researchers, outside activities that reasonably appear to be related to the researcher's university responsibilities during the twelve (12) months preceding disclosure, which include the following: <ol style="list-style-type: none"> <li>(1) Payments received, and/or equity interests held, in aggregate, exceeding \$10,000. For PHS-funded researchers, the aggregate threshold is \$5,000.</li> <li>(2) Any equity interest in a non-publicly traded entity;</li> <li>(3) Any equity interest in a publicly-traded company that is 5% or greater;</li> <li>(4) Intellectual property rights and interests from an organization other than The Ohio State University or its affiliates upon receipt of income.</li> </ol>
Unit	College or administrative unit.
University responsibilities	Collectively, the educational, healthcare, research, scholarship, service, and administration activities that constitute an employee's obligations to the university, including time and effort allocation and the protection of university resources and intellectual property. University responsibilities are the same as institutional responsibilities in federal regulations.



Applies to: Faculty, staff, student researchers, student employees, graduate associates, applicants

### Policy Details

- I. Expectations and Responsibilities
  - A. This policy conveys university practices and procedures to maintain compliance with laws, regulations, and policies while also protecting university employees pursuing outside activities.
  - B. All employees covered under this policy are required to devote their primary professional allegiance to the university. Outside activities, while often valuable in themselves, may interfere or appear to interfere with ones' expectations, obligations, and/or responsibilities to students, colleagues, and the university.
  - C. All employees must disclose outside activities, as set forth in this policy, for review and approval before engaging in them.
  - D. Employees must take all necessary steps to avoid, eliminate, remediate, and/or manage COCs, COIs, and FCOIs.
  - E. The ethical expectations and responsibilities for all employees are also requirements of various state and federal laws and regulations, two of which are highlighted below.
    1. All university employees are subject to the Ohio Ethics Law found in [Ohio Revised Code Chapter 102, Section 2921.42](#), and [Section 2921.43](#). Employees may be exempt from certain restrictions based on their positions in accordance with applicable law. Additional information is available on the Ohio Ethics Commission's website and in the university's Guide to the Ohio Ethics Law and Outside Activities [\[link to be added\]](#). Under the Ohio Ethics Law, university employees may not:
      - a. Have a prohibited financial or fiduciary interest in a contract involving the university;
      - b. Use their authority or influence to obtain or authorize a contract between the university and themselves, a family member, or business associate;
      - c. Accept compensation for the performance of their university duties from any person or entity other than the university; or
      - d. Accept anything of value that may have a substantial and improper influence upon them with respect to their university duties.
    2. Federal regulations require the university to adopt a policy and procedures for identifying, managing, and reporting FCOIs. Specifically, the university must comply with the requirements of [42 C.F.R. 50, Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought"](#) as implemented in the 2011 Final Rule for grants and cooperative agreements and [45 C.F.R., Part 94, "Responsible Prospective Contractors."](#)
  - F. Units may have additional, more restrictive requirements or patterns of administration, such as the [Ohio State Wexner Medical Center Vender Interaction Policy](#) and the College of Medicine Guidance on Faculty Consulting.
  - G. All employees must disclose all outside activities to their unit, in accordance with Procedure I-II below. An employee also must provide additional relevant information concerning disclosed or undisclosed matters as may be requested by their supervising authority for the purpose of evaluating actual or potential COCs, COICs, and FCOIs.
- II. Conflict of Commitment (COC)
  - A. The responsibilities and professional activities that constitute an appropriate and primary commitment will differ among units but must be in accord with university policies and based on an understanding between the employee and their unit.
  - B. Faculty
    1. Faculty members, including administrators with faculty appointments, are encouraged to engage in outside activities to the extent that their unit supports such activities. However, any such activities must be clearly related to the mission of the university and the expertise of the faculty member, and must not create an unmanageable conflict.
    2. The proportion of a full-time faculty member's professional effort devoted to outside activities is not to exceed one business day per week during a fiscal year. Faculty with an appointment of at least fifty percent but less than full-time may be allowed a prorated number of days for outside activities as



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determined by their employing unit within its sole discretion. Faculty with an appointment of less than fifty percent are not allowed to engage in outside activities during on-duty periods. See [Faculty Rule 3335-5-07](#) for an explanation of on-duty periods.

3. Absent prior unit approval, situations that create an actual or a perceived COC include, but are not limited to, the following examples:
  - a. Teaching at another university during on-duty periods, or otherwise representing yourself as a faculty member of another university.
  - b. Using one's professional or clinical expertise during on-duty periods to provide services that compete with those provided by the university.
  - c. Participating in outside activities to the detriment of your university responsibilities.
  - d. Participating in professional and/or private business activities that interfere with or reduce effort and time committed to awarded federal or other external funds.
  - e. Conducting research or novel scientific investigation as an employee of or a private consultant to an outside entity when such work may be conducted as research sponsored through the Office of Sponsored Programs.
4. Outside activities during off-duty periods are not subject to time limitations; however, to ensure a conflict does not exist, the outside activities are still subject to prior approval and disclosure requirements.

### C. Staff

1. Staff engaging in outside activities must avoid a COC with their assigned university responsibilities.
2. Staff must use accrued vacation, compensatory time (non-exempt staff only), and/or leave without pay for both paid and unpaid outside activities occurring during **designated work time**.
3. Staff may perform unpaid outside activities that advance the university interests during designated work time if prior approval from the staff member's supervisor is obtained and the activities otherwise comply with this policy.

### D. Employees involved in outside activities with foreign entities may raise unique COC concerns. COCs may exist in outside activities with foreign entities in a variety of situations, including but not limited to when:

1. Activities interfere with the employee's time commitment and work obligations to the university;
2. An employee cites a primary affiliation with the foreign entity on publications;
3. An employee's activities at the foreign entity compete with their obligations to carry out similar activities at the university; or
4. Intellectual property that would be the sole property of the university becomes jointly shared with the foreign entity

## III. Conflict of Interest (COI)

- A. All employees are prohibited from engaging in outside activities that create an improper influence on their university decisions. All employees are also prohibited from engaging in outside activities that create a prohibited interest in a university contract or transaction or that otherwise violate the Ohio Ethics Law. (For more information see the Guide to the Ohio Ethics Law and Outside Activities [\[link to be added\]](#).)
- B. Faculty members must be especially sensitive to potential conflicts between their outside activities and their teaching responsibilities relative to students and trainees working under their supervision and/or grants. To avoid such conflicts, a faculty member may not hire or directly supervise a university student in outside activities while simultaneously serving as the student's advisor, supervisor, or as a participant on that student's thesis or dissertation committee without prior approval of the Conflict Approval Committee (CAC).

## IV. Financial Conflict of Interest (FCOI) in Research

- A. All individuals conducting university research must disclose outside activities so as to either avoid potential conflicts of interest or allow such conflicts to be managed as described in Procedure I-VIII and the [FCOI SOP](#).
- B. An FCOI may arise when the **researcher** (or the researcher's spouse or dependent child) holds a **significant financial interest (SFI)** that is related to the research. Examples include, but are not limited to, the following situations:





Applies to: Faculty, staff, student researchers, student employees, graduate associates, applicants

1. The SFI is held in an entity that is funding the research, providing in-kind support for the research, or participating in the research, or the entity may otherwise financially benefit from the research.
  2. The SFI could affect the design, conduct, or reporting of the research.
  3. The SFI could be affected by the research.
- C. If the unit or the CAC determines that a research conflict cannot be managed, the researcher must eliminate the outside activity or refrain from participating in the research.
- V. Use of University Resources, Name/Other Identifiers, and Employees for Outside Activities
- A. Employees may not use the university's facilities, equipment, services, supplies, or other resources for outside activities except when such use is pursuant to a contractual agreement with the university.
  - B. Employees must ensure that any publicity or advertising relating to authorized outside activities is not detrimental to the reputation and/or interests of Ohio State.
  - C. Employees may not use the university's name, trademarks, logos, indicia, or the fact that they are affiliated with the university in a manner that suggests that the university approves, disapproves, endorses, or promotes the following:
    1. A product or service provided by a for-profit, non-profit, or governmental entity;
    2. Research that the university has not performed or issued research findings when the university has not done so, or misleadingly states the results of university research; or
    3. Any communication that may be interpreted as the official position of the university on any issue, such as when providing expert testimony in a legal proceeding.
  - D. Employees engaging in outside activities may not use other university employees to assist in the outside activity unless they obtain pre-approval from the CAC. In the case of graduate associates, prior approval of the applicable dean is also required.
- VI. Intellectual Property
- A. Ohio law, federal law, and the university's [Intellectual Property policy](#) govern ownership of intellectual property rights. These laws and the university's Intellectual Property policy apply to university employees during both on-duty and off-duty periods.
  - B. For outside activities, whether paid or unpaid, university employees must not agree to transfer, license, grant, or assign to other people or entities any intellectual property rights that the university owns pursuant to applicable laws or the university's Intellectual Property policy. Before signing any agreement that transfers, licenses, grants, or assigns any intellectual property rights, a university employee must contact the university's technology commercialization office to determine the applicability of Ohio law, federal law, and/or the university's Intellectual Property policy, and the university employee must abide by the university's requirements to protect the university's intellectual property rights, which may include adding the university's intellectual property addendum to agreements for outside activities.
  - C. Employees who wish to participate in the commercialization of their university work must adhere to the specific standards and requirements as stated in the university's Intellectual Property policy and the University Rules Governing Faculty and Staff Participation in Companies Commercializing University Research. See [Rule 3335-13-07](#).
- VII. Accountability
- A. Violations of this policy include the failure to report potential conflicts or to abide by a **conflict management plan (CMP)**. Violations of this policy also include the failure to obtain prior approval before engaging in outside activities and failure to disclose outside activities with foreign entities, particularly participation in foreign government talent programs or other programs that would require an individual to not disclose their participation in such a program to the university.
  - B. Individuals who violate this policy may be subject to corrective or disciplinary action, up to and including termination or dismissal, in accordance with applicable policies, rules, collective bargaining agreements, or the [Code of Student Conduct](#).



