University of Kentucky
Office of the Vice President of Research
Institutional Conflicts of Interest Involving Research

I. Introduction

The University often enters into relationships with external business entities that help it carry out its mission. Due to financial interests of the University or its officials, such business relationships and commercial activities may create inherent conflicts of interest between the University and its external partners. The University has a responsibility to the residents of the Commonwealth and the public at-large to conduct its research activities with the utmost integrity. The University must be vigilant to segregate decisions involving its research programs, particularly research involving human subjects, from decisions involving the management of its financial interests and the solicitation of contributions.

This policy is intended to provide clear guidance and procedures for the disclosure and management, or elimination, of institutional conflicts of interest, whether real or perceived, that may otherwise compromise processes for the review or oversight of research.

II. Application

This policy applies to two different types of interests: interests held by University Officials that may appear to influence their institutional decisions, and interests held directly by the University itself that may also appear to influence institutional decisions.

Note: This policy is distinct from the Policy on Financial Conflict of Interest in Research , which provides for the management of conflicts of interest of individuals that are personal rather than institutional in scope.

III. Policy

It is the position of the University to ensure that its research programs are conducted with integrity and free from any real or perceived institutional conflict of interest.

Each significant financial interest that represents a potential institutional conflict of interest, whether real or perceived, shall be fully disclosed to the Institutional Conflict of Interest Official (ICOI Official). Once disclosed, the conflict or perceived conflict shall be managed, or eliminated, before any sponsored or contractual agreement is executed, or any research activity is undertaken that may be influenced by or appear to be influenced by the conflict.

For the purpose of this policy, two types of financial interests are of concern. The first category includes direct financial holdings of the University or any of its affiliated corporations. The second category includes personal financial holdings of a University Official who, by virtue of his or her institutional authority, may affect or reasonably appear to affect institutional processes for the conduct, review or oversight of research. This policy mandates that both types of financial interests be disclosed subject to certain thresholds that are stipulated below.

This policy does not preclude the University from conducting business with entities that have a financial relationship with the University. However, in such instances potential institutional conflicts of interest shall be identified promptly and resolved appropriately to preclude any real or perceived compromise of the integrity of the research or the safety of human research participants.

In the case of human subjects research, the University shall be governed by a rebuttable presumption against conducting research when certain types of institutional conflict of interest exist. The University shall not ordinarily participate in any clinical trial of a therapeutic strategy, product or device if: (i) the University has entered into a license agreement or acquired equity in a company sponsoring such trial; or (ii) if the University or University Official, or both, hold equity in a sponsoring company. The presumption may be overcome if the University is also the preferred or only feasible site for the research, going forward is recommended by the Institutional Conflict of Interest Committee (ICOI Committee), and the project and any recommended management plan has the joint approval of the Vice President for Research and the Executive Vice President for Health Affairs.

IV. Definitions

A. Business Entity: Any entity recognized by law through which business for profit is conducted, including a sole proprietorship, partnership, firm, corporation, holding company, joint stock company, receivership or trust.

B. Human Subjects Research: Research involving human subjects and that pursuant to applicable law or regulation shall be reviewed by an Institutional Review Board.

C. Institutional Conflict of Interest (ICOI): The University may have an institutional conflict of interest in research whenever the financial interests either of the University or of a University Official acting within his or her authority on behalf of the University may affect or reasonably appear to affect institutional processes for the review or oversight of research.

D. Significant Financial Interest: The following financial interests of the University, its affiliated corporations or University Officials (including spouse and dependent children) in any business entity that sponsors research at the University are defined as significant.

1. *"Significant Financial Interest"* for University Officials includes:

(a) Equity and ownership interests worth more than $10,000 in the aggregate in any publicly traded, for-profit organization. Excluded are equity interests held in publicly-traded mutual funds or retirement programs the investment of which is not under control of the University Official; and

(b) Any equity interest of any amount in any for-profit organization that is not publicly traded.

(c) Service as a member of the board of directors or other governing board of a for-profit organization, including a trustee or scientific advisory board member, service as an officer of the organization (whether paid or unpaid) or service as an employee.

(d) Payments, including royalty payments, resulting from technology transfer, licensing or any outside business activities that, for each arrangement, exceed $10,000 in the aggregate per year. Clinical care income and tuition income are excluded.

2. *"Significant Financial Interest"* for the University includes:

(a) Equity and ownership interests worth more than $500,000 in any publicly traded, for-profit organization. Excluded are investments in funds, whether public or private, that are managed by an independent investment manager.

