

POLICY FOR OVERSIGHT OF INSTITUTIONAL FINANCIAL INTERESTS IN RESEARCH

PURPOSE

The University of Louisville recognizes the need to manage apparent and/or real financial conflicts of interest that may appear to/or may put the institution's financial interests in a situation where research could appear to be/or be affected. With a mission that includes a focus on research and economic development, the university does carry out research projects that could lead to financial benefits for the institution or for institutional officials. Projects can be internally funded or funded through agreements that may be mutually beneficial to the university and a corporate entity. Such agreements can include, but not be limited to, receiving royalties from or holding an equity interest in a company.

POLICY

When a faculty member wishes to do research at the University of Louisville and the University of Louisville or an institutional official holds a financial interest greater than \$100,000 or 5% equity or holds an interest that can not be valued using a public price or other reasonable measure of fair market value and the value could increase based on the results of the study, the university and its employees will disclose the potential conflict to the Oversight Committee for the Management of Institutional Financial Interests. The Committee will determine whether the research should be done at U of L and determine what steps, in addition to disclosure of the university interest, are necessary to ensure the integrity of the research enterprise at the University of Louisville. This document describes additional steps that must be taken to manage the potential conflict if the research involves human subjects.

OVERSIGHT COMMITTEE FOR THE MANAGEMENT OF INSTITUTIONAL FINANCIAL INTERESTS IN RESEARCH

Membership:

The Vice President for External Affairs will chair the Oversight Committee for the Management of Institutional Financial Interests in Research. Members will be appointed by the President and will include a representative from the Board of Overseers, a faculty member with previous service on the university IRB, a faculty member with expertise in health policy and ethics, and three individuals from the community who have no professional, personal or financial ties to the University of Louisville. The committee reports to the Senior Vice President for Research

Responsibilities:

The Oversight Committee for the Management of Institutional Financial Interests in Research will determine if the research can be done at U of L and if so, make recommendations about actions, in addition to those required by this document, that are necessary when university financial interests could appear to influence research.

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The committee will conduct a fact-driven inquiry to determine what conditions, in addition to those required by this document, must be implemented to assure the public that the financial interests of the university or its officials will not affect or reasonably appear to affect the research. The Oversight Committee for the Management of Institutional Financial Interests in Research will notify the principal investigator(s) and their respective department chair and dean as well as the Senior Vice President for Research of its findings and the management conditions that should apply if the study is done at the university.

The Oversight Committee for the Management of Institutional Financial Interests in Research will communicate its findings and management conditions to the public. If the research involves human subjects, the Committee will communicate its findings and management conditions to the external IRB and assure that all relevant conflicts are disclosed to the external IRB and the research subjects. It will also communicate its findings to the University of Louisville Research Foundation.

If someone violates this policy, the Oversight Committee for the Management of Institutional Financial Interests in Research will recommend sanctions to the Senior Vice President for Research (or the President for Presidential direct reports) that may include actions ranging from a letter of reprimand to dismissal and termination of employment.

The University of Louisville Research Foundation, Inc. (ULRF): The University of Louisville Research Foundation must disclose and will segregate decision-making about financial and research activities by placing decision making authority about the disposition of an equity position, stock option, or entitlement to ownership in a company that is held by the ULRF to the Vice President for Finance. The Vice President for Finance will have authority over the disposition of the equity position, stock option or entitlement to ownership unless the Oversight Committee for the Management of Institutional Financial Interest determines whether other steps, including the placement of assets in a blind trust, are necessary.

Principal Investigators: Principal investigators responsible for the oversight of research will inform the Oversight Committee for the Management of Institutional Financial Interests if they are aware of any potential institutional financial interest (other than receiving a grant or contract to cover the costs of the research). If the research involves human subjects, the principal investigator will also inform the University Institutional Review Board.

Deans, Directors and Department Heads: For research that is supported internally, and is not under the cognizance of the Office of Technology Development and/or Office of Industry Contracts, the Dean, Director, or Department Head is responsible for notifying the Oversight Committee for the Management of Institutional Financial Interest of potential financial benefits to institutional officials or to the University of Louisville.

