



Approving University Official: Vice President for Research
Responsible Office: Conflict of Interest Office
Effective date: October 14, 2019
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INSTITUTIONAL CONFLICT OF INTEREST IN RESEARCH

Policy Statement

Northwestern University is committed to maintaining the objectivity and integrity of its research. Situations in which the financial interests of the institution or of University Officials could compromise or reasonably appear to compromise Northwestern research need to be monitored and managed appropriately.

Purpose

This Policy is intended to protect against exposure from risks related to Institutional Conflicts of Interest in Research as they may affect or reasonably appear to affect research performed at, or under the auspices of, Northwestern, including harm to human research participants and animal research subjects and damage to the integrity of the University's research and reputation.

Institutional Conflicts of Interest in Research (ICOIR) differ from individual conflicts because they relate to institutional management, oversight, and decision-making on behalf of the institution. ICOIRs have the potential to affect a broad spectrum of University activities. ICOIRs may arise from financial interests of the Institution that are not adequately covered by the disclosure and review requirements for individuals described in the Policy on Conflict of Interest and Conflict of Commitment, or the Policy on Conflict of Interest in Research.

This Policy defines what constitutes an Institutional Financial Interest (IFI), when IFIs may be perceived as ICOIRs, and how potential ICOIRs are reviewed by the Conflict of Interest Oversight Committee.

Audience

Faculty, staff and all other members of the Northwestern's research community.

Definitions

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 Research Interest: The interest of the University in ensuring the following in the context of research:

- (1) the safety and welfare of human research participants 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 of educational activities as they relate to research
- (5) objectivity and independence in managing and licensing intellectual property resulting from research activities
- (6) objectivity and integrity in research contracting and business transaction decisions

Institutional Financial Interest (IFI): Financial interests of the University, including:

- (1) Gifts to the University from any entity, whether for-profit or not-for-profit, or from any person (either per gift or in aggregate during the preceding 12-month period) when related to any given Institutional Research Interest, or
- (2) Gifts exceeding \$100,000 from any entity, whether for-profit or not-for-profit, or from any person (either per gift or in aggregate during the preceding 12-month period) made directly to a faculty member's laboratory or research program.
- (3) Royalty payments to the University that exceed \$100,000 (either per transaction or in aggregate during the preceding 12-month period), when such payments may be affected by University research. This includes licensing fees resulting from technology transfer and business activities.
- (4) 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 \$100,000.00 in the case of a publicly-traded entity; or b) a value of any amount in the case of a non-publicly traded entity. Any University investment managed via third-party investors who have discretion in investing decisions are not considered to be IFIs as the University has no direct control over those investments.
- (5) Financial interests of University Officials acting within the scope of their authority on behalf of the University. These interests include the financial interests of a University Official's spouse, dependent children, domestic or civil union partner, and others individuals as may be defined by the Faculty Handbook or Staff Handbook.

University Officials: All University officers, deans, center and institute directors, department chairs, division chiefs (in the Feinberg School of Medicine), and any other person so designated by the President, Provost, or the Vice President for Research for purposes of this policy.

Policy Implementation

A critical aspect of protecting the objectivity and integrity of the University's research mission requires identifying, carefully reviewing, and managing or eliminating any ICOIRs. This process mitigates risks to the Institution, individual investigators, research participants, and the integrity of the research activity. ICOIRs may arise in any situation where an Institutional Research Interest (IRI) may be compromised or could reasonably appear to be compromised by virtue of an Institutional Financial Interest (IFI).

The process of identifying, reviewing, and managing situations that may give rise to an ICOIR requires knowledge and understanding of the financial interests of the Institution and University Officials (IFIs) and IRIs that may be affected by those interests. When an IFI is related to any given research activity, the situation is referred to the Conflict of Interest Oversight Committee (COIOC) for evaluation and review. The COIOC will first determine whether any IRI of that research activity could be compromised, or could

reasonably appear compromised by the related IFI. If so, the identified potential ICOIR is reviewed to determine whether the research should proceed at or under the auspices of the University. Northwestern's Conflict of Interest Office (NUCOI) administers this process.