Applies to: Faculty, staff, student researchers, student employees, graduate associates, applicants

### PROCEDURE

Issued: **target effective date in Autumn 2022**

- I. General Procedure – **Electronic Conflict of Interest (eCOI) Disclosure Process**
  - A. Individuals engaged in university research activities (see [FCOI SOP](#)), employees otherwise identified by their unit, including those who have financial or fiduciary responsibilities, college/regional campus deans, and President’s Cabinet members must annually complete an eCOI disclosure form regardless of whether they are engaged in outside activities. Proper completion of the eCOI disclosure form promotes transparency and accountability. (See [Common Scenarios for eCOI](#) and [eCOI: What Not to Disclose](#)).
    1. Researchers must update their annual eCOI disclosure form within 30 days of when any disclosed activity changes or they engage in a new outside activity.
    2. All researchers must disclose all outside activities in eCOI and must complete the required formal COI training in eCOI before engaging in any PHS-funded research. (See [FCOI SOP](#).)
    3. Disclosures are normally updated automatically when a new outside activity is approved by the unit or the CAC. However, the employee is responsible for ensuring that their eCOI disclosure is accurate.
    4. Units are responsible for identifying employees not engaged in research who are also required to complete an eCOI disclosure based on criteria identified in the eCOI Disclosure Criteria Document and the Ohio State University Wexner Medical Center Conflict of Interest Protocol/Process Document.
- II. General Procedure – Outside Activities Approval Form Submission, Review, and Approval
  - A. Before participating in outside activities, all employees must submit an Outside Activities Approval Form [\[link to be added\]](#) to their unit, provide the required documentation, and obtain approval from the unit for all outside activities.
  - B. The unit is responsible for reviewing the Outside Activities Approval Form [\[link to be added\]](#) and determining, in consultation with conflict administrators (see Procedure IV below) as needed, whether the unit will approve, deny, or obtain required Conflict Approval Committee (CAC) approval of the outside activity.
  - C. If the unit determines that CAC approval is not required, the unit may approve or deny the outside activity using the Outside Activities Approval Form [\[link to be added\]](#).
  - D. Individuals may appeal a unit’s denial by submitting an appeal in writing to the CAC chair. The CAC chair, in consultation with the CAC, will review the appeal and decide whether to issue an advisory opinion to the unit.
  - E. CAC approval is required if the outside activity may:
    1. Create an FCOI that could affect the design, conduct, or reporting of research;
    2. Interfere with the employee’s time commitment to the university;
    3. Compete with coursework or services that are or may be provided by the university;
    4. Interfere with the employee’s ability to carry out their university responsibilities;
    5. Improperly influence the employee’s or another individual’s university decisions;
    6. Create a prohibited interest in a university contract or transaction;
    7. Involve the use of university resources, name/other identifiers, or employees; or
    8. Involve the use or generation of university-owned intellectual property
  - F. Individuals must cooperate fully in the review of the pertinent facts and circumstances.
  - G. Upon completing its review, the CAC will provide its decision to individuals in writing.
  - H. If the CAC determines that a conflict exists, the CAC will require a CMP to manage the conflict whenever possible. Employees must fulfill the requirements of CMPs to engage in the desired outside activities.
  - I. If an activity cannot be managed to avoid a conflict, the employee must refrain from participating in the activity.
  - J. The CAC will review information regarding the approval and denial of outside activities on an annual basis.
  - K. Employees do not need prior approval from their unit to engage in **professional service** within the U.S. However, employees do need prior approval from their unit to engage in professional service involving a



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foreign government agency or a foreign government institution. Approving units may consult with the Office of Secure Research for additional information.

- L. Unit approvers and employees are encouraged to consult with conflict administrators (see Procedure IV below) about complex outside activities requests.

### III. Financial Conflicts of Interest (FCOI) in Research

- A. The unit and/or conflict administrators (see Procedure IV below) will review eCOI disclosures with SFIs, or personally reimbursed or sponsored travel related to university responsibilities, and may refer such matters to the CAC for review if the activity presents a potential COI. (See [FCOI SOP](#).)
- B. If an individual fails to disclose or properly manage an FCOI or fails to comply with a CMP related to a PHS-funded project, the university may complete a retrospective review of the research at issue to evaluate whether these actions created any bias in the design, conduct, or reporting of the research. If bias is found, the university will take corrective action as it deems appropriate. (See [FCOI SOP](#).)
- C. The vice president for research or designee (see [FCOI SOP](#)) is responsible for providing FCOI reports to outside funding agencies as required by federal regulations or the terms of sponsored research agreements.
- D. Potential conflicts involving human subjects research require special scrutiny. Given the real or perceived risks to the welfare and rights of human subjects, the CAC will advise the Institutional Review Board (IRB) regarding such conflicts. (See [FCOI SOP](#).)
  - 1. Conflicted researchers may not serve as principal investigators in projects deemed greater than minimal risk by the IRB. Limited exceptions may be made in specific cases.
  - 2. Researchers who believe that the conflict management measures adopted by an IRB are not appropriate or are based on erroneous information must follow applicable IRB procedures for requesting additional review. Decisions made by the IRB are final.

### IV. Conflict Administrators

- A. The executive vice president and provost will appoint a conflict administrator in the Office of Academic Affairs (OAA) to support implementation of this policy, assist faculty in identifying conflicts, and inform the university community about the policy.
- B. The vice president for research will appoint a conflict administrator in the Office of Research Compliance (ORC) to support implementation of this policy; design procedures for reporting FCOIs to federal sponsors; assist faculty and other employees in the research community in identifying, managing, or COCs, COIs and FCOIs; and inform the university research community about regulatory or policy changes.
- C. The vice president and chief compliance officer will appoint a conflict administrator in the Office of University Compliance and Integrity (OUCI) to support implementation of this policy; assist employees in identifying conflicts; and inform the university community about the policy and issues relating to COCs, COIs, and compliance with the Ohio Ethics Law.
- D. The senior vice president for human resources will appoint a conflict administrator in the Office of Human Resources (OHR) to support implementation of this policy; assist employees in identifying conflicts; and inform the university community about the policy.
- E. The Ohio State University Wexner Medical Center (OSUWMC) chief compliance officer will appoint a conflict of interest officer to support OSUWMC faculty and staff with implementing this policy and unit-specific policies.
- F. The senior vice president and general counsel will appoint one or more attorneys to advise conflict administrators and the CAC on the requirements of the law and university policy.

### V. Conflict Approval Committee (CAC)

- A. CAC membership is comprised of the following:
  - 1. A chair selected by OUCI;
  - 2. Faculty or staff voting representatives recommended by units and approved by OUCI;
  - 3. Non-voting conflict administrators and representatives from major constituency groups, including ORC, OUCI, OSUWMC, OHR, OAA, Office of Legal Affairs, and Office of Responsible Research Practices.



Applies to: Faculty, staff, student researchers, student employees, graduate associates, applicants

- B. A majority of the CAC voting members will be tenured faculty.
- C. The CAC will review and approve or manage COC, COI, and FCOIs related to employees’ outside activities, as described in Procedure II.
- D. The CAC will periodically review the operations of this policy related to COCs, COIs, and FCOIs and make operational changes as needed, including those mandated by federal and state regulation or accreditation requirements.
- E. CAC members will meet for annual training sessions provided by the ORC and the OUCI regarding the Outside Activities and Conflicts policy and related federal regulations and state ethics laws.

### VI. CAC Reconsideration Process

- A. Within seven (7) days of receiving a CAC decision, an employee may request reconsideration by submitting a written request to the CAC chair. A request for reconsideration must show that the CAC decision was not appropriate or was based on erroneous or incomplete information. Employees may present relevant new or additional information in their reconsideration requests.
- B. The CAC chair, in consultation with the CAC, will review and consider requests for reconsideration.
- C. In cases where a CAC decision prevents an employee from participating in an outside activity because it is incompatible with the interests of the university, the CAC may request an additional evaluation from other university officials with relevant knowledge or expertise.
- D. The CAC chair will make every effort to respond in writing within fourteen (14) days to the employee requesting reconsideration.
- E. Reconsideration decisions by the CAC are final.