Administrative Offices: The Office of Technology Development and/or Office of Industry Contracts will inform the Oversight Committee for the Management of Institutional Financial Interests in Research of potential projects involving research that might benefit University of

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Louisville financial interests. The offices will also provide records of the corporate entities and their financial relationship to institutional officials or to the University of Louisville to the Research Integrity Specialist, and to the University of Louisville Institutional Review Board if clinical research at the University is involved. The Research Integrity Specialist will provide staff support to the Oversight Committee for the Management of Institutional Financial Interests in Research and serve as liaison between the Oversight Committee for the Management of Institutional Financial Interests in Research and the Research Conflict of Interest Review Committee.

Human Subjects Protection Program Office: The University of Louisville Institutional Review Board will require faculty to disclose potential individual and institutional financial conflicts of interest in the application for review of a study involving humans. Institutional financial conflicts include but are not limited to an equity position, stock option, entitlement to ownership interest in a company or receipt of royalties from a company (“financial relationship with the university”) that could benefit from research carried out at the University.

The Institutional Review Board will notify the chair of the Oversight Committee of the Management of Institutional Financial Interests in Clinical Research that an inquiry is required if the university could realize a financial gain (other than funding to cover the costs of the research) because of a financial relationship between the university or a university official and a for-profit entity. If the Oversight Committee determines that the study can be conducted at the University, the University IRB will require that a board that is independent of the university conduct IRB review. The independent IRB will be informed of the potential conflict and the institutional plans for management. The university and its investigators will comply with any requirements of the IRB before commencing the work and throughout the study.

Institutional Officials: All institutional officials (including the president, vice president for research, deans, chairs, institute heads, and the chairs of the IRB and CRIFIR committees) must complete an individual SFI disclosure annually and notify their supervisor of any changes that occur between annual disclosures. These disclosures will be shared with the Oversight Committee for the Management of Institutional Financial Interests in Research to enable the committee to address any potential situations where an institutional official’s individual financial interests could also be considered an “institutional conflict of interest.”

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PROCEDURES FOR REVIEW AND MANAGEMENT OF INSTITUTIONAL FINANCIAL INTERESTS IN RESEARCH

The university and its employees have an obligation to disclose potential conflicts to the Oversight Committee for the Management of Institutional Financial Interests in Research (OCMIFIR) as described in the Policy for Oversight of Institutional Financial Interests in Research.

The Research Integrity Specialist, Office of the Senior Vice President for Research, will provide staff support to the OCMIFIR. Those individuals required by the policy to notify the OCMIFIR of potential institutional conflicts should do so through the Research Integrity Specialist. The Research Integrity Specialist has the following procedural obligations:

- 1) to work with the person making the notification to assure that the description of institutional financial interest is sufficient for the Chair of the Committee, the Senior Vice President for Research and the Research Integrity Specialist to decide if a full review is necessary.
- 2) to serve as the liaison between the Research Conflict of Interest Review Committee that reviews disclosures and refer conflicts disclosed by institutional officials to the OCMIFIR.
- 3) to maintain an up to date list of university financial interests negotiated by the Office of Technology Development.
- 4) to assist the OCMIFIR in developing standard operating procedures.

If a full review is necessary, the Committee will carry out a fact-driven inquiry. University employees will provide the Committee with information and expertise necessary to support the review. The principal investigator must provide the OCMIFIR a clear explanation as to why the research is best carried out at U of L even though there is or appears to be a conflict.

Within sixty days of obtaining all necessary information, the Committee will determine whether the research can be done at the university with careful management and if so, will determine the management conditions. Management conditions will be communicated to the principal investigator(s) and their respective department chair and dean as well as to the Senior Vice President for Research. An individual that disagrees with the OCMIFIR may ask for an administrative review from the Executive Vice President/Provost.

The Senior Vice President for Research is responsible for assuring that the conflict is managed as recommended by the OCMIFIR and will report at least annually to the OCMIFIR on the operation of each management process.

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