

I. POLICY FOR OVERSIGHT OF INDIVIDUAL FINANCIAL INTERESTS IN RESEARCH

PURPOSE

The success of the University's research program depends upon that integrity and the public's confidence in it. Financial conflicts of interest in research strike at the heart of a University's integrity. 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. This knowledge transfer inevitably leads to increasingly close relationships between universities and those with financial capital in the private sector. The benefits that potentially accrue from this proximity are accompanied by real or apparent risks that economic interests might compromise academic research by influencing an investigator's judgment about the design, conduct, reporting, or management of research, and, in the case of research involving human subjects, imperil the safety of participants.

POLICY *(Corresponds to Section III, second sentence of the Conflict of Interest Policy (BOT Approved, 6/27/83))*

The University of Louisville, its faculty, and other members of the University research community commit themselves to the pursuit of the University's research mission in accordance with the highest standards of integrity and in compliance with legal, professional, ethical and other requirements that promote objectivity and protect against financial conflicts of interest in research. The University of Louisville will identify possible financial conflicts of interest in research, whether apparent or real, and provide mechanisms for their management, reduction, or elimination.

ORGANIZATIONAL RESPONSIBILITIES

Deans, Directors and Department Heads: Each chair or unit head shall ensure that all persons within each department or unit who are *covered individuals* are accurately identified -- either as defined by this policy or as individually determined to be *involved in research* by principal investigators, the chair or unit head -- and that all such *covered individuals* complete and sign *Disclosures of Significant Financial Interests* in a timely manner. Deans or their designees shall ensure that the responsibilities of chairs or unit heads as described above are carried out in a timely manner, that ambiguities as to the identification of *covered individuals* are appropriately resolved, and that *Disclosures of Significant Financial Interests*, as appropriate, are submitted and forwarded as required by this policy.

Institutional Officials: University officials, other than chairs or unit heads and deans, under whose general supervision there are *covered individuals* with obligations under this policy, shall resolve ambiguities, if any, as to the identification of such *covered individuals* under his or her general supervision, and shall be responsible for ensuring that *Disclosures of Significant Financial Interests* are completed, submitted and forwarded as required by this policy.

Covered Individuals: At least annually, each *covered individual* (and/or his/her spouse and dependent children) must complete a *Disclosure of Significant Financial Interests* under the provisions of this policy or sanctions may be imposed. In the event of changes, the covered individual (and/or

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his/her spouse and dependent children) must complete a Disclosure of Significant Financial Interest within 30 days after any significant change in the individual’s (and/or his/her spouse and dependent children) *significant financial interests*; or to reflect the emergence of other circumstances that might cause research the individual is conducting to be affected by significant financial interests.

Subcontractors or Subgrantees: University of Louisville subcontractors or subgrantees, funded from contract or grant awards to the University of Louisville, must provide appropriate assurances that they are in compliance with University of Louisville policies relating to financial conflicts of interest in research or that they have the equivalent of these policies and procedures in place, before funds are released.

Administrative Offices: The Office of the Executive Vice President for Research shall be responsible for administering all University conflicts of interest in research policies, including this policy. The designee of the Executive Vice President for Research shall be responsible for notifying the Human Studies Committees and the responsible institutional official(s) whenever a financially interested covered individual proposes to conduct research with human subjects. In addition the designee, in consultation with the chair of the Committee for Review of Individual Financial Interests in Research (CRIFIR), shall provide professional level staff review under this policy of each Disclosure Certification and Statement of Significant Financial Interests submitted to the University by covered individuals in respect to significant financial interests and potential financial conflicts of interest in research, make appropriate recommendations concerning the development of management plans for the elimination, reduction, or management of any potential financial conflict of interest in research, provide staff support for the CRIFIR, referring any issues or specific matters for its review and recommendations, and act on behalf of the CRIFIR or pursuant to any of its recommendations.

Committee for Review of Individual Financial Interests in Research

Membership: The Committee for Review of Individual Financial Interests in Research (CRIFIR) is a standing Committee of the University, consisting of 15 members appointed for three-year terms, renewable, by the Executive Vice President for Research. No more than one third of membership may be considered for renewal/replacement each year. The membership of the CRIFIR includes, but is not limited to the Chair of the CRIFIR, designated by the Executive Vice President for Research; individuals broadly representative of the membership of the research community at the University, including those who conduct human subjects research and other faculty and University staff members familiar with ethical, legal, and regulatory issues involved in the oversight of financial conflicts of interest in research. The CRIFIR reports to the Executive Vice President for Research or designee.

