I. PURPOSE / BACKGROUND

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.

II. SCOPE OF THIS POLICY

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.

III. POLICY

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.

IV. PROCEDURES

This procedure governs conflicts of interest and applies to situations involving the institution and institutional officials. The Institution and Institutional Officials at the University of Louisville must also comply with Board of Trustees Policy: Institutional Conflict of Interest and all applicable federal and state laws related to conflict of interest.

Due to their supervisory and institutional decision-making functions, these individuals frequently encounter conflict of interest situations beyond those faced by most Covered Individuals. They often do not directly conduct Sponsored Projects, teach or conduct outreach in their administrative capacities but may be in a position to influence how these activities are conducted and reported. Their external interests and activities must be disclosed to prevent any real or perceived institutional conflicts of interest.

V. DISCLOSURE REQUIREMENTS

An Attestation and Disclosure Form (ADF) must be completed by all Institutional Officials on an annual basis and within 30 calendar days of a change in their external interests and activities. The reporting period for the ADF includes the previous 12 months and the coming 12 months. As Covered Individuals, Institutional Officials are additionally required to comply with the disclosure requirements outlined in ***Addressing Potential Individual Conflict of Interest Policy and Procedures***.

A. EQUITY RELATIONSHIPS, SPONSORED PROJECTS AND TECHNOLOGY TRANSFER

1. For conflicts of interest that could arise when the University already holds equity in a company, the University generally avoids risks associated with this type of institutional conflict by separating equity information and decision-making from the research enterprise. Once an equity agreement is signed, decisions regarding the equity and voting are made by the Vice President for Business Affairs. Institutional Officials in the position to directly influence Sponsored Projects, teaching, outreach, or other activities do not make decisions regarding these equity interests. Institutional Officials maintaining an equity relationship with a project sponsor must be recused from any University decisions related to their normal institutional role that would be delegated to their supervisor, or the next highest person in the reporting line who does not maintain a relationship with the external entity. These decisions include: facilities use decisions, salary and promotion, adjustment of Facilities & Administrative rate, etc.
2. The University of Louisville Research Foundation, Inc. (ULRF) must disclose and will segregate decision-making about financial and project 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 Business Affairs. The Vice President for Business Affairs will have authority over the disposition of the equity position (other than through mutual funds), stock option or entitlement to ownership unless the Conflict Review Board (CRB) determines whether other steps, including the placement of assets in a blind trust, are necessary.
3. The Office of Technology Transfer (OTT) will inform the CRB of potential projects involving sponsored projects that might benefit University of Louisville financial interests. OTT will also provide records of the corporate entities and their financial relationship to institutional officials or to the University of Louisville to the Conflict of Interest Office, on a quarterly basis. Quarterly, OTT will generate a list of companies in which the University has an equity interest and which units and Institutional Officials benefit from this revenue. In addition, OTT will generate a list of companies that paid more than $50,000 the prior year to the University and will report the units and faculty that receive a share of the revenue. OTT will forward these

lists to the Conflict of Interest Office which will compare that list against a database of project sponsors in those units. If the company is on both lists, the Conflict of Interest Office will gather information about the project and forward the matter to the CRB to develop a management plan. OTT will contact the Conflict of Interest Office when preparing an exclusive license or option agreement. The Conflict of Interest Office will check information about project sponsors, vendors and gift donors to determine whether the potential licensee or startup company also has other types of financial or business relationships with the University. The Conflict of Interest Office will then inform OTT staff if execution of the license or option should be delayed pending review and management of any potential institutional conflict of interest.

