

Institutional Conflict of Interest in Research Policy Duke University

1. Introduction

An institutional conflict of interest ("Institutional COI") describes a situation in which the financial interests of an institution or an institutional official, acting within his or her authority on behalf of the institution, may affect or appear to affect the research, education, clinical care, business transactions, or other activities of the institution. Institutional COIs are of significant concern when financial interests create the potential for inappropriate influence over the institution's activities. This policy is intended to protect against exposure from risks related to Institutional COIs as they may affect research performed at or under the auspices of the University.

An institution like Duke University ("Duke"), including its officials, must balance many competing pressures. It engages in relationships with a variety of sponsors that may lead to financial benefit for the institution in many forms, including gifts, business ventures, royalty payments and equity from licensing intellectual property, as well as sponsored educational and research agreements. In addition, university-industry relationships are essential for advancing scientific frontiers and enabling the commercial development of academic discoveries to the benefit of the public. Nonetheless, while generally part of legitimate educational, research, and business activities, relationships with external entities or individuals cannot be allowed to compromise, or appear to compromise, the integrity of the Duke's primary missions, including the safety and integrity of its research, education, and clinical care.

2. Definitions

Institutional Conflict of Interest in Research: An Institutional COI in Research may occur whenever the financial interests of the institution, or of an institutional official who has authority to act on behalf of the institution, might affect—or reasonably appear to affect—institutional processes for the design, conduct, reporting, review, or oversight of research.

Covered Officials: This Institutional COI in Research Policy applies to the Board of Trustees, President, Chancellor for Health Affairs and Vice Chancellors, the Provost and vice-provosts, other senior officers, Deans and vice-deans, associate deans and other institutional administrators, particularly insofar as the individuals have oversight of research, with special attention to human subjects research, at the University. This policy will also require review of conflicts of interest involving department chairs, division chiefs, institute and center directors, Institutional Review Board chairs, the COI and Institutional COI committee chairs, the chair of the Institutional Biosafety Committee, the chair of the Stem Cell Review Committee, and chairs of other similar committees that might be created in the future.

Officials with Oversight of Research: Covered officials with responsibility for the supervision of faculty and staff participating in research conducted at or under the auspices of the institution. Of particular importance in defining an "official with oversight of research" are supervisory roles

like evaluation and management of promotion, pay raises, and the assignment of job responsibilities.

Significant Financial Interest (individual): For covered officials, “significant financial interest” is defined as being consistent with Duke University’s faculty conflict of interest policy and procedures. Areas of consideration include: payments, honoraria, royalties (even through the institution), equity, options and warrants, board of directors and management positions, and gifts.

Significant Financial Interest (institutional):

- A. *Royalties*: Institutional COI may be present when the institution has agreements to receive milestone payments and/or royalties from the sales of an investigational product that is the subject of the research;
- B. *Non-publicly traded equity*: When, through its technology licensing activities or investments related to such activities, the institution has obtained an equity interest or an entitlement to equity of any value (including options or warrants) in a *non-publicly traded* company that is: i) the sponsor of research at the institution, or ii) the manufacturer of a product to be studied or tested at or under the auspices of the institution;
- C. *Publicly traded equity*: When, through technology licensing activities or investments related to such activities, the institution has obtained an ownership interest or an entitlement to equity (including options or warrants) exceeding \$100,000 in value (when valued in reference to current public prices, or, where applicable, using accepted valuation methods), in a *publicly-traded* company that is i) the sponsor of research at the institution, or ii) the manufacturer of a product to be studied or tested at or under the auspices of the institution.
- D. *Gifts from sponsors*: When the institution has received substantial gifts (including gifts in kind) from a potential commercial sponsor of research or a company that owns or controls products being studied or tested, or an individual affiliated with these companies. The following circumstances should be evaluated:
 - 1. Whether a gift is of sufficient magnitude that even when held in the general endowment for the benefit of the entire institution, it might affect, or reasonably appear to affect, oversight of research at the institution;
 - 2. Whether a gift is held for the express benefit of the college, school, department, institute or other unit where the research is to be conducted; or
 - 3. Whether any institutional official who has the authority, by virtue of his or her position, to affect or appear to affect the conduct, review or oversight of the proposed research has been involved in solicitation of the gift.