### VII. Prospective Employees

- A. Job applicants must disclose potential COCs, COIs, and FCOIs and make acceptable arrangements with the unit, and if necessary, the CAC. These arrangements must be included in the offer letter. The inability to reach an acceptable arrangement regarding a conflict may result in revocation of the offer letter or non-selection.

### Responsibilities

Position or Office	Responsibilities
Conflict administrator	<ol style="list-style-type: none"> <li>1. Support implementation of this policy, assist employees in identifying conflicts, and inform university community about policy.</li> <li>2. Consult with unit to review Outside Activities Approval Form as needed.</li> <li>3. Review eCOI disclosures with SFIs or personally reimbursed or sponsored travel related to university responsibilities and design procedures for reporting FCOIs to federal sponsors (Conflict Administrator in ORC only).</li> </ol>
Conflict Approval Committee (CAC)	<ol style="list-style-type: none"> <li>1. Review and issue a decision on Outside Activities Approval Forms elevated by the unit.</li> <li>2. Consult with CAC chair to review appeals of unit denials and requests for reconsideration of CAC decisions as set forth in the policy.</li> <li>3. Review and approve or manage outside activities that meet any condition outlined in Procedure II.E.</li> <li>4. Require a CMP to manage a conflict, whenever possible, if a conflict is determined to exist.</li> <li>5. Review information regarding approval and denial of outside activities on an annual basis.</li> <li>6. Advise IRB regarding potential conflicts involving human subjects research.</li> <li>7. Periodically review the operations of this policy related to COCs, COIs, and FCOIs and make operational changes as needed.</li> <li>8. Meet for annual training sessions as set forth in the policy.</li> </ol>
CAC chair	<ol style="list-style-type: none"> <li>1. Review appeals of unit denials and requests for reconsideration of CAC decisions, in consultation with the CAC, as set forth in the policy.</li> <li>2. Make every effort to respond in writing within fourteen (14) days to employees requesting reconsideration.</li> </ol>
Employee	<ol style="list-style-type: none"> <li>1. Devote primary professional allegiance to the university and conduct university responsibilities with integrity.</li> </ol>



Applies to: Faculty, staff, student researchers, student employees, graduate associates, applicants

Position or Office	Responsibilities
	<ol style="list-style-type: none"> <li>2. Arrange outside obligations, financial interests, and activities so as not to conflict or interfere with commitment to the university or best interests of patients.</li> <li>3. Submit an Outside Activities Approval Form and obtain approval before engaging in outside activities.</li> <li>4. Take all necessary steps to avoid, eliminate, remediate, and/or manage COCs, COIs, and FCOIs.</li> <li>5. Refrain from participating in activities if an activity cannot be managed to avoid a conflict.</li> <li>6. Ensure that any publicity or advertising relating to authorized outside activities is not detrimental to the reputation and/or interests of Ohio State.</li> <li>7. Contact TCO to determine applicability of Ohio law, federal law, and/or the university's Intellectual Property policy before signing any agreement that transfers, licenses, grants, or assigns any intellectual property rights.</li> <li>8. Ensure that any required eCOI disclosure is accurate.</li> <li>9. Fulfill requirements of CMPs, if required, to engage in the desired outside activities.</li> <li>10. Receive prior approval from their unit to engage in professional service involving a foreign government agency or foreign government institution.</li> </ol>
Employees engaged in research at the university, employees identified by unit as having significant financial or fiduciary responsibilities, college and regional campus deans, and President's Cabinet members	Annually complete eCOI disclosure form regardless of whether they are engaged in outside activities.
Executive vice president and provost	Appoint a conflict administrator in OAA.
Individuals conducting university research	<ol style="list-style-type: none"> <li>1. Update annual eCOI disclosure form within 30 days of when any disclosed activity changes or engaging in a new outside activity.</li> <li>2. Complete required formal COI training in eCOI before engaging in any PHS-funded research.</li> </ol>
Job applicants	Disclose potential COCs, COIs, and FCOIs and make acceptable arrangements with unit, and if necessary, CAC.
Senior vice president and general counsel	Appoint one or more attorneys to advise conflict administrators and the CAC on the requirements of the law and university policy.
Office of University Compliance and Integrity (OUCI)	<ol style="list-style-type: none"> <li>1. Select CAC chair.</li> <li>2. Approve CAC faculty or staff voting representatives recommended by units.</li> <li>3. Provide annual training sessions to CAC members as set forth in the policy.</li> </ol>
OSUWMC chief compliance officer	Appoint a conflict of interest officer to support OSUWMC faculty and staff with implementing this policy and unit-specific policies.
Office of Research Compliance (ORC)	Provide annual training sessions to CAC members as set forth in the policy.
Unit	<ol style="list-style-type: none"> <li>1. Identify employees who are required to complete an eCOI disclosure.</li> <li>2. Review Outside Activities Approval Form and determine, in consultation with conflict administrators as needed, whether to approve, deny, or obtain required Conflict Approval Committee (CAC) approval of the outside activity.</li> <li>3. Review eCOI disclosures with SFIs or personally reimbursed or sponsored travel related to university responsibilities as set forth in the policy.</li> <li>4. Recommend CAC faculty or staff voting representatives to OUCI.</li> </ol>
Vice president and chief compliance officer	Appoint a conflict administrator in OUCI.
Vice president for research or designee	<ol style="list-style-type: none"> <li>1. Provide FCOI reports to outside funding agencies as required by federal regulations or the terms of sponsored research agreements.</li> <li>2. Appoint a conflict administrator in ORC.</li> </ol>



Applies to: Faculty, staff, student researchers, student employees, graduate associates, applicants

### Resources

#### Governance Documents

- 42 C.F.R. 50, Subpart F-Promoting Objectivity in Research, [ecfr.gov/current/title-42/part-50](http://ecfr.gov/current/title-42/part-50)
- 45 C.F.R., Part 94-Responsible Prospective Contractors, [ecfr.gov/current/title-45/part-94](http://ecfr.gov/current/title-45/part-94)
- Code of Student Conduct, [trustees.osu.edu/bylaws-and-rules/code](http://trustees.osu.edu/bylaws-and-rules/code)
- Corrective Action and Involuntary Termination policy, [hr.osu.edu/policy/policy815.pdf](http://hr.osu.edu/policy/policy815.pdf)
- Faculty Rule 3335-5-01, [trustees.osu.edu/bylaws-and-rules/3335-5](http://trustees.osu.edu/bylaws-and-rules/3335-5)
- Faculty Rule 3335-5-07, [trustees.osu.edu/bylaws-and-rules/3335-5](http://trustees.osu.edu/bylaws-and-rules/3335-5)
- Faculty Rule 3335-13-07, [trustees.osu.edu/university-faculty-rules/3335-13](http://trustees.osu.edu/university-faculty-rules/3335-13)
- Financial Conflict of Interest Standard Operating Procedures, [go.osu.edu/fcoiinresearchsop](http://go.osu.edu/fcoiinresearchsop)
- Intellectual Property policy, [oied.osu.edu/sites/default/files/pdfs/IP-Policy.pdf](http://oied.osu.edu/sites/default/files/pdfs/IP-Policy.pdf)
- Ohio Ethics Law, Ohio Revised Code Chapter 102, [codes.ohio.gov/ohio-revised-code/chapter-102](http://codes.ohio.gov/ohio-revised-code/chapter-102)
- Ohio Ethics Law, Ohio Revised Code §2921.42, [codes.ohio.gov/ohio-revised-code/section-2921.42](http://codes.ohio.gov/ohio-revised-code/section-2921.42)
- Ohio Ethics Law, Ohio Revised Code §2921.43, [codes.ohio.gov/ohio-revised-code/section-2921.43](http://codes.ohio.gov/ohio-revised-code/section-2921.43)
- Review of Research by The Convened IRB, [go.osu.edu/hrpppolicy12](http://go.osu.edu/hrpppolicy12)
- Wexner Medical Center Vendor Interaction Policy, [wexnermedical.osu.edu/about-us/employee-onesource](http://wexnermedical.osu.edu/about-us/employee-onesource)

#### Additional Guidance

- College of Medicine Guidance on Faculty Consulting, [onesource.osumc.edu/sites/forms/Pages/COM%20Faculty%20Affairs%20Forms.aspx](http://onesource.osumc.edu/sites/forms/Pages/COM%20Faculty%20Affairs%20Forms.aspx)
- Common Scenarios for eCOI, [go.osu.edu/commondisclosurescenarios](http://go.osu.edu/commondisclosurescenarios)
- eCOI: What Not to Disclose, [go.osu.edu/whatnottodisclose](http://go.osu.edu/whatnottodisclose)
- Guide to the Ohio Ethics Law and Outside Activities, [\[link to be added\]](#)
- Outside Activities Approval Form, [\[link to be added\]](#)
- The Ohio Ethics Law for Public Universities & Colleges, [ethics.ohio.gov/education/factsheets/PublicUniversitiesandColleges.pdf](http://ethics.ohio.gov/education/factsheets/PublicUniversitiesandColleges.pdf)

