



NORTHWESTERN
UNIVERSITY

Responsible University Official: Vice
President for Research
Responsible Office: Conflict of Interest
Office
Origination Date: January 13, 2014

INSTITUTIONAL CONFLICT OF INTEREST IN RESEARCH

Policy Statement

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

Reason for Policy/Purpose

This Policy is intended to protect against exposure from risks related to institutional conflicts of interest as they may affect or reasonably appear to affect research performed at, or under the auspices of, Northwestern, including harm to research subjects and damage to the integrity of the University's research and reputation.

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Who Approved This Policy

Provost
Senior Vice President for Business and Finance
Vice President for Research

Who Needs to Know This Policy

Officers of the University
Deans

Department Chairs
Center Directors and Institute Directors
Division Chiefs (in the Feinberg School of Medicine)
Any other person designated by the President or Provost as a University Official for purposes of this policy.

Website Address for this Policy

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

Contacts

If you have any questions with regards to the policy contact the Conflict of Interest Office at (847) 467-4515 or nucoi@northwestern.edu.

Definitions

Conflict of Interest Oversight Committee (COIOC)	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 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: <ol style="list-style-type: none">(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 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 Interests	<ol style="list-style-type: none">(1) Gifts to the University of \$100,000 or greater from any entity, whether for-profit or not-for-profit, or from any person (either per gift or in the aggregate).(2) Payments to the University for, or resulting from the conduct of, research at or under the auspices of the University which exceed \$100,000 (either per transaction or in the aggregate). Payments include income from sponsored research projects and royalties from the licensing of intellectual property when such payments may be affected by the research.

- (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 \$100,000.00 in the case of a publicly-traded entity; or b) a value of any amount in the case of a non-publicly traded entity.
- (4) 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.

Rebuttable Presumption For purposes of this Policy, the “rebuttable presumption” means that the University will presume, in order to assure that all potentially problematic circumstances are reviewed, that human subject research involving an Institutional Financial Interest should not be conducted at the University.

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 or the Provost for purposes of this policy.

Policy/Procedures

General Principles

Northwestern University recognizes the importance of relationships with industry in helping to advance research inquiry and discovery and in enabling the commercial development of academic discoveries for the benefit of the public. Some of these relationships may result in financial benefit to the University in a variety of forms, including major gifts, royalty payments and equity interests from licensing intellectual property, and sponsored research and educational agreements. An Institutional Conflict of Interest in Research (“ICOIR”) may consequently arise in the normal course of University research activities. However, important and multi-faceted decisions concerning research must not be unduly influenced, in appearance or in fact, by an Institutional Financial Interest.

One type of ICOIR occurs when the 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 financial interest in that company. Another type of ICOIR arises when a University Official's decisions relating to research may be compromised because the University itself (or one of its major units) has a financial interest at stake. While ICOIRs need not be avoided *per se*, they must be recognized, acknowledged, and managed in order to safeguard the University's research missions, including the safety of human or animal subjects and the integrity of research and educational activities.

Protecting the objectivity and integrity of the University's research mission requires that the 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 may be compromised or could reasonably appear to be compromised by virtue of an Institutional Financial Interest.

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

- 1) The review of conflict 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 the Conflict of Interest Office (NUCOI);
- 2) The review of human subject research and related conflict disclosures by the Office of the Institutional Review Board and the school-based conflict of interest committees;
- 3) The sharing of information regarding University licensing and start-up activity between the Innovations and New Ventures Office (INVO) and the NUCOI; and
- 4) Reports received through the University's third party hotline provider.

When a real or perceived ICOIR is identified, the matter should be referred to the COIOC for adjudication. The COIOC will review each ICOIR referred to it on a case-by-case basis, giving due consideration to the following factors in the case of research not involving human subjects:

- 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.

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

Institutional Conflicts of Interest in Human Subject Research

There is a rebuttable presumption that human subject research should not be conducted when an Institutional Financial Interest is involved. If the only relevant Institutional Financial Interest at issue derives from a personal or family financial interest of a University Official and the 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 exception to this presumption may be granted. (NOTE: ICOIRs differ from individual conflicts because they relate to institutional management and decision-making and have the potential to affect a broad spectrum of University activities. Individual conflicts of interest are subject to the University's Conflict of Interest and Commitment policies pertaining to faculty and staff. Disclosure of individual conflicts of interest in accordance with those policies does not satisfy the requirement of this policy to refer ICOIRs to the COIOC.)

In cases of research involving human subjects, before overcoming the rebuttable presumption and reaching a decision to proceed with the contemplated research, the COIOC will consider each of the five factors listed above under General Principles and, in addition, will assess: 1) the degree of risk that any ICOIR poses to the welfare of human subject participants; and 2) whether the University is uniquely qualified by virtue of such things as special facilities or equipment, a unique

patient population, and/or the experience and expertise of its investigators, to conduct the intended research and to protect the safety and welfare of the human subject 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 compelling circumstances override the rebuttable presumption and that an effective management plan can be implemented to protect the welfare of human subject participants and the integrity of the University's research. Alternatively, the COIOC may decide to overcome the rebuttable presumption by managing the ICOIR through either utilizing a third-party institutional review board (IRB) to review the contemplated research or requiring that the contemplated research take place at an institution not under the auspices of the University. The COIOC may also determine that the rebuttable presumption may only be overcome by the University eliminating its Institutional Financial Interest and without such divestment the contemplated research should not be conducted.

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

Where the Committee 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.

Forms/Instructions

NA

Appendices

NA

Related Information

[Northwestern University Policy on Conflict of Interest and Conflict of Commitment](#)

[Northwestern University Policy on Conflict of Interest in Research](#)

History/Revision Dates

Origination Date: January 13, 2014

Last Amended Date: Month, Day, Year

Next Review Date: January 15, 2015