

ADDRESSING POTENTIAL INDIVIDUAL CONFLICT OF INTEREST POLICY AND PROCEDURES

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| Responsible Party: Compliance Oversight Council | Contact: Institutional Compliance Officer | Original Effective Date: Jan 2011 Last Revised Date: Jan 2015 Next Review Date: 2016 | Page 1 of 17 |
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1. PURPOSE / BACKGROUND

In pursuit of its mission as a public institution of higher education, the University of Louisville (Institution) 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. The success of the Institution depends upon the integrity of its members and the public’s confidence in it. Accomplishment of its missions inevitably leads to increasingly close relationships between the University of Louisville and those with external interests in the broader community. The benefits that potentially accrue from this proximity are accompanied by real or apparent risks that external interests might compromise Institution 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 individual conflicts of interest. These procedures are not intended to discourage research, creative activity and scholarship.

2. SCOPE

This policy governs individual conflict of interest and applies to covered individuals at the University of Louisville (Institution). This policy covers academic, business, clinical and research transactions and activities conducted under the auspices of and / or for the benefit of the University of Louisville.

3. POLICY

This policy governs conflicts of interest and applies to situations involving covered individuals. It is the policy of the University of Louisville to ensure its transactions are conducted with integrity. It is the policy of the University of Louisville to require disclosure of external interests from covered individuals in order to manage, reduce, and/or eliminate identified conflicts of interest. 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 actual or perceived objectivity of transactions conducted in the name of the University of Louisville. This policy enables covered individuals to comply with these requirements. In addition, the required reporting is designed to assist covered individuals in arranging external professional activities or relationships so as not to interfere with their primary duties to the Institution nor compromise the educational interests of Institution students with whom they work.

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5. DEFINITIONS

Appropriate Authority. Means the Covered Individual’s direct supervisor. In the case of the President, the Board of Trustees will serve as the Appropriate Authority.

Associated Organizations. Means University of Louisville Foundation, University of Louisville Research Foundation and University of Louisville Athletic Association.

Attestation and Disclosure Form (ADF). Means a Covered Individual’s (who are Faculty, Institutional Officials, or individuals conducting research under the auspices of the University of Louisville) annual attestation to the Standards of Conduct and disclosure of external interests to an Institution.

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.

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.

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

FCOI Report. Means an Institution’s report of a financial conflict of interest to a Public Health Service Awarding Component.

Financial Interest. Anything of monetary value including, but not limited to: an interest in a business consisting of any stock, 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 Covered Individual 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.

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Ghostwriting. Ghostwriting shall mean the provision of written material that is officially credited to someone other than the writer(s) of the material. Transparent writing collaboration with attribution between academic and industry investigators, medical writers, and/or technical experts is not ghostwriting. The unacknowledged, undisclosed provision of content should not be permitted under any circumstances.

Immediate Family Member. Immediate family member shall mean the Covered Individual'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 Covered Individual 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 Covered Individual and spouse and / or qualifying adult.

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

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.

Institutional Responsibilities. Means an Covered Individual's professional responsibilities on behalf of the Institution including, but not limited to, activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Interest. Means shall mean direct (ownership) or indirect (receipt by Covered Individual of direct financial) gain, benefit, monetary value, right, claim or share.

Instructional Materials include textbooks, software, laboratory equipment, etc.

Manage. Means to take action to address a conflict of interest, which includes reducing or eliminating the conflict of interest, to ensure that affected activity is free from bias or the appearance of bias.

Management Plan. Means a written plan for the management, reduction or elimination of a known or likely conflict of interest. It relies upon good faith disclosures about external interests and activities made in the ADF, 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

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or elimination of the conflict), for the identity, nature and any monetary amount of the conflict, and for the other circumstances in question.

Non-University Commitment. Non-University commitment shall mean outside consulting or other activity, paid or unpaid, that is beyond the work assignment of the individual's University employment responsibilities.

Non-University Consulting. Non-University consulting shall mean an outside commitment that is paid professional service intended to further the interests of an external entity, regardless of whether such services are provided as an employee of the external entity, an independent contractor, a business owner, or a director or manager.

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.

Personal Benefit. Include cash, profits, securities, gifts, performed work, sex, and other benefits.

Personal Gain. Utilize University Resources for personal commercial purposes or personal commercial financial benefit.

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 covered individual (as used in KRS 391.010), and, must be residing in the covered individual'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.

Remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship, travel reimbursement); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value

Research. Means a systematic investigation designed to develop or contribute to generalizable knowledge. The term encompasses basic and applied research, service and testing, and product development. The term includes any such activity for which research funding is available through a grant, cooperative agreement, or contract, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

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

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

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Term of Appointment. Means the duration of an individual's University employment, status as student or affiliation with the institution.

Vendor. Means businesses and individuals who provide goods and services to the University of Louisville. This term includes pharmaceutical company and medical equipment representatives, as well as equipment and service providers.

6. 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.

7. ASSOCIATED POLICY AND PROCEDURES

The Redbook

PER 5.01 Staff Disciplinary Policy

Policy and Procedures for Responding to Violations of University of Louisville Research Policies

8. CONFLICTS OF INTEREST CATEGORIES

8.1. GENERAL PROHIBITED ACTIVITIES

Covered Individuals conducting the affairs on behalf of the university, including hiring and procurement, must do so in a manner that is objective, ethical and with integrity. This includes individuals that use a ProCard for the purpose of procuring goods or services for the University of Louisville or one of its associated organizations.