### Contacts

Subject	Office	Telephone	E-mail/URL
COC questions regarding faculty	Office of Academic Affairs	614-292-5881	<a href="http://oaa.osu.edu">oaa.osu.edu</a>
COC questions regarding staff	Office of University Compliance and Integrity	614-292-3251	<a href="mailto:Compliance-integrity@osu.edu">Compliance-integrity@osu.edu</a> <a href="http://Compliance.osu.edu">Compliance.osu.edu</a>
COI questions	Office of University Compliance and Integrity	614-292-3251	<a href="mailto:Compliance-integrity@osu.edu">Compliance-integrity@osu.edu</a> <a href="http://Compliance.osu.edu">Compliance.osu.edu</a>
FCOI in Research questions	Office of Research Compliance	614-292-9258	<a href="mailto:conflictinfo@osu.edu">conflictinfo@osu.edu</a> <a href="http://orc.osu.edu">orc.osu.edu</a>
International engagement questions	Office of Secure Research	614-688-0725	<a href="mailto:secureresearch@osu.edu">secureresearch@osu.edu</a> <a href="http://go.osu.edu/international-engagements">go.osu.edu/international-engagements</a>
Legal issues	Office of Legal Affairs	614-292-0611	<a href="http://legal.osu.edu">legal.osu.edu</a>

### History

Issued: **XX/XX/2022** This policy replaces the Faculty Financial Conflict of Interest policy, Faculty Conflict of Commitment policy, Faculty Paid External Consulting policy, and Conflict of Interest and Work Outside the University policy, which are being retired as standalone policies.



# Faculty Paid External Consulting

## Office of Academic Affairs

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Applies to: Faculty (including administrators with faculty appointments)

### POLICY

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Issued: 04/04/98

Revised:

Edited: 05/14/12

Reviewed:

#### I. Preamble

Participation by faculty members of The Ohio State University in activities of government, in industry and in other private institutions generally serves the academic interests of the university. As a result of such activities, the people of Ohio benefit from the dissemination of knowledge and technology developed within the university and students benefit from experiences faculty bring to the classroom. Moreover, the professional experience and recognition that such participation brings to the faculty member is shared indirectly by the university. The patterns of administration of tenure-initiating units (TIUs), colleges, and university offices may discuss in greater detail the relation of such participation to the missions of those units.

The purpose of this policy is to establish guidelines and reporting requirements for paid consulting, external to the university, that is undertaken by faculty members, including administrators with faculty appointments, and that is related to their areas of professional expertise. The following activities are not subject to this policy's guidelines and reporting requirements:

- 1) External professional activities that reflect normal and expected public service activities of faculty and that do not entail compensation beyond reimbursement for expenses and/or a nominal honorarium. These activities include service to governmental agencies and boards such as peer review panels and advisory bodies to other universities; presentations to either professional or public audiences in such forums as professional societies, libraries, and other universities; and peer review activities undertaken for either for-profit or nonprofit publishers.
- 2) Health care activities that are explicitly covered by approved practice plans.

#### II. Policy

Faculty members, including administrators with faculty appointments, are encouraged to engage in paid external consulting to the extent that these activities are clearly related to the mission of the university and the expertise of the faculty member, provide direct or indirect benefits to the university, and do not entail a conflict of interest as defined in the Conflict of Interest Policy.

As a general rule, the proportion of a faculty member's professional effort devoted to consulting should not exceed one business day per week. Prior approval must be obtained as outlined in the procedures below. Faculty members should avoid any conflict or appearance of conflict between consulting and university responsibilities. In particular, the disruption of formal instructional activities because of consulting must be avoided. Consulting during off-duty periods is not subject to time limitations.

Under Ohio law, the university owns any intellectual property that is a "product of university research" as defined in Section B of the Policy on Patents and Copyrights. The external consulting policy applies to faculty members from the initial date of employment, including during off-duty periods, until the date of resignation. When consulting, faculty members must not assign to other entities the rights to a product of university research. Before signing a consulting agreement that requires assignment of intellectual property rights, a faculty member should contact the Office of Technology Licensing and Commercialization to determine the applicability of the Policy on Patents and Copyrights.

Faculty may not, in connection with paid external consulting, use the university name or the fact that they are affiliated with the university, in a manner that:



# Faculty Paid External Consulting

## Office of Academic Affairs

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Applies to: Faculty (including administrators with faculty appointments)

- 1) Suggests that the university approves or disapproves of a product or service provided by a profit, non-profit or governmental entity; or
- 2) Suggests that the university has performed research or issued research findings when it has not done so, or misleadingly states the results of university research; or
- 3) May be interpreted to communicate the official position of the university on any issue of public interest.

Faculty may not use university letterhead in connection with paid external consulting, nor may they use university facilities and other resources to support consulting unless permission is obtained from the TIU chair and the university is appropriately compensated.

Faculty may not use university Institutional Reviews Boards, e.g., the Human Subjects Review Board, for research conducted as part of a consulting arrangement.

Faculty are personally responsible for any damages or claims for damages which may arise in connection with their consulting activities. The limited immunity conferred by Section 9.86 of the Ohio Revised Code does not apply to consulting.

### III. Procedures

#### 1) Reporting Requirements

##### a) Prior approval

A faculty member must complete the Paid External Consulting Approval Form for each consulting arrangement. These forms shall be filed with the TIU chair or, in the case of an administrator, with the individual to whom he or she reports. All paid external consulting related to one's area of expertise requires prior approval. If a faculty member engages in paid external consulting without first obtaining approval or participates in activities that have been disapproved, a complaint may be filed against the faculty member under Faculty Rule 3335-5-04.

If a proposed consulting arrangement causes or could be perceived to cause a potential conflict of interest, the faculty member must file a Conflict of Interest Form along with the Paid External Consulting Approval Form.

All absences from duty of one full business day or more resulting from consulting, and all absences resulting from consulting that cause a missed commitment such as a class, require the prior approval of the TIU chair or other unit administrator. The Human Resources Application for Leave Form is used for this purpose.

##### b) Timing of reporting

Some consulting arrangements are on-going whereas others occur at a specific moment in time. For on-going activities, a faculty member may complete a single Paid External Consulting Approval Form for that activity to cover the entire time during which the activity will take place, but not beyond the end of the fiscal year in which the form is filed. A new form is required if the activity continues into another fiscal year. Each non-continuing activity during a fiscal year requires a separate form. These forms must be filed sufficiently in advance of the planned activity to permit time for a meaningful approval process including the development of a plan to manage any conflict of interest or other legal issues posed by the proposed activity.

##### c) Approval mechanism

The Paid External Consulting Approval Form must be approved by the tenure unit initiating unit chair and dean, or by a regional campus dean. In the case of administrators, the form must be approved by the person to whom he or she reports. A copy of the form shall be included in the faculty member's primary personnel file. If the TIU chair





# Faculty Paid External Consulting

## Office of Academic Affairs

Applies to: Faculty (including administrators with faculty appointments)

does not approve the proposed activity, the faculty member may appeal to the dean. If the dean does not approve the proposed activity, the faculty member may appeal to the provost. The provost's decision shall be final.

### Resources

- Application for Leave Form, <http://hr.osu.edu/forms/index.aspx#leave>
- Faculty Financial Conflict of Interest, <http://orc.osu.edu/files/Policy-on-Faculty-Financial-Conflict-of-Interest.pdf>
- Faculty Conflict of Commitment, [https://oaa.osu.edu/sites/default/files/links\\_files/conflictofcommitment.pdf](https://oaa.osu.edu/sites/default/files/links_files/conflictofcommitment.pdf)
- Ohio Revised Code, <http://codes.ohio.gov/>
- Paid External Consulting Approval Form, <https://oaa.osu.edu/policies-guidelines-forms>
- Policy on Patents and Copyrights, <http://research.osu.edu/researchers/policies/patents-and-copyrights/>
- Rules of the University Faculty, <http://trustees.osu.edu/ChapIndex/index.php>

### Contacts

Subject	Office	Telephone	E-mail/URL
Consulting agreements	Office of Technology Licensing and Commercialization	614-292-1315	<a href="http://tlc.osu.edu/">http://tlc.osu.edu/</a>
Intellectual property rights	Office of Technology Licensing and Commercialization	614-292-1315	<a href="http://tlc.osu.edu/">http://tlc.osu.edu/</a>
Paid external consulting	Office of Academic Affairs	614-292-5881	<a href="http://oaa.osu.edu">http://oaa.osu.edu</a>
Technology licensing and commercialization	Office of Technology Licensing and Commercialization	614-292-1315	<a href="http://tlc.osu.edu/">http://tlc.osu.edu/</a>

### History

Reviewed and approved by the University Senate.

