Background
The University of Cincinnati is committed to the highest standards of conduct in all activities that support its core mission. The university is obligated to prevent potential institutional conflicts of interest from compromising objectivity and integrity in the conduct of research. An institutional conflict of interest in research (ICOIR) describes a situation in which the financial interests of the institution or a University Official may compromise, or appear to compromise, the research mission. The university will not permit its financial interests or the financial interests of University Officials to compromise research integrity. This policy is intended to protect against, define, and manage risks related to institutional conflicts of interest in research.

Policy
The University of Cincinnati values the advancement of research and the external relationships that support it. Decisions concerning research must not be unduly influenced, in appearance or in fact, by an Institutional Financial Interest. The university must balance competing pressures that might result from industry relationships with the university or with University Officials. These relationships might benefit the university in a variety of forms, including gifts, business ventures, royalty payments, equity from licensing intellectual property, and sponsored agreements. An ICOIR might arise in the normal course of university research activities. This policy supplements the individual conflicts of interest policy that applies to all university personnel.

Definitions
Immediate Family: A spouse and dependent children.

Individual Significant Financial Interests: Significant Financial Interests (SFI) for University Officials include Immediate Family that reasonably appear to be related to the University Official's Institutional Responsibilities:

a) With regard to any publicly traded entity, a SFI exists if the value of any remuneration received from a single entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock options, or other
ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

b) With regard to any non-publicly traded entity, a SFI exists if the value of any remuneration received from a single entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the University Official (or his/her Immediate Family) holds any equity interest (e.g., stock, stock options, or other ownership interest); or

c) Intellectual property rights and interests (e.g., patents, copyrights), when there is a right to receive income related to such rights and interests.

d) University Officials also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their Institutional Responsibilities. Provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, medical center or research institute affiliated with an institution of higher education. University Officials shall disclose the dates of travel, destination, entity that paid for the travel, purpose of the trip, and travel paid for the individual's spouse and/or dependent child(ren) by the entity (if applicable) (42 CFR 50.603).

Significant Financial Interest (SFI) shall not include:

a) Salary, royalties, or other remuneration paid by the university to the University Official if the University Official is currently employed or otherwise appointed by the university, including intellectual property rights assigned to the university and agreements to share in royalties related to such rights;

b) Income from investment vehicles, such as mutual funds and retirement accounts, as long as the University Official does not directly control the investment decisions made in these vehicles;

c) Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education;

d) Income from service on advisory committees or review panels for a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or

e) Salary earned through employment with University of Cincinnati Physicians, Inc.

Institutional Conflict of Interest in Research (ICOIR): A situation in which an Institutional Research Interest may be affected or could reasonably appear to be affected by Institutional Financial Interests.
Institutional Conflict of Interest Review Committee (ICOIRC): A committee established by the university to consider matters referred to it in accordance with this policy or any other university conflict of interest policy.

Institutional Financial Interests:
1. Gifts to the university of $100,000 or greater from any entity, whether for-profit or not-for-profit, or from any person within a 5-year period.
2. Payments to the university for, or resulting from the conduct of, research at or under the auspices of the university that exceed $100,000 within a 5-year period (either per transaction or in the aggregate). Payments include income from sponsored research projects and royalties from the licensing of intellectual property when the research may be affected by such payments.
3. Equity, ownership, or financial interests held by the university in for-profit entities, including equity and ownership interests resulting from the transfer of university technology where such interests have: a) a value in excess of $100,000 in the case of a publicly-traded entity; or b) a value of any amount in the case of a non-publicly traded entity.
4. Individual Significant Financial Interests of University Officials acting within the scope of their authority on behalf of the university, and the financial interests of a University Official's immediate family.

Institutional Research Interest: The University’s interest in ensuring the following in the context of research:
1. The safety and welfare of human and animal research subjects;
2. Integrity in the conduct of research;
3. The dissemination of research results in accordance with the highest scientific, professional, and ethical standards;
4. Objectivity and independence in managing and licensing intellectual property resulting from research activities; and
5. Objectivity and integrity in research contracting and business transaction decisions.

Institutional Responsibilities: The University Officials’ responsibilities associated with or resulting from his or her university appointment or position. Institutional responsibilities may include but are not limited to: research; education/teaching; professional activities; administration; and services to the university and to internal and external professional organizations.

University Official(s): The president, vice presidents, deans, center and institute directors, department chairs and division chiefs (in the College of Medicine), particularly insofar as the individuals have oversight of research at the university, and any other person so designated by the President, Vice President for Research, or the Provost for purposes of this policy.

Potential Institutional Conflicts of Interest in Research
1. Individual Significant Financial Interests on the part of a University Official responsible for the oversight of research. A University Official with responsibility for approving the use of university research resources by or on behalf of an outside company has a personal or family interest in that company could result in ICOIR. An Individual Significant Financial Interest shall result in formal review by the ICOIRC.
2. Institutional Financial Interests. A University Official’s decisions relating to research could be compromised when the university (or one of its units) has a financial interest at stake. An Institutional Financial Interest shall result in formal review by the ICOIRC.
3. ICOIR could occur when an investigator, research administrator, or University Official with research oversight authority participates materially in a procurement or purchasing decision involving major institutional purchases from, or non-routine supply contracts with, a company that sponsors research at the institution, or whose product is being evaluated at the institution. These situations shall result in formal review by the ICOIRC.