3. Identification of Potential Institutional Conflicts of Interest

The following significant financial and fiduciary interests of the institution warrant formal review for potential Institutional COI with respect to research:

Significant financial interests for the institution.

Significant financial interests on the part of covered officials responsible for the oversight of research.

Situations when an investigator, research administrator, or Duke institutional 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 studied or tested in human subjects research at the institution.

In addition to those circumstances indicated above, other financial relationships with research sponsors may warrant formal scrutiny, depending on the circumstances. In general, the institution should assess the potential for conflict of interest and weigh the magnitude of any risk to the research's integrity.

Although the listed circumstances are potential areas of concern, the goal of this policy is not to preclude Duke from accepting philanthropy from companies that sponsor research, or that own or control products that are being studied or tested. Rather, the policy is intended to require the institution to develop means of identifying and examining such circumstances, and of managing, through disclosure, separation of responsibilities, and as otherwise appropriate, mitigate any actual or apparent conflicts of interest that may result. All gifts should be accepted in conformance with these policies and accepted by the development office for record-keeping purposes. All faculty and staff members are accountable for adhering to the institutional gift policy.

4. Establishment of an Institutional Conflict of Interest Committee

In order to review and manage Institutional COIs, a committee will be established that includes members who are not employed by Duke as well as senior Duke employees. A member of the General Counsel's Office will be a non-voting participant. The Board will be advisory to the University Board of Trustees, which holds final authority regarding questions of Institutional COIs.

5. Management of Potential Institutional Conflicts of Interest

The reasons to manage Institutional COIs include: 1) To maintain the highest possible standards in research; 2) To adhere to all applicable federal and state regulations; 3) To maintain the primacy of the university's educational mission; 4) To protect the reputation and credibility of the University, its faculty and staff. Based on those needs, the following basic principles will be applied in the management of potential Institutional COI:

A. When Duke itself has a significant financial interest:

- a. **Human Subjects Research:** There is a "rebuttable presumption" that human subjects research should not be carried out at Duke when the institution has a significant financial COI. In those situations where Duke faculty have unique capabilities, or where there are unique resources at the institution, the research

may be performed at Duke after the establishment of a formal institutional management plan. This plan will include establishment of an oversight board for the project made up of non-Duke individuals. Other management steps may be required (e.g. use of a non-Duke IRB, external monitoring, etc).

- b. **Non-Human Subjects Research:** Because research subject safety is not an issue in the case of non-human subjects research, the primary reasons to manage Institutional COI focus on protection of the integrity of the University's research and educational missions. If a decision is made by the Institutional Conflict of Interest Committee that the potential value of a line of research exceeds the potential risks related to Institutional COI, management will usually include some form of oversight external provided from outside Duke. The level of oversight should be proportional to the risk to the institution's reputation and/or educational mission.
- B. When an individual in a supervisory administrative role has a conflict of interest:**
- a. **Human Subjects Research:** In this situation, there is not the same "rebuttable presumption" made that the work cannot be performed, since in most cases alternative supervision can be arranged. The Institutional Conflict of Interest Committee should review the administrator's role in relation to the research and to the researchers, the nature of the administrator's conflict of interest, and should then formulate a plan so that an appropriately objective administrator can oversee the research for the institution.
 - b. **Non-Human Subjects Research:** In most cases for this circumstance, an alternative administrator should be identified, and the conflicted administrator should voluntarily recuse themselves. The situation should be reviewed by the Institutional Conflict of Interest Committee to be certain no bias will be introduced that could affect the research, the researchers, or any students working on the research project. If there is potential for bias or pressures, particularly in the case of a student, alternative supervision should be arranged by the Committee.