Issued: 04/04/98

Revised:

Edited: 01/01/11, 05/14/12

Reviewed:



# Faculty Conflict of Commitment

## Office of Academic Affairs

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Applies to: Full-time faculty (including administrators and staff with faculty appointments)

### POLICY

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Issued: 07/08/05

Revised:

Edited: 05/14/12

Reviewed:

#### I. Preamble

Faculty at The Ohio State University accept an obligation to avoid conflicts of commitment in carrying out their university education, research, scholarship or service responsibilities. This policy is intended to assist faculty members, including administrators and staff with faculty appointments, in avoiding these conflicts and in finding a balance between activities that enhance the university's core purpose—to advance the well-being of the people of Ohio and the global community through the creation and dissemination of knowledge—and those that detract from it.

#### II. State and Federal Laws and Regulations

Federal regulations require the university to adopt a policy governing conflicts of interest in research. In addition, faculty members should be aware that they are also subject to various provisions of Ohio law governing ethics and conflicts of interest in public employment. Additional information about the requirements of Ohio law may be obtained by consulting the Office of Legal Affairs.

#### III. Definition

For purposes of this policy, a conflict of commitment exists when external or other activities are so substantial or demanding as to interfere with the individual's teaching, research, scholarship or service responsibilities to the university or its students.

#### IV. Policy

Ohio State University full-time faculty members, including administrators with faculty appointments, owe their primary professional allegiance to the university, and their primary commitment of time and intellectual energies should be to the education, research, service and scholarship programs of the institution. The specific responsibilities and professional activities that constitute an appropriate and primary commitment will differ across schools and departments and will be based on academic practice and/or specific written agreement between the faculty member and his or her department chair and/or college dean.

Even with such understandings in place, however, attempts by faculty to balance university responsibilities with non-university related external activities can result in conflicts regarding allocation of professional time and energies. Conflicts of commitment usually involve issues of time allocation. For example, whenever a faculty member's outside consulting activities (as defined in the university's Faculty Paid External Consulting Policy) exceed the permitted limits (normally one eight hour day per week or less, as may otherwise be established by formal college or departmental policy) or whenever a full-time faculty member's primary professional obligation is not to Ohio State, a conflict of commitment exists.

Faculty should disclose and discuss external commitments with their department chairs and/or deans. If an activity cannot be managed by the faculty member and his/her chair or dean to avoid a conflict of commitment or the reasonable appearance of a conflict of commitment, the faculty member must refrain from participating in the activity.

Examples of situations that, absent prior department or college review and approval, may create an actual or a perceived conflict of commitment are presented below. The examples are by no means exhaustive, and are provided only as samples of some commonly encountered situations.



# Faculty Conflict of Commitment

## Office of Academic Affairs

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Applies to: Full-time faculty (including administrators and staff with faculty appointments)

- Teaching at another university during on-duty periods in an academic year, or otherwise representing yourself as a faculty member of another university.
- Use of one's professional expertise during on-duty periods in an academic year to provide services that compete with services provided by an academic or service entity within the university.
- Participating in private business activities to the detriment of your university education, research, scholarship or service responsibilities.
- Conducting research or novel scientific investigation as a private consultant to outside entities, which should be conducted more appropriately as research sponsored through the Office of Sponsored Research Programs.

Failure to comply with this policy may result in administrative or disciplinary actions against the faculty or staff member in accordance with the procedures set forth in Faculty Rule 3335-5-04. If the conflict of commitment involves a research project administered by the university, whether or not that administration is through the Office of Sponsored Research Programs, any action required by funding or regulatory agencies will also be taken. The procedures for reporting such conflicts and management plans shall be promulgated by the Office of Academic Affairs in consultation with the Conflict of Interest Policy Advisory Committee.

### Resources

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- Faculty Paid External Consulting Policy, <http://oaa.osu.edu/assets/files/documents/paidexternalconsulting.pdf>
- Rules of the University Faculty, <https://trustees.osu.edu/bylaws-and-rules/university-faculty-rules>

### Contacts

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Subject	Office	Telephone	E-mail/URL
Faculty conflict of commitment	Office of Academic Affairs	614-292-5881	<a href="http://oaa.osu.edu">http://oaa.osu.edu</a>
Requirements under Ohio law	Office Of Legal Affairs	614-292-0611	<a href="http://legal.osu.edu">http://legal.osu.edu</a>
Sponsored research	Office of Sponsored Research Programs	614-292-3815	<a href="http://rf.osu.edu/">http://rf.osu.edu/</a>

### History

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Policy reviewed and approved by the University Senate and the Board of Trustees.

Issued: 07/08/05

Revised:

Edited: 08/10/05, 01/01/11, 05/14/12

Reviewed:



**POLICY**

Issued: 07/10/98  
Revised: 03/02/07  
Edited: 01/01/11, 05/29/12, 02/05/13, 05/01/18

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**I. Preamble**

Faculty at The Ohio State University accept an obligation to avoid financial conflicts of interest in carrying out their institutional responsibilities. This policy is intended to assist faculty members, including administrators with faculty appointments, in avoiding these conflicts.

**II. State and Federal Laws and Regulations**

Federal regulations require the university to adopt a policy governing conflicts of interest in research. In addition, faculty members should be aware that they are also subject to various provisions of Ohio law governing ethics and conflicts of interest in public employment. For example, as a general rule, a university employee may not have an interest in a contract involving the university. In addition, an employee may not use his or her authority or influence to obtain a contract between the university and a family member or business associate of the employee. A university employee may not accept compensation for the performance of his or her university duties from any person or entity other than the university. Finally, the Ohio Ethics Law prohibits university employees from accepting anything of value that will exert a substantial and improper influence upon them with respect to their university duties. Additional information about the requirements of Ohio law may be obtained by consulting the Office of Legal Affairs.



### III. Policy Advisory Committee

In consultation with the provost and the Executive Committee of Faculty Council, the vice president for research shall appoint a Conflict of Interest Advisory Committee composed of a minimum of six faculty members, two from colleges in the health sciences, two from the college of arts and sciences and two from professional colleges (Business; Education and Human Ecology; Engineering; Food, Agricultural and Environmental Sciences; Law; Social Work). This committee shall periodically review the operation of this policy and make recommendations for change as needed, including changes mandated by federal and state regulation or accreditation requirements. In addition, the vice president for research shall consult with the committee regarding particularly difficult or complicated conflict of interest situations.

### IV. Definition

For purposes of this policy, a conflict of interest exists if financial interests or other opportunities for tangible personal benefit may exert a substantial and improper influence upon a faculty member or administrator's professional judgment in exercising any institutional responsibility.

### V. Policy

Faculty members, including administrators with faculty appointments, are expected to review their professional activities to determine if financial conflicts of interest may exist, and to avoid activities that entail or create a conflict of interest. Faculty members shall report and conduct their activities in a way that will avoid potential conflicts of interest, or allow conflicts to be managed. The procedures for reporting and managing such activities shall be promulgated by the Office of Academic Affairs in consultation with the Conflict of Interest Advisory Committee. If the activity cannot be managed to avoid the conflict, the faculty member must refrain from participating in the activity. Examples of situations that might entail or create a conflict of interest are presented below. The examples are by no means exhaustive, and are provided only as samples of some commonly encountered situations.

- Having significant involvement and/or financial interest in an entity that does business with the university.
- Participation in research that is funded by an entity in which the faculty member or the faculty member's family is involved or holds a significant financial interest.
- Entering into consulting agreements that purport to transfer to a private entity intellectual property that belongs to the university. (See the university's policy on [Intellectual Property](#) for further detail.)
- Use of one's professional expertise to provide services that compete with services provided by an academic entity within the university.

The university encourages faculty authorship of instructional materials and does not discourage the use of such materials in courses in the faculty member's department. However, every academic unit should establish a policy appropriate to its circumstances that ensures that instructional materials are selected on their academic merit and also ensures that there is no significant conflict of interest or appearance of conflict of interest in the selection of such materials.

This policy shall apply to ongoing and future activities, but not to completed purchases, past transactions or past professional activities. The latter are subject to applicable university policies in place at the time these activities were undertaken.

Failure to comply with this policy may result in the filing of a complaint against the faculty member under Faculty Rule 3335-5-04. If the conflict of interest involves a research project administered by the university, whether or not that administration is through the Office of Sponsored Programs, any action legally required by the funding agency will also be taken.



**History**

Reviewed and approved by the University Senate and the Board of Trustees.