Responsibilities: The CRIFIR is charged with reviewing and/or making recommendations concerning appropriate measures for the reduction or elimination or management (including *management plans*) of any potential *financial conflict of interest* relating to research. With specific respect to *human subjects research*, the CRIFIR will determine if an individual with a significant financial interest has overcome the *rebuttable presumption against financial interests in human subjects research* and establish the conditions under which the human studies research may proceed with their involvement. In such cases that an institutional conflict of interest exists, or appears to exist, the CRIFIR is charged with referring any issues to the Oversight Committee for the Management of Institutional Financial Interests in Research (OCMIFIR).

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VIOLATIONS OF THIS POLICY

A violation of this policy may be the basis for discipline of any individual committing it. Violations of this policy include, but are not limited to, failure to file; intentionally filing an incomplete, erroneous, or misleading disclosure form; failure to provide additional information as requested by the reviewing or approving authority and intentionally tardy responses or a pattern of non-cooperation in responding to requests for additional information by the reviewing or approving authority. If sanctions are necessary, they will be imposed in accordance with University policies and procedures and may include, but are not limited to:

- a) Letter of reprimand or admonition;
- b) Suspension of the processing of any grant applications made by the individual, or a declaration of ineligibility of the individual for future such applications;
- c) Suspension of research contract negotiations involving the individual as investigator, or a declaration of ineligibility of the individual for future research contracts;
- d) Suspension or ineligibility of the individual for Institutional Review Board (IRB) approval or for supervision of graduate students;
- e) Removal as principal or co-principal investigator in respect to any current research activity;
- f) Suspension;
- g) Non-renewal of appointment;
- h) Dismissal.

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II. PROCEDURE FOR OVERSIGHT OF INDIVIDUAL FINANCIAL INTERESTS IN RESEARCH

Individuals, involved in research for which the University of Louisville is responsible, have an obligation to disclose potential financial conflicts to the Committee for Review of Individual Financial Interests in Research (CRIFIR) as described in the Policy for Oversight of Individual Financial Interests in Research.

The Research Integrity Specialist, Office of the Executive Vice President for Research, will provide staff support to the CRIFIR. Those individuals required by the policy to notify the CRIFIR of potential individual financial interests should do so through the Disclosure Certifications and Statements of Significant Financial Interests.

The Research Integrity Specialist has the following procedural obligations:

- 1) To work with the person making the notification to assure that the description of individual financial interest is sufficient for the Chair of the Committee, the Executive 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 CRIFIR and the Oversight Committee for the Management of Institutional Financial Interests in Research (OCMIFIR) to ensure that appropriate review takes place
- 3) To maintain an up to date list of covered individuals, current and proposed research and current disclosures.
- 4) To assist the CRIFIR in developing standard operating procedures.

If a full review is necessary, the CRIFIR will carry out a fact-driven inquiry. University employees will provide the CRIFIR with information and expertise necessary to support the review. The covered individual must provide the CRIFIR with a clear explanation of all significant financial interests so that an appropriate management plan may be adopted. Within 60 days of obtaining all necessary information, the Committee will recommend the appropriate management conditions, if necessary. Recommendations will be forwarded to the Executive Vice President for Research for a final determination. Approved management conditions will be communicated to the covered individual and their respective department chair and dean. The Research Integrity Specialist will maintain a complete archive of the final approved management plan, including any subsequent revisions.

Appeals Process Any Covered Individual shall have the right to appeal any final decision under this Policy and Procedures involving that individual to the Appeals Committee. The Appeals Committee is authorized to hear, mediate, and advise with respect to the adjustment of appeals arising under this Policy and Procedures. The power of the Appeals Committee is solely to hear representations by the persons directly involved in the decision under appeal, to mediate voluntary adjustment by the parties, and to advise adjustment by the administration when appropriate. Advice for adjustment in favor of the appellant may be given to the Provost only after the administrator making the decision being appealed has been given similar advice and has not acted upon it within 60 days. Advice for adjustment given to the Provost will not be binding, but if the Provost should not accept such advice, he or she will provide a written rationale to the Appellant and Appeals Committee within 15 days as to why the advice was not accepted. The Appeals Committee may act as a whole or, by designation of the Chair, in panels of

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two or more for the consideration of particular appeals. It may promulgate rules of procedure for its operations subject to approval by the Provost. In the event the Provost has a conflict of interest related to the appeal, the final decision on the appeal will be ceded to the President, or designee.

The appropriate dean or designee is responsible for assuring that the conflict is managed as recommended by the Executive Vice President for Research and will report at least annually to the CRIFIR on the operation of each management process.