In addition to those circumstances indicated above, other financial relationships with research sponsors may warrant formal ICOIRC scrutiny, depending on the circumstances. University Officials who make decisions related to research activities on behalf of the university (including any school, department, division, institute, or center of the university) must carefully evaluate any situation where an Institutional Research Interest might be compromised or could reasonably appear to be compromised by virtue of an Institutional Financial Interest or an Individual Significant Financial Interest. While ICOIRs need not be avoided *per se*, they must be recognized, acknowledged, and managed in order to safeguard the university’s research enterprise, the safety of human or animal subjects, and the integrity of research conducted at the university.

**Identification of Institutional Conflicts of Interest in Research**
ICOIRs are identified and reported through various mechanisms, including:

1. The review of disclosures from Outside Activity Reports (OARs) by the Office for Ethics in Industry Engagement (OEIE), the University Conflict of Interest Committee (individual conflicts), and/or the ICOIRC;
3. The sharing of information regarding university licensing and start-up activity between the Technology Accelerator for Commercialization Office and the OEIE; or
4. Reports received through the university’s third party hotline provider.

When a real or perceived ICOIR is identified, the matter shall be referred to the ICOIRC for adjudication. The ICOIRC will review each ICOIR on a case-by-case basis, giving due consideration to the following factors:

1. The nature of the underlying research;
2. The nature of the Institutional Financial Interest;
3. The extent to which an Institutional Research Interest might be affected by the Institutional Financial Interest;
4. The risk the ICOIR poses to the integrity of university research, either in appearance or in fact; and
5. The degree to which the ICOIR can be managed effectively.

Whenever the ICOIRC concludes that an ICOIR may occur, it shall prepare a report and a management plan to address the ICOIR that includes actual or reasonably-perceived risks to the integrity of the university’s research and reputation and/or specific risks. The management plan will state specifically who will be responsible for the plan’s implementation and monitoring. All ICOIRC decisions and management strategies with respect to ICOIRs shall be reviewed and approved by the Vice President for Research. If the Vice President for Research has made the determination that the research may move forward, the IRB shall have final approval when the ICOIR involves human subjects research.
Establishment of an Institutional Conflict of Interest Review Committee
The president of the university shall appoint committee members to the ICOIRC (University Rule 3361: 10-17-11). The ICOIRC shall have the authority to review potential ICOIRs and recommend management strategies for the Vice President for Research's approval. The ICOIRC shall have access to the OARs of all University Officials.

Management of Institutional Conflicts of Interest in Research
The following basic principles shall be applied in the management of ICOIRs:

A. Human Subjects Research.
ICOIRs that involve human research subjects must also be approved by the IRB. With rare exception, human subjects research shall not be conducted when an Institutional Financial Interest exists. When university faculty have unique capabilities, or there are unique resources at the institution, the ICOIRC may recommend that the research occur at or under the auspices of the university if an effective ICOIR management plan can be implemented that fully protects the welfare of human research subjects and the integrity of the research. If the Institutional Financial Interest exists because a University Official in a supervisory administrative role has a Significant Individual Financial Interest, the ICOIRC shall review the University Official’s role in the research and, if possible, incorporate into the plan an appropriately-objective research administrator to oversee the research for the university. Once approved by the ICOIRC and Vice President for Research, it must also be approved by the IRB before the research may take place. The IRB may add to the ICOIR management plan but cannot remove any stipulations. Implementation of the ICOIR management plan shall be monitored by the OEIE.

Management strategies may include:
• disclosure of the Institutional Financial Interest in the informed consent process;
• recusal of the conflicted University Official from overseeing the research or other authority over the project;
• use of an external IRB;
• external monitoring of the research, particular endpoint assessments; and
• use of an external Data Safety Monitoring Board (DSMB) or similar review board to evaluate the design, protocol, and primary and secondary end-point assessments, and ongoing evaluation of the research for safety and performance issues.

Where the ICOIRC has determined that any contemplated research referred to it should go forward, it shall prepare a report and a management plan to address the ICOIR, actual or reasonably perceived risks to the integrity of the university’s research and reputation, and specific risks to human subject participants. The management plan will state specifically who will be responsible for the plan’s implementation and monitoring.

B. Non-Human Subjects Research.
Because research subject safety is not an issue in the case of non-human subjects research, ICOIRs that do not involve human subjects shall follow the same process as those that do, except that the IRB will not be involved.

Anonymous Reporting of Potential Institutional Conflicts of Interest in Research
Any individual may anonymously report a situation involving a possible ICOIR. Such reports can be made by:
1. Contacting the Office for Ethics in Industry Engagement; or
2. Using the university-wide anonymous reporting hotline (1-800-889-1547); or
3. Make a report via the internet (see Related links below)

The university is obligated to protect anyone who reports a violation from reprisal. The university shall take appropriate measures to preserve confidentiality and protect whistleblowers.

**Failure to Comply**
Failure to comply with the disclosure requirements or any directives to manage or eliminate conflicts pursuant to this policy could result in disciplinary actions.

For purposes of this policy, non-compliance shall include:
1. Failure to report outside interests accurately, fully, and in a timely manner;
2. Failure to provide additional information as requested by the ICOIRC;
3. Failure to comply fully and promptly with management plans or decisions of the ICOIRC; or
4. Failure to update disclosures as required herein.

Applicable state and federal law and university policies, rules, and applicable collective bargaining agreements shall govern the procedures for imposing any disciplinary action pursuant to this policy.

**Related links:**

- University (Board) Rules
- Anonymous Hotline

**Phone Contacts:**

- Conflict of Interest Office 556-5501
- Office of General Counsel 556-3483
- Office of VP for Research 558-0026