



# Faculty Financial Conflict of Interest

## Office of Research

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### POLICY

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### Table of Contents

#### Policy

I. Preamble .....	1
II. State and Federal Laws and Regulations .....	1
III. Policy and Advisory Committee .....	2
IV. Definition .....	2
V. Policy .....	2

#### Procedures

I. Disclosure and training requirements .....	5
II. Review of conflicts of interest .....	7
III. Conflict of interest management standards .....	8
IV. Review and management of conflicts of interest in human subjects research.....	10
V. Legal Obligations .....	11
VI. Appeals.....	13
VII. Sanctions for failure to comply.....	13

#### 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.



# Faculty Financial Conflict of Interest

## Office of Research

---

### 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 Patents and Copyrights 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.



# Faculty Financial Conflict of Interest

## Office of Research

### History

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### 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



# Faculty Financial Conflict of Interest

## Office of Research

	<p>Research and Quality (AHRQ), Centers for Medicare &amp; Medicaid Services (CMS), Administration for Children and Families (ACF), or Administration on Aging (AOA).</p>
<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</p>



# Faculty Financial Conflict of Interest

## Office of Research

	<p>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>
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

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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;
- 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);
- 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?

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
    - 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.



# Faculty Financial Conflict of Interest

## Office of Research

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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 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 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



# Faculty Financial Conflict of Interest

## Office of Research

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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)**

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.



# Faculty Financial Conflict of Interest

## Office of Research

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### **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.



# Faculty Financial Conflict of Interest

## Office of Research

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### Resources

- Conflict of Interest Screening/Disclosure Form, <http://go.osu.edu/coi>
- Ohio Ethics Law, <http://legal.osu.edu/ethics.php>
- Policy on Patents and Copyrights, <http://tco.osu.edu/wp-content/uploads/downloads/2011/10/PatentCopyrightPolicy.pdf>
- Rules of the University Faculty, <http://trustees.osu.edu/rules/university-rules.html>

### Contacts

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>
Research compliance	Office of Research Compliance	614-292-4284	<a href="http://orc.osu.edu">http://orc.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>
Human subjects research	Office of Responsible Research Practices	614-688-8457	<a href="http://orpp.osu.edu">http://orpp.osu.edu</a>
Institutional Review Boards	Office of Responsible Research Practices	614-688-8457	<a href="http://orpp.osu.edu">http://orpp.osu.edu</a>
Sponsored research	Office of Sponsored Programs	614-292-3815	<a href="http://osp.osu.edu">http://osp.osu.edu</a>

### History

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