Awareness of Institutional Financial Interests (IFIs) is primarily, though not exclusively, gained through:

- 1) Disclosure by University Officials during the annual disclosure process and throughout the year, as required by applicable policies;
- 2) Communication and sharing of information between units and NUCOI regarding:
 - a. Gifts to the University (Alumni Relations and Development),
 - b. University investments (Investment Office), and
 - c. University licensing agreements and startup activity (Innovations and New Ventures Office; INVO);
- 3) Reports received through the University's third party hotline provider.

Proposed research activities and other IRIs are reviewed by NUCOI, School Dean's Offices, school-based conflict of interest committees, and the Conflict of Interest Oversight Committee (COIOC) as required by the Policy on Conflict of Interest in Research.

Potential ICOIRs are thus identified and reported through various compliance processes, including:

- 1) The review of disclosures from University Officials by the Conflict of Interest Oversight Committee (COIOC), the Staff Conflict of Interest Committee, the school-based conflict of interest committees and/or NUCOI;
- 2) The review of proposed research activities, grants, contracts, and protocols for research involving human participants by NUCOI, the Institutional Review Board (IRB) Office, and the school-based conflict of interest committees, as applicable;
- 3) Review of requests to add vendors, bids, negotiate contracts, or process payments by Procurement and Payment Services and/or Accounting Services for Research and Sponsored Programs (ASRSP);
- 4) Other agreements or transactions brought to the attention of NUCOI or the COIOC; and
- 5) Reports received through the University's third party hotline provider.

When a real or perceived ICOIR is referred to the COIOC for adjudication, the COIOC will review it on a case-by-case basis, giving due consideration to the following factors in the case of research not involving human research participants:

- 1) The nature of the underlying research;
- 2) The nature of the Institutional Financial Interest;
- 3) The extent to which Institutional Research Interests may 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.

In cases of research involving human research participants, the COIOC will consider each of the five factors listed above and, in addition, will assess:

- 6) The degree of risk that any ICOIR poses to the welfare of human research participants;
- 7) The extent to which the University is best positioned to conduct the intended research by virtue of such things as special facilities or equipment, a unique patient population, and/or the experience and expertise of its investigators; and

- 8) In consultation with the IRB Office, whether management strategies can be implemented that are adequately able to protect the safety and welfare of the human research participants.

The COIOC may decide to grant permission to move forward with the intended research at or under the auspices of the University if it concludes that an effective management plan can be implemented to protect the integrity of the University's research and the welfare of human research participants, as applicable. Management strategies may include instituting independent, external review strategies, or utilizing a third-party institutional review board (IRB) to review the contemplated research. Alternatively, the COIOC may determine that the potential risk of conducting research where the institution is, or appears to be, conflicted outweighs the benefit of conducting the study at Northwestern and require that the contemplated research take place at an institution not under the auspices of the University. Similarly, the COIOC may determine that management of the ICOIR is not sufficient and that the contemplated research may only proceed at Northwestern if the University eliminates its Institutional Financial Interest through divestment.

Any COIOC decision to recommend proceeding with research involving human research participants notwithstanding the ICOIR shall be communicated to the Institutional Review Board and the relevant school conflict of interest committee.

Where the COIOC 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 research participants. The management plan will state specifically who will be responsible for the plan's implementation and monitoring.

If the only relevant Institutional Financial Interest at issue derives from a personal or family financial interest of a University Official and that University Official can be segregated from both the decision on whether to engage in the contemplated research activity and from supervision of the research activity, an ICOIR may not exist or the segregation of activities may be sufficient management.

All decisions of the COIOC with respect to ICOIRs are final.

Related Information

[Policy on Conflict of Interest and Conflict of Commitment](#)
[Policy on Conflict of Interest in Research](#)

Contacts

The following office can address questions regarding this Policy:
Northwestern's Conflict of Interest Office, phone: (847) 467-4515, email: nucoi@northwestern.edu

History

Revised: October 14, 2019
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Policy URL:

https://www.northwestern.edu/coi/policy/institutional_policy.pdf