

ORGANIZATIONAL FINANCIAL CONFLICTS OF INTEREST

1. Overview

As an organization that conducts research involving human subjects, The Ohio State University has an obligation to protect the rights and welfare of research participants and to ensure the integrity of the research. The university and/or one or more of its key leaders may have a financial interest in or relationship with an external entity that has the potential to conflict with these obligations. For example, the university or one of its key leaders may have a financial interest in a company sponsoring human subjects research being conducted by the university or own proprietary technology that is being utilized in the research. Such financial or proprietary interests must be disclosed and managed in a way that meets the above obligations.

The purpose of this policy is to describe the process to identify, evaluate, manage, and minimize or eliminate the organization's proprietary interests, financial investments or holdings, and the personal financial interests of key organizational leaders when such interests could conflict with the organization's obligations to protect research participants, maintain the integrity of research, and ensure the credibility of the human research protection program.

2. Definitions

Organizational Conflict of Interest (OCOI): A situation in which the financial investments or holdings of an organization (including licenses, royalties, intellectual property rights, patents, certain gifts) or the personal financial interests or holdings of a key leader might affect or reasonably appear to affect organizational processes for the design, conduct, reporting, review, or oversight of human subjects research.

Key Organizational Leader: For purposes of HRPP policy, a faculty member or administrator who has direct authority over personnel appointments, salaries, promotions, and/or allocation of organizational resources (e.g., funding, space, assignment of graduate students or other trainees) for individuals involved in the design, conduct, reporting, review, or oversight of human subjects research.

3. General Information

A. When The Ohio State University licenses technology or other intellectual property, the university may receive a royalty or other fee as compensation for the use of that intellectual property or equity in a company as a result of that license. A potential organizational conflict of interest is created if an Ohio State researcher engages in human subjects research involving a drug, biologic, device, or other intellectual property or technology for which the university has a patent, has licensed the technology or

intellectual property, or receives royalties or other fees from a third party for use of the university-owned technology or intellectual property.

- B. The Office of University Development, with applicable college development offices, has responsibility for administering all gifts and in-kind donations from individuals and corporate entities, as well as gifts to the university's endowment. In addition, gifts made to The Ohio State University Wexner Medical Center by entities providing good or services must comply with the [Vendor Interaction Policy](#).

4. Procedures for Identifying and Reporting Potential Organizational Conflicts

Organizational financial interests and personal financial interests of key organizational leaders are identified and reported through various research compliance processes, as described below.

- A. Deans, Department Chairs, and/or their designees are required to review and sign off on research submitted by faculty in their colleges, departments, divisions, or institutes, including projects involving the use of human subjects. Deans and Chairs also review annual conflict of interest disclosures (and updated disclosures), which are required for faculty and staff working as investigators or key personnel, as described by the university's [Faculty Financial Conflict of Interest](#) policy and procedures (COI Policy). Any potential financial conflicts of interest involving key organizational leaders determined to be "significant" under the COI Policy (see Section 5.B. below) will be reported to the Conflict of Interest Administrator (COI Administrator).
- B. The university's *Authorization to Seek Off-Campus Funding (ePA-005)* electronic form (available on the [Office of Sponsored Programs website](#)) requires principal investigators to disclose whether they or individuals named as co-investigators or key personnel on a project have a significant financial interest in the sponsor, or whether any other company or organization is providing financial or in-kind assistance for the research. The *ePA-005* also asks investigators whether the proposed research involves the use of Ohio State technology licensed by the Office of Technology Commercialization and Knowledge Transfer (TCO) to third parties. This information is routed electronically to the COI Administrator for review.
- C. The *Initial Review of Human Subjects Research* application and *Application for Exemption* require that investigators disclose whether any Ohio State investigator, key personnel, or their immediate family members has a financial interest that would reasonably appear to be affected by the research. Such financial interests involving key organizational leaders, or other potential organizational conflicts of interest, are forwarded by the Office of Responsible Research Practices (ORRP) professional staff to the COI Administrator for review.