4. The Office of Industry Contracts (OIC) will inform the CRB of potential projects sponsored by industry that might benefit University of Louisville financial interests. OIC will also provide records of the corporate entities and their financial relationship to institutional officials or to the University of Louisville to the Conflict of Interest Office, on a quarterly basis.
5. The Sponsored Programs Grants Administration (SPGA) will inform the CRB of potential projects sponsored by non-profit, non-governmental agencies that might benefit University of Louisville financial interests.
6. For a project that is supported internally, and is not conducted under the cognizance of the OTT, SPGA and/or OIC, the Dean, Director, or Department Head is responsible for notifying the CRB, prior to the initiation of the project, of potential financial benefits to Institutional Officials or to the University of Louisville. If a potential institutional conflict is disclosed during the execution of the project, the Dean, Director, or Department Head is responsible for notifying the CRB, as soon as the matter is brought to their attention.
7. The University of Louisville Institutional Review Board (IRB) will require faculty to disclose potential institutional 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, and entitlement to ownership interest in a company or receipt of royalties from a company ("financial relationship with the university") that could benefit from sponsored projects carried out at the University. The IRB will notify the chair of the Conflict Review Board that an inquiry is required if the university could realize a financial gain (other than funding to cover the costs of the project) because of an external relationship between the University or an Institutional Official and a for-profit entity. If the CRB determines that the study can be conducted at the University, the U of L IRB or another IRB that is independent of the university will conduct human subject research review. The independent board 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 independent board before commencing the work and throughout the study. The investigators will provide copies of all documentation sent to and received from the independent boards to the individuals responsible for the management of the conflict.

B. EXTERNAL BOARD RELATIONSHIPS

It is anticipated that Institutional Officials of the University will be asked to serve on particular outside boards because of their University related areas of expertise or the offices or positions

they hold. External board service is generally deemed to be in the best interest of U of L because it broadens the experience of the Institutional Officials involved and exposes U of L to a larger audience of business, civic, professional, and social leaders. However, the participation in the external board may not create an unmanageable conflict of interest and may not impose an unreasonable time requirement. An Institutional Official may not use his/her role on the board, in conjunction with his/her Institutional role to influence business, academic, clinical, and / or research practices at the University of Louisville.

1. Before accepting a position on an external board, the Institutional Official wishing to accept the position shall first advise the Conflict of Interest Office to evaluate any potential conflict of interest and then shall obtain the approval of the Appropriate Authority. The Appropriate Authority may not unreasonably withhold approval.
2. In addition to any required reporting on the ADF, Institutional Officials serving on external boards will file a report with the Conflict of Interest Office annually that includes the following information:
   a) The number of hours normally required by the service, either monthly, quarterly or annually; and
   b) Amount of compensation.
3. If the Institutional Official joins additional boards after submitting the annual report, an updated ADF must be filed within 30 calendar days.
4. This disclosure requirement does not apply to service on the board of a municipality; local religious congregation; neighborhood association; public or private school; youth sports or recreation league; affinity group such as the local orchid society or model train collectors club; and other similar external boards the service on which is primarily personal rather than professional in nature and does not require significant time away from University responsibilities.

C. GIFTS AND INVESTMENTS

1. On a quarterly basis, the University of Louisville Foundation, Inc. (ULF) will be requested to provide a listing to the Conflict of Interest Office of all individuals and entities giving donations in the following categories:
   a) In excess of $100,000 in the prior year or a pledge to donate in excess of $100,000 in the current year, or
   b) Any gift, regardless of amount, with stipulations regarding a category of sponsored project or university activity, or in support or recognition of a specific Covered Individual.

   The Conflict of Interest Office will compare that list against a database of research sponsors and vendors. If the individual or entity is on both lists, the Conflict of Interest Office will gather information about the project/activity and forward the matter to the Conflict Review Board (CRB) for review.
2. The University manages potential conflicts of interest related to investments by segregating the decision-making for investment transactions from the decision-making for University research, teaching and outreach activities. An independent financial investment firm engaged

by the University manages the University's endowment and investment portfolios and determines when to buy and sell stock and other holdings on behalf of the University.

D. INFLUENCES ON THE ACADEMIC MISSION

Institutional Officials must not use their institutional capacity to exert improper influence on, directly or indirectly, the academic progression of students. Such prohibited actions may include: serving as the thesis / dissertation advisor or committee member or instructor of an immediate family member; allowing the receipt of degree without prior completion of requirements; allowing admittance of an unqualified student into the institution or degree program; exerting pressure on faculty to modify student(s) grade; requiring use of specific instructional material or vendor in which the Institutional Official has an external interest.