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DEFINITIONS FOR OVERSIGHT OF INDIVIDUAL FINANCIAL INTERESTS IN RESEARCH

(1) **“Compelling circumstances in human subjects research”** are those facts that convince the University, through the Committee for Review of Individual Financial Interests in Research (CRIFIR) and its responsible institutional official, that an individual with financial or other interests that might affect or compromise, or appear to affect or compromise, the design, conduct, reporting, or management of human subjects research, should nonetheless be permitted to conduct the research. A covered individual in a written “Request to Show Compelling Circumstances” must present such facts to the CRIFIR for its consideration. The process of showing such circumstances is called rebutting the presumption against financial interests in human subjects research. When considering a “Request to Show Compelling Circumstances” by an interested covered individual, the circumstances that the CRIFIR and the responsible institutional official should consider include the nature of the research, the magnitude and nature of the interest and the degree to which it is related to the research, the extent to which the interest could be directly and significantly affected by the research, the risk (measured in terms of its nature, probability, severity, duration, and frequency) to the human subjects involved that is inherent in the research protocol, and, where future royalty interests might be involved, the anticipated time interval between the research activity and marketing approval of the investigational product. The designated official and the CRIFIR should also consider the extent to which the interest is amenable to effective oversight and management.

(2) **“Conflict of interest”** refers to a divergence between an individual’s personal financial, relational, or other interests and his/her professional obligations to the University of Louisville – whether through teaching, involvement in research, contracting, purchasing, or performing other administrative duties -- such that an independent observer might reasonably determine that the individual’s professional actions or decisions are, or potentially could be adversely affected, distorted or otherwise compromised by the individual’s personal interest. The term conflict of interest is broader and encompasses more professional activities than the term financial conflict of interest in research, defined below, which is the subject of this policy

(3) **“Committee for Review of Individual Financial Interests in Research” (CRIFIR)** refers to the standing Committee that reviews the Disclosure of Significant Financial Interests, and other documentation and information, of a covered individual, for the purpose of recommending whether a financial conflict of interest in research exists with respect to the individual’s financial interests. The Committee consists of 15 members appointed for three-year terms, renewable, by the Executive Vice President for Research.

(4) **“Covered individual”** includes any faculty member (whether fully-, partially-, or non-salaried), staff member, student, fellow, trainee, administrator or other employee who, under the aegis of the University, is involved in research, or pursuant to the review and approval of the University’s Institutional Review Board (IRB), conducts research involving human subjects, or is otherwise identified as involved in research by a principal investigator, chair or unit head, or other University administrative officer responsible for research activities.

(5) **“Entity”** means any public or private organization, corporation, partnership, proprietorship, or firm, regardless of whether organized for profit or as a non-profit entity. The term does not include the

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University of Louisville, the University of Louisville Research Foundation or the University of Louisville Foundation.

(6) **“Fiduciary interest”** refers to the interest of a covered individual that derives from a legal and/or ethical role the individual has to act in the best interests (e.g. the financial success) of another. Examples of fiduciary interests include, but are not limited to membership on a board of directors, a management role in a company or partnership.

(7) **“Financial conflict of interest in research”** is the existence of a significant financial interest that an independent observer might reasonably determine affects or compromises, or appears to affect or compromise, the design, conduct, reporting or management of research.

(8) **“Financially interested entity”** means a commercial or non-profit entity with financial interests that to an independent observer would reasonably be affected, or appear individual to be affected, by the design, conduct, reporting or management of research in which the covered is involved. The term includes entities that compete with the sponsor of the research or the manufacturer of the investigational product, if the covered individual actually knows, or could reasonably be expected to know, that the financial interests of such an entity would reasonably appear to be affected by the research. The term also includes any entity acting as the agent of a financially interested company (e.g., a contract research organization).

(9) **“Financially interested individual”** means a covered individual who holds a significant financial interest that to an independent observer could reasonably appear to be affected by the individual’s research.

(10) **“Human subjects research”** includes all research meeting the definition of “research” involving a “human subject” as these terms are defined or used in the federal Common Rule 45 C.F.R. Section 46.102(d) and (f) and 21 C.F.R. Part 56, regardless of the source of research funding or whether the research is otherwise subject to federal regulation, and includes but is not limited to clinical trials.

(11) **“Immediate Family Member”** means any individual having a relationship to a person (whether by blood, law or marriage) as spouse, parent, child, grandparent, grandchild, stepchild, or sibling.

(12) **“Investigator”** means an individual responsible for the design, conduct, reporting or management of research, and includes, but is not limited to, a principal investigator and a co-principal investigator.