Issued: 07/10/98 (BOT Resolution No. 99-4)  
 Revised: 03/02/07 (BOT Resolution No. 2007-100)  
 Edited: 01/01/11, 05/29/12, 02/05/13, 05/01/18

**Definitions**

Term	Definition
Conflict of Interest Advisory Committee (COIAC)	A standing faculty committee created under the Faculty Conflict of Interest Policy.
Externally funded research	Research funded by a public or private entity separate from the university through a gift, grant, award, contract, cooperative agreement or similar arrangement and administered through the university or the Office of Sponsored Programs (OSP).
Family member	For the purposes of this Faculty Conflict of Interest Policy, family members include spouses or domestic partners and dependent children.
Fiduciary role	A legal or ethical obligation on the part of an individual to act in the best interests (the financial success) of another, such as membership on a board of directors or a management role in a company or partnership.
Human subjects research	Human subjects research means any activity that either meets the Department of Health and Human Services (DHHS) definition of “research” and involves “human subjects” as defined by DHHS or the Food and Drug Administration (FDA) definition of “research” and involves “human subjects” as defined by FDA.
Research or conducting research	Any organized program of scientific inquiry, including designing research, directing or serving as an investigator performing laboratory experiments, having a role in soliciting consent from research subjects or making decisions related to eligibility of patients to participate in research, analyzing or reporting research data, or submitting manuscripts or abstracts concerning the research for publication. Specific examples include projects for which outside support is requested and projects for which approval of an IRB (or exemption) is required. The determination of what constitutes research and what constitutes the conduct of research will be made by COIAC.
Institutional responsibilities	An investigator’s institutional responsibilities refers to professional responsibilities on behalf of the institution including, but not limited to, research, research consultation, teaching, extension/outreach, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.
Investigator	Project director, principal investigator, and any other person, regardless of title or position, who is responsible for the design, conduct or reporting of university research, which may include, for example, collaborators or consultants. This definition does not include individuals who perform only incidental or isolated tasks related to a university research project.
Public Health Service (PHS) Agencies	PHS agencies include the National Institutes of Health (NIH), Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), Indian Health Service (IHS), Health Resources and Services Administration (HRSA), Substance Abuse and Mental Health Services Administration (SAMHSA), Agency for Healthcare Research and Quality (AHRQ), Centers for Medicare & Medicaid Services (CMS), Administration for Children and Families (ACF), or Administration on Aging (AOA).



<p>Significant financial interest (non-PHS)</p>	<p>Financial interest consisting of one or more of the following interests of the investigator (and those of the investigator's family members) that reasonably appears to be related to the investigator's institutional responsibilities:</p> <ol style="list-style-type: none"> <li>1) Any equity interest in a non-publicly traded entity or any financial remuneration received from the entity in the twelve (12) months preceding the disclosure that, when aggregated, exceeds \$10,000;</li> <li>2) An equity interest in a publicly traded company that is 5% or greater or any financial remuneration received from the entity in the twelve (12) months preceding the disclosure that, when aggregated, exceeds \$10,000; and</li> <li>3) Intellectual property rights and interests upon receipt of income related to those rights and interests.</li> </ol> <p>The above terms do not include the following types of financial interests: Salary, royalties, or other remuneration paid by the institution to the investigator, if the investigator is currently employed or otherwise appointed by the institution. The term also does not apply to diversified mutual funds in which the shareholder has no control over the equities held by the fund.</p> <p>The terms also do not include income from seminars, lectures or teaching engagements sponsored by a federal, state or local government agency, an accredited U.S. college or university, a U.S. academic health center, or a U.S. research institution that is formally affiliated with a U.S. college or university.</p> <p>The terms do not include income from serving on advisory committees or review panels for a federal, state or local government agency, an accredited U.S. college or university, a U.S. academic health center, or a U.S. research institution that is formally affiliated with a U.S. college or university.</p>
<p>Significant financial interest (PHS only)</p>	<p>Federal regulations require a lower financial threshold for financial interests of investigators who work on research funded by Public Health Service Agencies. As a result, significant financial interests involving PHS-funded research consist of one or more of the following interests of the investigator (and those of the investigator's family members) that reasonably appears to be related to the investigator's institutional responsibilities:</p> <ol style="list-style-type: none"> <li>1) Any equity interest in a non-publicly traded entity; or any financial remuneration received from the entity in the twelve (12) months preceding the disclosure that, when aggregated, exceeds \$5,000;</li> <li>2) An equity interest in a publicly traded company that is 5% or greater or any financial remuneration received from the entity in the twelve (12) months preceding the disclosure that, when aggregated, exceeds \$5,000; and</li> <li>3) Intellectual property rights and interests upon receipt of income related to those rights and interests.</li> </ol> <p>The above terms do not include the following types of financial interests: Salary, royalties, or other remuneration paid by the institution to the investigator, if the investigator is currently employed or otherwise appointed by the institution. The term also does not apply to diversified mutual funds in which the shareholder has no control over the equities held by the fund.</p> <p>The terms also do not include income from seminars, lectures or teaching engagements sponsored by a federal, state or local government agency, an accredited U.S. college or university, a U.S. academic health center, or a U.S. research institution that is formally affiliated with a U.S. college or university.</p> <p>The terms do not include income from serving on advisory committees or review panels for a federal, state or local government agency, an accredited U.S. college or university,</p>



	a U.S. academic health center, or a U.S. research institution that is formally affiliated with a U.S. college or university.
Sponsor or financially interested company	A commercial entity, or in certain cases, a not-for-profit entity that is sponsoring research to commercialize a product, whose financial interests would reasonably appear to be affected by the conduct or outcome of the research, including commercial companies that directly sponsor research, companies that hold patent rights for discoveries, drugs, or devices being studied in research protocols, or companies that provide financial or “in-kind” support for research projects. A financially interested company may also include a company that competes with the sponsor of the research or the manufacturer of the investigational product, if the researcher knows that the financial interests of such a company would reasonably appear to be affected by the research. This term also includes any entity acting as the agent of a sponsor or financially interested company such as a contract research organization.

## **PROCEDURE**

Issued: 02/01/99  
 Revised: 08/01/07  
 Edited: 01/01/11, 03/20/12, 02/05/13, 05/01/18

The vice president for research will be responsible for administering the Financial Conflict of Interest Policy. The vice president for research may designate an associate or assistant vice president to perform his/her responsibilities under the policy.

The vice president for research will appoint a conflict of interest administrator in consultation with the provost. The conflict of interest administrator will provide professional staff support for implementation of the policy. With the approval of the provost, and in consultation with the Conflicts of Interest Policy Advisory Committee (COIAC), the conflict of interest administrator will design procedures for the reporting of potential conflicts of interest. The administrator will also assist faculty and other university employees in identifying, managing or eliminating conflicts of interest and will periodically inform the university community about the policy and other issues relating to conflicts of interest.

The general counsel will designate a conflict of interest legal advisor who will assist the vice president for research, the COIAC, and the conflict of interest administrator with respect to the requirements of state and federal law and university rules. Counsel represents the university and not the individual faculty member. Joint representation can be provided where warranted if there is no conflict of interest or the conflict is waived in writing by both parties after full disclosure. Further, faculty members have the right to have their own (private) attorney.

The vice president for research will be responsible for providing reports to outside funding agencies as may be required by federal regulations or the terms of sponsored research agreements.

### **I. Conflict of Interest disclosure and training requirements**

#### **Financial interest disclosure**

An On-line Electronic Financial Interest Disclosure must be filed by the following persons who may, in carrying out their institutional responsibilities, meet the definition of “Investigator” under this policy:

- Faculty who have been identified as a project director, principal investigator or senior/key personnel (including non-university employee consultants) on a sponsored project during the past twelve (12) months;





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- Faculty, who are investigators, or key personnel on protocols requiring review (or exemption) by the Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC) or Institutional Biosafety Committee (IBC) during the past twelve (12) months;
  - Member physicians of The Ohio State University Faculty Group Practice; and
  - Research staff members and students, who are listed as investigators or senior or key personnel on sponsored projects, or protocols requiring IRB, IACUC, or IBC review (or exemption) are also required to comply with these reporting requirements and the following procedures.

Financial interest disclosures must be filed annually. Updates must be made to the disclosure within thirty (30) days if the filing party acquires any new financial interests, external professional activities, or business or financial transactions that were previously unreported, or if changes occur in the circumstances of a previously reported transaction or activity.

Faculty financial interest disclosures containing significant personal financial interests (as defined in this policy) must be reviewed by their department chair or with their regional campus dean. For regional campus faculty, the dean fulfills the responsibilities of the department chair noted elsewhere in these procedures. The chair or dean will determine whether the significant financial interest may be related to the faculty member's institutional responsibilities.

Staff and student financial interest disclosures containing significant personal financial interests (as defined in this policy) must be reviewed by the chair of their department or appropriate supervisory official (in the case where the filing party is not a member of an academic department), who shall perform the duties of a department chair under these procedures, in cases where a potential conflict is disclosed.

Electronic disclosures filed by faculty, staff and students will be automatically routed to the appropriate signatory. The chair, dean or supervisory official will determine whether a significant financial interest may be related to a faculty, student or staff member's institutional responsibilities on a case-by-case basis using the following general considerations:

- Is the financial interest with a company, foundation or other organization that provides products or services in the faculty, staff member or student's academic discipline - or area of study?
- Will the entity likely make use of the scholarly work or research - either directly or indirectly?
- Is the financial interest with a member of an industry, trade, or advocacy group that funds scholarly work or research in the faculty, staff member or student's discipline or area of study?
- Does the entity have some other relationship not described above that could be related to or could be affected by the faculty, staff member or student's university responsibilities?