E. PURCHASES

1. Buyers and staff in the Department of Purchasing may identify potential institutional conflicts when they participate in or review purchasing decisions. Any potential conflicts identified should be forwarded to the Director of Procurement and Contract Management. Other individuals concerned about possible institutional conflicts of interest in purchasing may report situations to the Director of Procurement and Contract Management. The Director of Procurement and Contract Management conducts a written assessment of the potential conflict. The written assessment is forwarded to the CRB for review. If the conflict cannot be adequately addressed and managed, the purchase will not be approved.

2. When an Institutional Official maintains a relationship with a vendor that provides instructional materials for University coursework, the Institutional Official in the position to directly influence teaching, outreach or other activities must not make final decisions regarding adoption of the instructional materials for the affected courses.

VI. REVIEW OF ADFS AND DETERMINATION OF MANAGEMENT PLAN

The COI Office will perform initial review of submitted ADFs and refer appropriate cases to the CRB for review and management determination. The convened CRB will review each case brought before the body and make an institutional determination as to whether the disclosed interests create a conflict of interest. In making that determination, the CRB will consider the following issues: the size and nature of the external interest, when the relationship commenced, whether the conditions of the relationship have changed during the past year, the likelihood of actual conflict (will the results of the activity likely be biased or compromised by the external interest), how closely the University activity is related to the external interest, mechanisms to ensure integrity (peer review, other independent research sites, and independent monitors or controls), the importance of the proposed activity, the participation of human subjects, the availability of alternatives to avoid the conflict or apparent conflict and any other relevant information. The CRB will consult appropriate individuals, including the Institutional Official, as needed, to ensure a complete understanding of the relationship and its potential impact on university activities. Based upon this review, the CRB will issue a recommended management plan, which will be forwarded to the Institutional Compliance Officer for review and approval.

Research activities involving the participation of humans are reviewed with extra scrutiny because of the potential to compromise the welfare of human subjects. Normally, researchers are not permitted to conduct human subject research at the University when they hold relevant external interest related to the research. However, Institutional Officials may submit a rebuttable presumption statement to the CRB and present the circumstances they believe would justify a departure from this general principle. Following the additional review, the CRB will forward their recommendation to mitigate the identified conflict to the COI Officer. The mitigation can involve acceptable or denial of the rebuttable presumption. The Conflict of Interest Officer will review the CRB recommendation and formally approve the recommendation, modify the recommendation or reject the recommendation and approve an alternate management plan.

The COI Office forwards any approved conflict management plans involving human subjects' research to the Institutional Review Board (IRB). Even if the CRB has approved a management plan, the IRB has final authority to determine whether the plan adequately protects research subjects and whether the research may proceed.

A. IMPLEMENTATION OF APPROVED MANAGEMENT PLAN

Once a management plan is approved, the Conflict of Interest Office will send the approved plan to the Appropriate Authority for implementation. The approved management plan will include a timeline for implementation and any additional management requirements to address the identified conflict of interest. Unless a reconsideration request is filed (discussed in next section), all elements of the approved management plan must be put into practice and verified back to the Conflict of Interest Office on or before the established implementation date. If a reconsideration request has been filed, the Appropriate Authority should implement all elements not involved in the reconsideration.