(b) Receipt or pledge of a gift or gifts to the University exceeding $500,000 in annual aggregate value from a for-profit organization or the philanthropic unit affiliated with a for-profit organization.

(c) Payments, including royalty payments, resulting from technology transfer, licensing and similar business activities that, for each arrangement, exceed $500,000 per year. Clinical care income and tuition income are excluded.

E. University Official: An individual who, because of his or her position within the University, has the capacity to affect, or can reasonably appear to affect, University processes for the review or oversight of research or the capacity to allocate institutional resources used for research. Such officials include:

- President
- Provost, vice provosts, and associate provosts
- Executive vice presidents, vice presidents, and associate vice presidents
- Treasurer and Controller
- General Counsel, associate and assistant general counsels
- Deans and associate deans for research
- Center and institute directors

V. Roles and Responsibilities

A. Institutional Conflict of Interest Official

1. The Vice President for Research is designated as the Institutional Conflict of Interest Official (ICOI Official) with authority and responsibility for overseeing the implementation of this policy and ensuring that credible and effective decisions for resolving and monitoring institutional conflicts of interest are made.

The ICOI Official shall obtain at least annually, for the most current fiscal year:

(a) A list of the University's equity holdings that are Significant Financial Interests;

(b) A list of the University of Kentucky Research Foundation's (UKRF) licensees, optionees and royalty payments; and

(c) A list of gifts or donations from for-profit organizations and philanthropic units affiliated with for-profit organizations that exceed $500,000 in aggregate.

2. The ICOI Official shall review these holdings against a list of UKRF sponsored research agreements to determine if a potential conflict of interest exists in any areas, and shall notify the heads of those areas thus affected as to the existence of potential conflicts. Additionally, the ICOI Official shall provide a "watch list" to the Director of the Office of Sponsored Project Administration (OSPA) to assist in the identification of potential institutional conflicts of interest.

3. The ICOI Official shall advise University Officials, on an annual basis, of their obligation to disclose any Significant Financial Interest in any transaction in which the official:

   (a) Participates; or

   (b) Has actual knowledge that the University is negotiating an agreement that would be covered under this policy.

4. On a case-by-case basis, when research sponsored by a private company involves the use of human research participants, the ICOI Official shall provide information on the Significant Financial Interest to the relevant University offices, including but not limited to OSPA and the Office of Research Integrity.

5. When a University Official determines that she or he holds a Significant Financial Interest relevant to a pending transaction, she or he shall complete and submit a disclosure form and submit it to the ICOI Official. This includes situations where the University Official has any type of direct participation in the transaction or has actual knowledge that the University is negotiating an agreement with such an entity.

6. Once identified by the ICOI Official, all potential conflicts shall be disclosed to the ICOI Committee, which shall review the disclosures and recommend to the ICOI Official the proper management, if any.

7. If the ICOI Official has a real or perceived conflict of interest in any matter under review, he or she shall so report to the President, and the President shall name an alternate to serve in place of the ICOI Official.

B. Institutional Conflict of Interest Committee

1. The ICOI Committee is appointed by the President, and shall include:

   (a) One senior university administrator;

   (b) Three faculty members, at least one of whom shall be from the health care colleges (i.e., Medicine, Pharmacy, Nursing, Dentistry, Public Health and Health Sciences);

   (c) One staff member;

   (d) One public member who has no affiliation with the University;

   (e) A member of the Office of General Counsel (non-voting ex officio); and

(f) A representative from the OSPA (non-voting ex officio).

2. The committee shall be chaired by a designee of the Vice President for Research.

3. A committee member shall not participate in a review whenever he or she has a real or perceived conflict of interest with any matter under review. At least three participating committee members shall review disclosures and make recommendations. If needed, the President shall name one or more alternate members to serve in place of those members who have recused themselves from the review.

4. The ICOI Committee is responsible for:

   (a) Reviewing disclosures that present or appear to present an Institutional Conflict of Interest due to a Significant Financial Interest;

   (b) Developing specific plans to manage instances of Institutional Conflict of Interest due to a Significant Financial Interest;

   (c) Providing oversight of projects that are being managed in accordance with this policy;

   (d) Documenting the committee's findings and the basis for the approval of conflict management plans, including steps to be taken to manage the conflict or minimize the potential for conflict of interest by reducing or eliminating the interest; and

   (e) Making recommendations to the ICOI Official for prohibiting those activities for which a conflict management plan is not reasonably achievable.