### Travel disclosure

In addition to financial disclosures, faculty, staff and students who have participated as project directors, principal investigators or senior/key personnel on U.S. Public Health Service-funded research projects in the past twelve (12) months or who reasonably expect to receive new PHS funding during the current year must disclose the occurrence of any reimbursed or sponsored travel related to their institutional responsibilities. Public Health Service agencies include the National Institutes of Health (NIH), Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), Indian Health Service (IHS), Health Resources and Services Administration (HRSA), Substance Abuse and Mental Health Services Administration (SAMHSA), Agency for Healthcare Research and Quality (AHRQ), Centers for Medicare & Medicaid Services (CMS), Administration for Children and Families (ACF), or Administration on Aging (AOA).

This specific travel disclosure requirement does not apply to the following types of travel:

- Travel that is reimbursed or sponsored by a federal, state or local government agency (e.g., travel associated with service on an NIH or NSF or other federal agency study section, site visits, and/or grant peer review panel);
- Travel that is sponsored by an accredited U.S. college or university (e.g., travel for providing peer review consultation or speaking engagements);



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- Travel sponsored by a U.S. academic health center (e.g., speaking engagements);
  - Travel sponsored by a U.S. research institution that is formally affiliated with a U.S. college or university; or
  - Travel that is paid for as part of an Office of Sponsored Program sponsored research study/program (e.g., investigator meetings).

The On-line Electronic Conflict of Interest Disclosure application will also be used for travel reporting. At a minimum, faculty, research staff and students who are required to report reimbursed and sponsored travel must indicate the purpose of the trip, the identity of the sponsoring organization/business, the destination of the travel and the duration of the trip.

### **Training requirement**

The federal financial conflict of interest regulations also require that the institution provide formal conflict of interest training to investigators. The COIAC shall recommend a formal training process, which will reasonably comply with the applicable federal regulations.

Deans, department chairs, or other supervisory officials will be responsible for ensuring the faculty, staff and students complete the required formal conflict of interest training before engaging in research related to any PHS-funded grant and at least every four (4) years and immediately when any of the following circumstances apply:

- The institution substantially revises its financial conflict of interest policy in a manner that affects the requirements of investigators;
- An investigator is new to the institution; or
- The institution finds an investigator that is not in compliance with the institution's financial conflict of interest policy or management plan.

## **II. Review of financial disclosures for possible conflicts of interest**

Chairs will review financial disclosures containing significant financial interests within 15 days of receipt. Disclosures reviewed through the electronic application will automatically be forwarded to the conflict of interest administrator. If the conflict of interest administrator determines that a disclosed financial interest or activity presents a potential conflict of interest related to a particular research project, s/he will forward to COIAC for review. Disclosures and documentation of plans to minimize or manage possible conflicts of interest will be maintained in the office of the conflict of interest administrator.

The COIAC will review significant personal financial interests related to an investigator's activities, which are reported to the COIAC by the chair, dean or supervisor (in the case of staff), or the conflict of interest administrator.

The COIAC will determine whether a financial interest with an external entity (or travel sponsored by an external entity if travel disclosure is required) is related to a particular research project or protocol on a case-by-case basis using the following general considerations:

- Is the financial interest with a sponsor, subcontractor, supplier or lessor of goods, materials, proprietary information, services, or facilities of the investigator's current or proposed research?
- Will the entity likely make use of the research or scholarly work - either directly or indirectly?
- Is the financial interest with a member of an industry, trade, or advocacy group that funds the involved research or scholarly work?
- Is the entity manufacturing, commercializing or developing a product that is being used, evaluated, or further developed by the research or scholarly work at issue?
- Will the entity receive materials, data, or other information from the investigator?
- Is the entity a competitor of the investigator's sponsor?
- Does the entity have some other relationship not described above that could be related to or could be affected by the investigator's university responsibilities?



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If the COIAC determines that a financial interest (or travel sponsored by an external entity when travel disclosure is required) is reasonably related to an investigator's institutional responsibilities, the COIAC will then review the potential impact of the financial interest on the following:

- The integrity of the research;
- Risks to the rights and safety of human research subjects;
- Risks to the rights and obligations of students and trainees participating in research;
- The availability of research results to the scientific community for use in the public interest;
- The appearance of a conflict of interest; and
- The perception to the university community (In agreements and contracts related to the arrangements under review by COIAC, the university will require terms that ensure the freedom of timely academic publication, uphold the rights and responsibilities of students and trainees, and ensure appropriate reporting of inventions and assignment of intellectual property rights.)

### III. Conflict of interest management standards

Upon completing its review, COIAC will recommend that the personal financial interests of the individual in a financially interested company or entity are either eliminated or managed, subject to the development of a formal conflict management plan. COIAC will render a final decision and will communicate that decision, along with the recommended management plan to the involved faculty, staff member or student in writing.

#### Conflict of interest management plans

Conflict of interest management plans may include one or more of the following requirements:

- **Disclosure:** public disclosure of potential financial conflicts of interest is required in all management plans and includes the following:
  - public disclosure of the financial interests of the investigator and of the university, if applicable, in all relevant publications, presentations (whether or not academic), including presentations at the level of the individual's primary department or higher
  - disclosure to the appropriate co-investigators, members of the laboratory or research group, and students or trainees
  - disclosure of an investigator's financial interest on human subjects consent forms
- **Restriction on equity:** requirements that options, warrants, and similar instruments not be exercised without prior permission of COIAC (Researchers should be aware that separate Securities and Exchange Commission and other state and federal regulations may apply to their ownership of such equity. Obtaining the necessary information and complying with such regulations is the responsibility of the individual researcher.)
- **Limiting the role of the investigator with a financial interest:** requiring that the role of the investigator with a significant financial interest be limited in some way; in research involving the use of human or animal subjects, investigators are generally not permitted to:
  - serve as principal investigator
  - analyze data
  - determine whether potential subjects are eligible for enrollment
  - solicit consent
  - determine whether an adverse event report is required
- **Oversight:** appointment of a disinterested individual or group to monitor the relevant research activity; an oversight committee might be charged 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



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- o meeting at specific intervals to review protocols, subject accrual, subject safety and complications, review the resulting project data before publication, and other issues as appropriate

Oversight committees are required in management plans involving human subjects research where the principal investigator has a significant financial interest in the research and the research involves greater than minimal risk to human subjects.

- Divestiture: allow arrangements to go forward contingent upon sale or disposal of specified financial interests to eliminate or reduce the financial conflict of interest by a certain date
- Severance of relationships that heighten or create actual or potential conflicts: relinquishing a seat on a board of directors or terminating a consulting arrangement with an outside entity in order to reduce the financial or fiduciary conflict of interest.

COIAC may recommend other conditions or restrictions on the proposed arrangements if, in its view, such conditions will contribute to the elimination, reduction, or management of the conflict of interest. For conflict of interest management plans involving human subject research, the COIAC will make a recommendation to the IRB.

A written update will be required annually for all active personal financial conflict of interest conflict management plans. Significant financial interests disclosed or discovered after a funded research project has begun must be reviewed and approved and any necessary conflict of interest management plans must be in place within sixty (60) days.

As required by Public Health Service (PHS) rules, the university must report potential financial conflicts of interest involving federally-sponsored research to the sponsor prior to the expenditure of federal research funding, or within sixty (60) days of the university identifying potential financial conflicts of interests after a project has begun. The conflict of interest administrator and the Offices of Research Compliance and Sponsored Programs will be responsible for reporting potential financial conflicts of interest to the PHS, National Science Foundation or other sponsors, along with additional information concerning the COIAC-approved management plan that may be requested by the sponsor. PHS regulations require that the university also submit an annual conflict of interest update to the agency at the time the investigator's annual project report/update is due.

PHS regulations also require that the university provide the following information within five (5) business days to a public records request for information disclosed by faculty and staff investigators under this Policy: the investigator's name; the investigator's title and role with respect to a specific research project; the name of the entity in which the significant financial interest is held; the nature of the significant financial interest; and the value of the significant financial interest within the following dollar ranges (\$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

If an investigator fails to disclose a significant financial interest that the COIAC determines to be a financial conflict of interest related to a particular research project, if the university fails to review or manage a financial conflict of interest, or if an investigator fails to comply with the terms of a conflict of interest management plan, the university will within one hundred and twenty (120) days complete a retrospective review of the investigator's research to determine whether there was any bias in the design, conduct or reporting of the research. The Office of Research will keep a record of the retrospective review and make any necessary reports to funding agencies in accordance with federal regulations.

In cases where the COIAC or a federal sponsor determines that a financial conflict of interest was not managed or reported by the university as required by federal law, the investigator involved will be required to disclose the



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financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

#### **IV. Review and management of potential conflicts of interest in human subjects research**

In preparing this section, the university acknowledges the document titled “Preserving Trust, Promoting Progress: Guidelines for Developing and Implementing a Policy Concerning Individual Financial Interests in Human Subjects Research,” issued in December 2001 by the Association of American Medical Colleges.

