



University of Louisville

OFFICIAL UNIVERSITY ADMINISTRATIVE POLICY

Board of Trustees, Institutional Officials

POLICY NAME Addressing Institutional Conflicts of Interest	EFFECTIVE DATE January 2011	POLICY NUMBER COI-1.01
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POLICY STATEMENT

This policy governs conflicts of interest and applies to situations involving the institution, as a whole, as well as Institutional Officials. It is the policy of the University of Louisville to ensure its transactions are conducted with integrity. This policy, and its associated procedures, outlines the guiding principles and procedures utilized by the University of Louisville to identify and manage conflicts of interest that present a significant risk to the actual or perceived objectivity of transactions conducted in the name of the University of Louisville.

Potential institutional conflicts of interest typically may arise in one of four areas:

- A. when an entity that has an academic, business, clinical or research relationship with the Institution also donates a gift to the Institution;
- B. when the Institution owns equity in an entity and the entity has an academic, business, clinical or research relationship with the Institution;
- C. when the Institution licenses an invention to an entity that also has an academic, business, clinical or research relationship with the Institution; and
- D. when an Institutional Official has an external and/or professional relationship with an entity and the entity has an academic, business, clinical or research relationship with the Institution.

REASON FOR POLICY

In pursuit of its mission as a public institution of higher education, the University of Louisville seeks excellence in the quality of its research, in the teaching and education it provides to its students, and in the service it provides to the broader community. Accomplishment of its missions inevitably leads to increasingly close relationships between the University of Louisville and those with outside interests in the broader community, including financial interests. The benefits that potentially accrue from this proximity are accompanied by real or apparent risks that external interests might compromise University decisions by influencing the judgment of the Institution or one of its members. To guard against these external influences, the Institution has put procedures in place to identify and address institutional conflicts of interest. These procedures are not intended to discourage research, creative activity and scholarship.

This policy governs institutional conflict of interest at the University of Louisville (Institution) and applies to members of the Board of Trustees (Board), Institutional officials, department/unit heads, and other individuals as required by administrative policies and procedures. This policy covers academic, business, clinical and research transactions and activities conducted under the auspices or for the benefit for the University of Louisville.

RELATED INFORMATION

GOVERNING LAWS, REGULATIONS, STATUTES, STANDARDS

42 CFR 50; NSF GPM Section 510; 21 CFR Parts 54, 312, 314, 320, 330, 601, 807, 812, 814, and 860; OMB Circular A-110; KRS 45A.340, 164.367, 164.390, 164.821; AAHRPP Standards: I-6, II-1, III-1.

GOVERNING POLICY

[Institutional Conflict of Interest Policy](#) (Board of Trustees Approved)

ASSOCIATED POLICY AND PROCEDURES

[Addressing Potential Individual Conflict of Interest Policy](#)
[Addressing Potential Individual Conflict of Interest Procedures](#)
 The Redbook
[PER 5.01 Staff Disciplinary Policy](#)

DEFINITIONS

A. Associated Entity. Any trust, organization, business, or enterprise over which the Institutional Official, alone or together with an immediate family member, exercises a controlling interest.

B. Appropriate Authority means the Institutional Official's direct supervisor. In the case of the President, the Board of Trustees will serve as the Appropriate Authority.

C. Board of External Entity. Any corporation, partnership, sole proprietorship, firm, franchise, association, organization, holding company, joint stock company, receivership, business or real estate trust, or any other nongovernmental legal entity organized for profit, nonprofit, or charitable purposes.

D. Conflict Review Board (CRB). A board established by the president or delegate to evaluate potential conflict of interest situations, develop, review, and assist with enforcing management plans, review information relating to post-approval implementation of conflict management plans, and generally serve as a resource for the Conflict of Interest Program and other members of the University community. The CRB is chaired by the Institutional Compliance Officer.

E. Controlling Interest. Means the Institutional Official or immediate family member's ownership of an entity is sufficient to grant the Institutional Official the power to direct the entity's management.

F. Covered Individual. Shall mean all University employees. It also includes other individuals with responsibility for the design, performance, or reporting of Institution research, regardless of pay or enrollment status. It also includes individuals conducting research at the University of Louisville, or using University of Louisville researchers, or using University of Louisville facilities or resources.

G. Financial Interest. Anything of monetary value including, but not limited to: an interest in a business consisting of any stock (other than through mutual fund purchase), stock option, or similar ownership interest in such business, but excluding any interest arising solely by reason of investment in such business by a mutual, pension, or other institutional investment fund over which the employee does not exercise control; or receipt of, or the right or expectation to receive, any income in one or more of the following forms: a consulting fee, honoraria, salary, allowance, forbearance, forgiveness, interest in real or personal property, dividend, royalty derived from the licensing of technology or other processes or products, rent, capital gain, or any other form of compensation.

H. Immediate Family Member. Immediate family member shall mean the Institutional Official 's biological, foster or adoptive parent, a stepparent, spouse, qualifying adult, a biological, adoptive or foster child, a step child, a legal ward or a person whom the Institutional Official has (or had during the person's youth) daily responsibility and financial support, mother, father, brother, sister, son, daughter, mother-in-law, father-in-law, brother-in-law, sister-in-law, son-in-law, daughter-in-law, grandparents, and grandchildren of both the Institutional Official and spouse and / or qualifying adult.

I. Institutional Conflict of Interest. Institutional conflict of interest shall mean a situation in which the research, teaching, outreach, or other activities of the Institution may be compromised because of an external financial or business relationship held at the institutional level that may bring financial gain to the institution, any of its units, or the individuals covered by this policy.

J. Institutional Official. Persons holding administrator positions, including those holding these positions in a temporary capacity. This term includes, but is not limited to individuals serving as: Deans, Associate Deans, and Assistant Deans; Institute and Center Directors; General Counsel; University Compliance Officers; Director of Audit Services; Provost, Vice Provosts, Associate Vice Provosts, and Assistant Vice Provosts; President, Executive Vice Presidents, Senior Vice Presidents, Vice Presidents, Associate Vice Presidents, and Assistant Vice Presidents; and chairs of the Institutional Review Board, Institutional Biosafety Committee, Institutional Animal Care and Use Committee, Conflict Review Board and other similar committees that might be created in the future.

K. Participate. To be part of the Institution activity in any capacity, including, but not limited to, serving as the principal investigator, co-investigator, research collaborator, or provider of direct services or patient care. The term does not apply to individuals who provide primarily technical or advisory support and have no direct access to the data or control over its collection or analysis. The term also does not apply to the study participants, unless they are in a position to influence the study's results or have privileged information as to the outcome.

L. Qualifying Adult A qualifying adult must be over 18 years of age, and, if a blood relative (or relative by adoption or marriage) must be of the same or younger generation of the Institutional Official (as used in KRS 391.010), and, must be residing in the Institutional Official's household and have done so for a period of at least 12 months, and, must be financially interdependent (for example, have joint checking account or joint mortgage) for 12 months or longer, and, must be unmarried.

M. Support. Means providing anything of value (e.g., funds, supplies, equipment, staff, etc.), regardless of whether restricted or unrestricted.

N. Supported Activities. Means any agreement with an external entity that is providing support.

FORMS/ONLINE PROCESSES

The Attestation and Disclosure Form (ADF) is located at: <https://iris.louisville.edu>.

HISTORY

Revision Date(s): November 2015, April 2015, October 2013, January 2013, January 2011
Reviewed Date(s): 2016

ADMINISTRATIVE AUTHORITY

Compliance Oversight Council

RESPONSIBLE UNIVERSITY DEPARTMENT/DIVISION

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