B. REQUESTING A RECONSIDERATION OF APPROVED MANAGEMENT PLAN

Any Institutional Official shall have the right to request reconsideration of any final decision under this Procedure involving that individual. A Request for Reconsideration must be submitted in writing to the Institutional Compliance Officer within ten (10) working days. The Request should include, at a minimum, the management clause(s) needing reconsideration, an explanation of why the approved management will not work, and a proposed revision to the approved management clause(s). The Conflict of Interest Office will present the Request for Reconsideration at the next convened meeting of the CRB. The convened CRB will review the Request and determine whether it has sufficient information to make a decision. If adequate detail is provided, the CRB will determine whether the original approved clause(s) will stand or if a modification is approved; otherwise, additional detail will be sought from the Institutional Official. If a modification is approved, the CRB can accept the resolution proposed by the Institutional Official, or adopt an alternate resolution. Regardless of the chosen resolution, the CRB will provide the Institutional Official with a written determination, including a justification for the chosen resolution, within fifteen (15) business days of the convened meeting. The reconsideration resolution is considered final and must be implemented. Requests submitted that impact the design, proposing, conduct, perform or analysis of research may require a hold (including expenditures) to be placed upon the

specific project in question until the management issue is resolved. If such a hold is required, the Conflict of Interest Office will communicate the need for a hold to OTT, OIC and / or SPGA.

C. ADDRESSING CONFLICTS IN THE REVIEW/OVERSIGHT PROCESS

To avoid real or perceived conflicts of interest by participants in the conflict review and oversight process, the following recusal procedures will apply:

1. At meetings of the CRB, individual members will disclose any relationships or conflicts they may have related to the case under review and recuse themselves from discussion and voting on the case.
2. The Institutional Compliance Officer will recuse him/herself from review and oversight of all potential conflicts of interest involving staff from the Conflict of Interest Office, including the Institutional Compliance Officer.

VII. COMPLIANCE WITH THESE PROCEDURES

Institutional Officials are responsible for knowing, understanding, and complying with this procedure as it relates to their role, position or employment, or enrollment at the Institution. Breaches of this procedure include, but are not limited to, intentionally filing an incomplete, erroneous, or misleading ADF; failing to provide additional information as required by the approving authority; or failing to follow an approved plan for managing, reducing or eliminating a potential conflict. A violation of this procedure may result in sanctions, corrective measures and appropriate disciplinary actions, up to and including termination as determined by existing University policies.

VIII. ASSOCIATED FORM

Attestation and Disclosure Form (link to be added)

IX. ASSOCIATED POLICY AND PROCEDURES

Addressing Potential Individual Conflict of Interest Policy and Procedures
The Redbook
PER 5.01 Staff Disciplinary Policy
Policy and Procedures for Responding to Violations of University of Louisville Research Policies

X. 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.

XI. GOVERNING POLICY

Institutional Conflict of Interest Policy (Board of Trustees Approved)

XII. 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 Office and other members of the University community. The CRB is chaired by the Institutional Compliance Officer. The CRB is comprised of at least eight voting seats: one community voting seat, three tenured faculty voting seats, a voting seat from the Office of the Vice President for Finance, a voting seat from the Office of the Executive Vice President for Research, a voting seat from Executive Vice President for Health Affairs, and a voting seat from Office of the Vice President for Business Affairs. In addition to the voting seats, representatives from Institutional Compliance, Technology Transfer and University Counsel will serve as ex-officio members. A qualified quorum is defined as attendance of five of the eight votes. For issues related to institutional conflicts of interest, the community vote must be in attendance at the convened meeting. The CRB can consult other institutional officials and offices.

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 U of L or using U of L researchers or other U of L facilities or resources. It also includes consultants, and individuals receiving a commission.

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. ***Individual Conflict of Interest.*** A situation that compromises an Institutional Official's professional judgment in carrying out University teaching, research, outreach, or public service activities because of an external relationship that directly or indirectly affects a business or financial interest of the Institutional Official, an immediate family member, or an associated entity.

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. ***Sponsored Project.*** Means research, training, and instructional projects involving funds, materials, other compensation, or anything else of value from outside sources under agreements that contain any of the following: the agreement binds the Institution or an affiliated institution to a line of scholarly or scientific inquiry specified to a substantial level of detail; a line-item budget is involved; financial reports are required; the award is subject to external audit; unexpended funds must be returned to the sponsor at the conclusion of the project; or the agreement provides for the disposition of either tangible or intangible properties that may result from the activity.