5. Due to the complex nature of an ICOI, the committee may, at its discretion, consult additional internal or external consultants, or may appoint an ad hoc review team to work on specific issues. If appointed, ad hoc teams will make recommendations to the ICOI Committee.

6. The ICOI Committee shall consider whether the financial or fiduciary interests disclosed in accordance with this policy have the potential to affect or appear to affect any of the following: safety of human research subjects; integrity of research or scholarship; appropriate allocation of University resources to research projects; objectivity and independence of sponsored educational activities, including undergraduate, graduate, professional, post-graduate and continuing education; or objectivity in business and contracting decisions.

7. The ICOI Committee review of a specific case may result in one of three types of recommendations to the ICOI Official:

   (a) The arrangement does not represent a significant real, potential, or perceived Institutional Conflict of Interest that needs to be managed ("type-one");

   (b) The arrangement represents a significant real, potential, or perceived Institutional Conflict of Interest, but can be managed and recommended management activities, if any ("type-two"); or

(c) The arrangement represents a significant real, potential, or perceived Institutional Conflict of Interest and is not manageable and either the activity may not proceed or the financial interest must be eliminated ("type-three").

In type-one recommendations, the committee concludes no additional action is needed.

In type-two recommendations, the committee shall recommend to the ICOI Official one or more management measures. These may include, but are not limited to: (1) effective recusal from decision-making regarding the proposed arrangement by the financially interested University Official; (2) reduction in the magnitude of the financial interest by divestiture to below the threshold values noted above; (3) disclosure of the financial interest in relevant publications, presentations, educational materials, human subject consent forms, clinical procedure or other consent forms; (4) oversight by a disinterested senior individual or committee; and/or (5) other measures deemed appropriate by the committee.

In type-three recommendations, the committee shall report its recommendation to the ICOI Official. In cases judged to involve unmanageable ICOI, it is expected that the committee should most often recommend the elimination or reduction of the financial interest rather than prohibition of the proposed research or sponsored activity. The committee should generally give precedence to activities that carry out institutional mission over conflicting financial interests.

7. Upon receiving the committee's decision, the ICOI Official shall accept the Committee's recommendation, return the matter for further consideration, or reject the recommendation. If rejected, the reasons for that rejection shall be documented and shared with the committee. The ICOI Official shall then notify all interested parties of the determination, including (if applicable) the University Official whose interest was at issue. The decision of the ICOI Official may be appealed to the President.

8. ICOI in human subjects research is a particularly sensitive subject. If human subjects research is involved, the University shall take particular care with respect to the review, management, or elimination of any potential institutional conflict of interest to assure that the welfare of human research subjects and the integrity of the research are not compromised.

9. In all cases, the committee and the ICOI Official shall retain documentation of their respective review and determination in accord with the University's records retention schedule. The ICOI Official shall be the custodian of those documents.

VI. Violations and Sanctions

A. Whenever there is an allegation that a University Official has violated this policy, the ICOI Official shall refer the allegation to the ICOI Committee for investigation. The ICOI Committee shall first determine if the alleged violation involves matters outside the scope of this policy, and whether the investigation should more appropriately be referred to other areas or other officials. If so, it shall so advise the ICOI Official, who shall refer the matter to

the appropriate office.

B. The ICOI Committee shall conclude whether it is more likely than not that a violation of this policy occurred, based upon a preponderance of evidence.

C. If the ICOI Committee concludes that a violation occurred, it shall so report and shall recommend to the ICOI Official sanctions, which may include disciplinary action ranging from a public letter of reprimand to dismissal and termination of University employment. Upon receiving the ICOI Committee's decision, the ICOI Official shall accept the Committee's recommendation, reject some or all of the recommendation, or impose additional sanctions. Any disciplinary action outside of the scope of the ICOI Official's authority shall be referred to the appropriate individual(s) and shall proceed as outlined in applicable sections of the University's *Governing Regulations* or *Administrative Regulations* or, if a staff employee is involved, applicable sections of Human Resources Policies and Procedures. In a case in which the accused party is the President, the matter shall be referred to the Board of Trustees.

D. In cases that might impact federal funding of sponsored projects, the University shall follow federal regulations, if any, regarding the notification of the sponsoring agency in the event an individual has failed to comply with this policy.

VII. References and Related Materials

Association of American Medical Colleges, 2008 Task Force Report, *Protecting Patients, Preserving Integrity, Advancing Health: Accelerating the Implementation of COI Policies in Human Subjects Research*