(13) **“Involved in research”** means having responsibilities that include the design, conduct, reporting or management of research, that include enrolling research subjects (including obtaining subject’s informed consent) or making decisions related to eligibility to participate in research, or that include direct and significant access to research data with control over its collection, analysis, or reporting (including submission for publication).

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(14) **“Management Plan”** means a written plan for the management, reduction or elimination of a known or likely financial conflict of interest relating to research. It relies upon, and is therefore limited by, good faith disclosures about significant financial interests made in the financial disclosure statement, as well as other information provided, by the covered individual to the University. In general, the management plan shall contain provisions appropriate for the purposes intended (e.g. management, reduction or elimination of the research-related financial conflict), for the identity, nature and amount of the financial conflict, and for the other circumstances in question. These provisions may include one or more of the following requirements:

- disclosure of significant financial interests -- in writing or verbally as appropriate to the public, to human subjects, to sponsors, to IRBs, to researchers and other participants, to publishers, and to conference organizers and attendees;
- monitoring and/or auditing the conduct of the research activity by independent, qualified overseers or reviewers or panel thereof (e.g. a data safety monitoring board), who have no professional ties to the research or direct reporting relationships to the researchers, and who are empowered to obtain whatever information they need from the researchers in order to conduct their oversight activities;
- safeguarding data or the placement of copies of research data in custody of impartial party;
- modification of the research plan, methodology, or conduct;
- disqualification from participation or restrictions on a researcher’s role in all or a portion of the research (e.g. data analysis);
- divestiture or restructuring of the significant financial interest;
- placement of the significant financial interest in a blind trust;
- modification of the significant financial interest or severance of relationships that create actual or perceived potential conflicts of financial interest;
- oversight of covered individual’s research activities and significant financial interests creating the possible conflict, and the management plan, by disinterested individuals or committees;
- change in terms and conditions of agreement relating to the research;
- requiring specific compliance with other University policies, such as those relating to adoption of educational materials, conflict of commitment, outside employment or consulting, use of human subjects in research;
- prohibiting or restricting involvement of covered individual in recruitment of human subjects and/or in the informed consent process;

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- requiring that a patient or human subject representative or ombudsperson be present during recruitment and/or the informed consent process;
- requiring that the significant financial interest be held in escrow until the investigational product has been approved and on the market for a specified time period;
- requiring additional disclosures or actions with respect to the significant financial interest to an IRB for its consideration and possible disclosure to human subjects as part of informed consent;
- requiring non-participation in any business transactions between the University and parties to sponsored research agreements; and
- in the case of human subjects research conducted by a covered individual with significant financial interests and justified by compelling circumstances, rigorous, effective, and disinterested monitoring undertaken by individuals with no financial or professional ties to the research or direct reporting relationships to the researchers, which might include the following monitoring mechanisms:
 - regular audits of the informed consent and enrollment process;
 - the involvement of a patient representative or ombudsman when subjects are recruited and informed consent is obtained;
 - a requirement to escrow the financial interest until the investigational product has been approved and on the market for a specified time period; and
 - the use of data and safety monitoring boards.

(15) “Oversight Committee for the Management of Institutional Financial Interests in Research”(OCMIFIR) refers to the standing Committee that reviews documentation and information for the purpose of recommending whether a financial conflict of interest in research exists with respect to the institution’s or an institutional official’s financial interests. The Committee consists of 6 members appointed for three-year terms, renewable, by the Executive Vice President for Research.

(16) “Rebuttable presumption against financial interests in human subjects research” is a presumption that a financially interested individual may not be involved in research that uses human subjects. This rule is not intended to be absolute: a financially interested individual may rebut the presumption by demonstrating facts that, in the opinion of the reviewing bodies (including an IRB, the CRIFIR and the OCMIFIR) and administrative officers, constitute compelling circumstances. If compelling circumstances were found, the individual would then be allowed to design, conduct, report and or manage the research under conditions specified in an approved management plan and any other conditions specified by the reviewing bodies and administrative offices, in accordance with regulatory and ethical requirements.

(17) “Research” means a systematic investigation designed to develop or contribute to knowledge, and includes both sponsored research and non-sponsored research, that involves use of University personnel, patients, students, facilities, or resources, or the expenditure of University funds. The term

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includes clinical and health-related research, and behavioral and social science research, and encompasses basic and applied research and product development.

(18) **“Responsible institutional official”** or “designated official” for purposes of any reporting requirements or final decision-making required by or pursuant to this policy shall mean the Executive Vice President for Research or designee.