Financial interests in human subject research require special scrutiny. Such interests may present real or perceived risks to the welfare and rights of human subjects, in addition to presenting risks to research integrity.

The university presumes that faculty may not participate as principal investigators in greater than minimal risk research projects involving human subjects (as determined by the IRB) while they have a significant financial interest in the research project or in a financially interested company. Limited exceptions may be made in specific cases when, in the judgment of COIAC, individuals holding significant conflicting financial interests provide the COIAC with a compelling justification (s/he is the only researcher at the university who possesses the expertise, know-how, or the necessary technical or procedural skills) in writing for being permitted to simultaneously hold the financial interest and participate in the human subjects research project. Principal investigators who seek exceptions to the above presumption are required to obtain a letter of support from their chair and dean (or vice dean for research), noting that the department and college support the compelling justification and will provide the resources necessary to manage the potential financial conflict of interest. Such resources may include, for example, the cost of external review boards, data integrity consultants or committees, or subject safety monitoring committees that may be needed to ensure the integrity of the research and the protection of human subjects involved in the research.

As per Ohio State University Rule 3335-13-07, faculty and staff members who hold financial interests in companies commercializing technology owned by the university may not serve as principal investigators in sponsored research projects funded by technology commercialization companies in which they have a personal financial interest if the projects involve the use of human subjects or veterinary clinical trials involving the use of animals.

The COIAC will review reports of all significant financial interests in proposed human subjects research projects. Information concerning a faculty, staff, or student’s relationship to the outside sponsor will be communicated in writing to the appropriate convened IRB, including the proposed management plan. To ensure the primacy of the welfare and rights of the human subjects, the convened IRB will have the full and final authority for implementing the decision concerning the role of the concerned individual in the human subjects research protocol. Accordingly, the convened IRB will communicate its decision concerning participation in the human subjects research protocol to the investigator and will provide a copy of that communication to COIAC.

Conflict of interest issues associated with research projects involving human subjects that are determined by the Office of Responsible Research Practices to be exempt are subject to COIAC review.

COIAC’s recommendation may involve either prohibition or management.

- **Prohibition:** If, upon reviewing specific information provided by the investigator with the relevant financial interest, COIAC believes that a conflict of interest is incompatible with human subjects research, it will recommend to the appropriate IRB that the involved investigator be required to eliminate the relevant financial interest before beginning the project or be barred from participating in the research.
- **Management:** In a limited number of cases involving significant financial interests, if COIAC concludes that the justification provided by the investigator is sufficiently compelling and that the conflict of interest can be managed, it will recommend specific project-related management measures to the appropriate IRB.

In all cases involving human subjects research in which informed consent is required and an involved investigator has a relevant financial interest of any magnitude, a financial disclosure statement including the name of the financially



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interested individual and description of the source and nature of the relevant financial interests must be included in the consent process/form.

Additional project-related management measures may include prohibiting the investigator from one or more of the following:

- Serving as principal investigator
- Analyzing data
- Determining whether potential subjects are eligible for enrollment
- Soliciting consent
- Determining whether an adverse event report is required.

COIAC's recommendation, accompanied by a description of the nature and magnitude of the potential conflict of interest, will be communicated in writing to the appropriate IRB. The IRB, which is responsible for ensuring the ethical acceptability of the research, will evaluate the recommendations of the COIAC and decide whether to:

- Accept the recommendations
- Accept the recommendations with additional management measures prescribed by the IRB
- Conclude that the human subjects research cannot proceed.

COIAC will communicate its determination to the investigator in writing. Upon concluding its evaluation, the IRB will inform COIAC of its determination, and the IRB's decision is final.

## **V. Legal Obligations**

Investigators should be aware that financial interests in companies or external entities may result in personal or institutional obligations under federal and state laws, formal contractual requirements of commercial research sponsors, as well as with conflict of interest requirements of accreditation entities. The Ohio State University is also required to comply with federal conflict of interest regulations, including maintaining a written and enforced financial conflict of interest policy, managing, reducing or eliminating identified conflicts, and reporting identified conflicts to federal agencies within prescribed timeframes.

When the institution carries out federally-funded research through a subrecipient (e.g., subcontractors or consortium members), the institution must also meet applicable agency requirements to ensure that subrecipient investigators also comply with the federal conflict of interest regulations.

The Office of Research Compliance, in consultation with the Offices of Legal Affairs and Sponsored Programs, will be responsible for complying with sponsor and regulatory agency reporting requirements, as well as the maintenance of conflict of interest records, pursuant to applicable federal and state requirements and Ohio State University Office of Research record retention policies.

### **A. Public Health Service (PHS)/National Science Foundation (NSF)**

Individuals who receive research funding from either the Public Health Service (PHS) (including the National Institutes of Health) or National Science Foundation (NSF) must comply with agency regulations, which ensure that personal financial interests do not affect the design, conduct, or reporting of federally-funded research. The PHS regulations on "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought" (42 C.F.R. Part 50, Subpart F) and "Responsible Prospective Contractors" (45 C.F.R. Part 94) can be found at <http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>. The NSF conflict of interest policy can be found in Chapter V, Grantee Standards, Section 510, Conflict of Interest Policies, in the NSF Grant Policy Manual at [http://www.nsf.gov/pubs/manuals/gpm05\\_131/gpm5.jsp#510](http://www.nsf.gov/pubs/manuals/gpm05_131/gpm5.jsp#510).

### **B. Food and Drug Administration (FDA)**



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The FDA requires applicants, under its regulations at 21 CFR Part 54, to submit to FDA a list of clinical investigators who conduct covered clinical studies and to certify the absence of and/or disclose the existence of certain financial arrangements. The FDA's most recent guidance is available at

<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM256525.pdf> (May 2011).

In cases where an individual investigator holds an Investigational New Drug application (IND) for a study drug, or an Investigational Device Exemption (IDE) for an experimental study device, the investigator him/herself may be required to personally comply with the above FDA conflict of interest reporting requirements and should consult the FDA or legal counsel at the Office of Legal Affairs concerning applicable rules and regulations.

The Office of Research Compliance, in consultation with the Offices of Legal Affairs and Sponsored Programs, will be responsible for complying with sponsor and regulatory agency reporting requirements, as well as the maintenance of conflict of interest records, pursuant to applicable federal and state requirements and Ohio State University Office of Research record retention policies.

### **C. Securities and Exchange Commission (SEC)**

The SEC enforces regulations concerning equity ownership, including insider trading, which may affect investigators who hold equity in research sponsors. For additional information, investigators should seek advice from their personal legal counsel or the Office of Legal Affairs. It is the obligation of the financially interested individual to ensure that s/he complies with applicable SEC regulations.

### **D. Other sponsors**

Outside sponsors may also have specific requirements regarding investigators who have personal interests with the sponsor. For more information, contact your sponsored program officer at the Office of Sponsored Programs (OSP).

### **E. Accreditation entities**

Outside academic accreditation entities and programs, such as the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP), require that the institution's human research protection program specifically include policies and procedures to identify and manage potential personal financial conflicts of interest, as well as potential institutional conflicts of interest, to ensure that all human research participants are respected and are protected from unnecessary harm. For more information on these AAHRPP requirements, contact the Office of Responsible Research Practices.

## **VI. Appeals**

If an investigator believes that a determination made by COIAC is not appropriate or is based on erroneous information, s/he may request reconsideration by COIAC by submitting a written request to the chair of the COIAC. If, after a second review by COIAC, the investigator still wishes to appeal COIAC's decision, s/he may appeal to the vice president for research. The vice president for research's decision is final.

Investigators who believe that the conflict of interest management measures adopted by an IRB are not appropriate or are based on erroneous information must follow applicable IRB procedures for requesting additional review. Decisions made by the IRB are final.

## **VII. Sanctions for failure to comply**

Failure by faculty to comply with the conflict of interest policy or procedures, or with COIAC management plans, will be subject to review by the vice president for research. If the vice president for research determines that a violation of university rules may have occurred, s/he may file a complaint against the faculty member pursuant to Faculty Rule 3335-5-04. Failure by university staff or students to comply with the conflict of interest policy or procedures, or with COIAC management plans, will be subject to review by the applicable Human Resources (for staff) or Office of Student Life (for student) policies.



## Resources

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- Conflict of Interest Screening/Disclosure Form, <http://go.osu.edu/coi>
- Ohio Ethics Law, <http://legal.osu.edu/ethics.php>
- Policy on Intellectual Property, <https://tco.osu.edu/v2/wp-content/uploads/IP-Policy.pdf>
- Rules of the University Faculty, <http://trustees.osu.edu/rules/university-rules.html>

## Contacts

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Subject	Office	Telephone	E-mail/URL
Conflict of interest	Office of Research Compliance	614-292-4284	<a href="http://orc.osu.edu">http://orc.osu.edu</a>
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## History

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