- D. The Office of Technology Commercialization and Knowledge Transfer coordinates institutional interactions with companies commercializing university-owned technology as described in the [Rules Governing Faculty and Staff Participation in Companies Commercializing University Research \(3335-13-07\)](#). As part of these management responsibilities, TCO maintains a list of approved commercial entities (also known as “start-up companies”) that are owned in whole or in part by a university employee to develop and commercialize university-owned technology created by that employee (faculty and staff start-up companies). TCO will provide lists of approved faculty and staff start-up companies to the Office of Business and Industry Contracts and the COI Administrator.
- E. All gifts and in-kind donations to the university of \$10,000 or more in value, or those designated for specific activities, require the execution of a formal gift agreement reviewed and approved by the Office of Legal Affairs. Gifts identified by the Office of University Development or Office of Legal Affairs as having been made by donors with an interest in specific Ohio State human subjects research projects will be reviewed under this policy using the procedures described below.

5. Procedures for the Review and Management of Potential Organizational Conflicts

- A. Organizational conflicts of interest identified through the above procedures will be initially reviewed by the COI Administrator.
- B. The COI Administrator, in consultation as necessary with the appropriate Department Chair, College Dean, legal counsel in the Office of Legal Affairs, and/or the Chair of the Conflict of Interest Advisory Committee (COIAC), will determine if an identified organizational conflict of interest is significant. For the purpose of this policy, an OCOI is “significant” if it involves any of the following:
- Personal financial interests or holdings of a key organizational leader who has a direct role in reviewing the submission of a specific human subjects research project or internally-funded human subjects research, and the key organizational leader’s financial interest or holding meets the definition of “significant” under the current COI policy
 - Any financial interest in a non-publicly-traded company
 - Any financial interest in an approved start-up company that is commercializing university-licensed technology
 - Current or pending ownership interest (including shares, partnership stakes, or derivative interests such as stock options) in a publically-traded company of \$50,000 or more
 - A gift of \$50,000 or more by an individual or third-party company that may reasonably be seen as directly benefitting from a specific human subjects research project

- The use of university technology licensed by the Office of Technology Commercialization and Knowledge Transfer in human subjects research conducted at Ohio State or reviewed by a university IRB.
- C. Significant organizational conflicts will be reviewed by the COIAC under the procedures described in the COI policy. When necessary, the COIAC will develop formal management plans for OCOIs and provide these recommended plans to the reviewing IRB and to the Institutional Official for final approval.
- D. In reviewing potential organizational conflicts, the COIAC will evaluate relevant factors, including the following:
- Level of risk to research participants
 - Effect on the integrity and objectivity of the proposed human subjects research
 - Level and type of financial interests or relationships held by the university and/or a key organizational leader
 - How direct and immediate a key organizational leader's authority is over the research or the investigator and research staff involved in conducting the research
 - Status of the third-party company (e.g., whether a privately held start-up company, small publicly-traded company, or large publicly-traded company)
 - Perceived reputational risk to the university.
- E. In managing potential organizational conflicts, the COIAC will follow current academic best practices, including the following:
- The “rebuttable presumption” standard adopted by the Association of American Universities and the Association of American Medical Colleges (AAMC) on decisions about whether or not to move forward with a proposed human subjects research project in the presence of a significant OCOI
 - Identification of the individuals (usually the investigator and the investigator's Chair or his/her designee) responsible for ensuring that the requirements of OCOI management plans are followed
 - Formal recusal by a key organizational leader from his/her chain-of-authority over a project and from authority over salary, promotions, space, or trainee assignments of an affected investigator
 - Disclosure of the potential OCOI in the informed consent document
 - Disclosure of the potential OCOI to other centers in a multi-center trial
 - Disclosure of the potential OCOI to sponsors, if required by federal law, agency policy, or the terms of a sponsored program agreement
 - Formal commitment by the investigator(s) to disclose the OCOI in public presentations and publications
 - Any other requirements that the COIAC determines to be necessary.

F. For more information on financial conflicts of interest in research, clinical care, and medical education, see [AAMC Conflicts of Interest in Research](#).

6. Applicable Regulations/Guidance

42 CFR 50, Subpart F; 45 CFR 94; Association of American Universities and Association of American Medical Colleges “Protecting Patients, Preserving Integrity, Advancing Health: Accelerating the Implementation of COI Policies in Human Subjects” (02/08); The Ohio State University Wexner Medical Center “Vendor Interaction Policy” (03/12/09)