(19) **“Significant financial interest”** means anything of economic or monetary value that to an independent observer would be or reasonably appear to be affected by research, with inclusions and exclusions as set forth below:

(1) **Inclusions.** Significant financial interest includes, but is not limited to, any economic or monetary interest of the following types or categories that is held either i) by a covered individual (or his or her spouse or dependent children), or ii) by any entity in which a covered individual (or his or her spouse or dependent children) has a financial or fiduciary interest:

(a) **“Compensation interest,”** meaning non-university salary, consulting fees, wages, retainers, honoraria (including honoraria from a third party, if the original source is a financially interested company), gifts, “in kind” compensation from a financially interested company (or entitlement to the same), or any other thing of economic or monetary value whether for consulting, lecturing, travel, service on an advisory board, or for any other purpose not directly related to the reasonable costs of conducting the research (as specified in the research agreement), that in the aggregate have in the past 12 months exceeded \$10,000, or are expected to exceed that amount in the next 12 months;

(b) **“Equity interest,”** meaning i) any equity interest (or entitlement to the same), in a publicly-traded financially interested entity that exceeds \$10,000 in value or represents more than 5% ownership interest in any single entity (see exclusions below), or ii) equity interests, including stock options, warrants, or other convertible securities, of any amount in a non-publicly-traded financially interested entity (or entitlement to the same);

(c) **“Intellectual property interest”** meaning i) royalty income or the right to receive future royalties under a patent license or copyright, where the research is directly related to the licensed technology or work; or ii) any other direct or indirect interest in a patent, trademark, copyright, trade secret, know-how or other intellectual property right where the research is directly related to the interest;

(d) **“Extraneous research payments,”** meaning any non-royalty payments or entitlements to payments in connection with the research that are not directly related to the reasonable costs of the research (as specified in the research agreement between the sponsor and the institution), including any bonus or milestone payments to the investigators in excess of reasonable costs incurred, whether such payments are received from a financially interested *entity* or from the institution;

(e) **“Fiduciary relationship,”** meaning service as an officer, director, or in any other fiduciary role for a financially interested entity, regardless of whether remuneration is received for such service.

(2) **Exclusions.** Significant financial interest excludes, and therefore is not meant to refer to, the following types or categories of economic or monetary interest:

(a) **“Mutual fund interests,”** meaning interests of any amount in publicly traded, diversified mutual funds;

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(b) “*De minimis equity interests*,” meaning stock or stock options in a publicly traded company that, when aggregated for the covered individual (and/or his or her spouse or dependent children) meets both the following tests: it does not exceed \$10,000 in value (as measured in reference to public prices or other reasonable measure of fair market value) and does not represent more than a 5% ownership interest in any single entity;

(c) “*Outside payments*,” meaning salary, royalties, and other payments from entities other than the University, or via the University to the individual, that when aggregated for the covered individual (and/or his or her spouse or dependent children), over the next 12 months, are not expected to exceed \$10,000;

(d) “*Regular research payments*,” meaning payments to the University, or via the University to the individual, that are directly related to reasonable costs incurred in the conduct of research as specified in the research agreement between the sponsor and the University;

(e) “*University compensation*,” meaning salary, royalties, and other remuneration for services from the University;

(f) “*Public or non-profit income*,” meaning income for service on advisory committees or review panels for public or non-profit entities, or from seminars, lectures, or teaching engagements sponsored by public or non-profit entities.

(20) “***Sponsored research***” means research funded or otherwise supported by anything of economic or monetary value, in whole or in part, by an entity.

(21) “***Sponsored research agreement***” means a contract or formal agreement between an outside sponsor and the University of Louisville or one of its affiliated entities (e.g. the University of Louisville Research Foundation).

(22) “***Disclosure of Significant Financial Interests***” means a written statement made, signed, and attested to by a covered individual that discloses all significant financial interests (and those of his/her spouse and dependent children) that to an independent observer would reasonably appear to be affected by research in which the individual is involved or that exist in entities whose financial interests to an independent observer would reasonably appear to be affected by the research (e.g. stock values, etc). The Statement of Significant Financial Interests must identify and describe, and state the nature and amount, of the significant financial interest. The Disclosure of Significant Financial Interests must be made at least annually, and must be brought current at the time of a grant application, or at the time of negotiation of a sponsored research agreement, or to disclose a significant change in a covered individual’s (and those of his/her spouse or dependent children) financial interests. The Statement of Significant Financial Interests is treated as confidential by the University and is considered part of the personnel file of the covered individual.

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