Regarding external interests and activities, the following actions by Covered Individuals are prohibited (exemptions noted in 10.1.7.):

1. Using the University name, marks, or logos for advertising purposes without prior Institutional approval;
2. Using any University address or communication method (including email, telephone, fax) for personal gain;
3. Using the official stationery of the University for personal or non-University business;
4. Giving as a consulting business address any University building or department name when participating in non-University commitments without approved license;
5. Using University personnel, equipment, or services for personal gain;
6. Using position or role to determine or influence the hiring, promotion, reappointment, evaluation, responsibilities, salary and termination status for an immediate family member;
7. Using position or role to determine or influence the selection of a vendor, which you or your immediate family member have an Interest, to provide goods or services to the University;
8. Participation in non-University commitments that interfere with the performance of regular duties, or compete with coursework offered by the University or services offered by the University, including non-University consulting that exceeds, on average, one day per week during the term of your appointment or the terms of a professional practice plan not addressed in an approved work plan or work assignment;

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9. Engaging in non-University sanctioned, (i.e. without the express approval of the Vice-President for Advancement) philanthropic or fund-raising activity related to one's University duties; and
10. Expression of endorsement or speech, actions or representations on behalf of the University in relation to the external activity, when rendering service to or cooperating with an organization outside the University.

8.2 INTEREST IN A CONTRACT WITH THE UNIVERSITY

Covered Individuals who are University employees are not permitted to have an interest in a contract with the University for the sale of property, materials, supplies, equipment, or services, with the exception of compensation to the faculty, staff and students.

8.3. CLINICAL PROHIBITED ACTIVITIES

Covered Individuals involved in clinical activities at the University of Louisville must ensure that the clinical service provided to patients/clients as well as the educational environment provided for students are free from bias and influence of external interests and activities. It is the responsibility of the Units, Departments and Divisions conducting clinical activities to establish criteria and processes, as noted, within this section. All Covered Individuals who are members of occupations or professions having established standards of conduct shall, in addition to any obligations and responsibilities imposed by this policy, be bound by the standards of conduct applicable to such occupations or professions.

8.3.1. Gifts

Covered Individuals may not receive any form of gifts from vendors (whether cash or an item of any value) at U of L Health Care, the Schools of Dentistry, Medicine, Public Health and Nursing and all other clinical, administrative, educational, and research venues and activities on the Health Science Campus.

Covered Individuals may not receive any form of food, cash, or gifts from vendors (or their companies) in person, by phone, email, mail or any other means on U of L Health Care premises or at any U of L affiliated educational sites. Displays of products, cash incentive programs for prescribing, product pamphlets, pre-printed prescription pads with product names, and other materials are prohibited.

While Covered Individuals are personally prohibited from accepting any form of gifts, food, or products (of any type or value) from vendors or their companies, at U of L Health Care Kentuckiana locations, other forms of professional interaction, employment, and consulting do exist. Although this policy does not call for institutional policing of off-site activities (i.e., vendor gifting in person, or by phone, e-mail, mail or any other means at any time outside the U of L premises to faculty, staff, residents, fellows, and health care students), adherence to the principles outlined in this policy is not reserved for duty hours.

8.3.2. Travel

Travel funds may not be directly given to any U of L faculty, residents, or students, except in the cases of legitimate reimbursement or contractual services to those vendors. Travel funds for educational purposes must be otherwise handled using the accounts established as described above. It is recognized that members of the faculty may, in the course of their leadership roles in non-profit professional and scientific organizations, be expected to participate in programs, meetings, and events that involve vendor relationships. Vendor

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interaction with Covered Individuals in the course of representing legitimate professional organizations will be governed by the policies and procedures of the specific organization.

8.3.3. Marketing

Vendors may not be allowed to product or brand detail (i.e., in-person marketing visits by vendors), or market, at U of L Health Care, the Health Science Center clinics, and all other clinical, administrative, educational, and research venues and activities on the Health Science Campus. Detailing and marketing at hospitals and facilities outside of U of L HealthCare and the Health Sciences Campus will be governed by the policies and procedures of those respective institutions.

8.3.4. Vendors on premises

Covered Individuals may not allow vendors to enter the following clinical locations: patient care areas, operating rooms, delivery rooms, emergency rooms, professional student and resident lounges, and staff elevators except to provide in-service training or assistance on devices and equipment, for example, in the operating room. In such cases, there must be prior disclosure to and consent by the patient or surrogate (if the patient is incapacitated) whenever possible, i.e., if it is known ahead of time that a vendor will be involved. However, in such cases that crisis or emergency treatment with devices, equipment, etc. from a vendor is required during an operation or procedure in order to provide the best care for the patient, and if the patient is incapacitated and no surrogate is available, the requirement for consent will be waived.

8.4. RESEARCH AND SCHOLARLY PROHIBITED ACTIVITIES

Regarding external interests and activities and the design, conduct, reporting of research or scholarly activity, the following actions by Covered Individuals are prohibited:

1. Using nonpublic research information to buy or sell stock;
2. Disclosing nonpublic research information to investment companies or other third parties for personal gain. **Note:** Individuals who have access to preliminary nonpublic research results related to clinical trials or other research with potential commercial value may be considered insiders for purposes of federal insider trading laws if the research is sponsored by companies with publicly traded stock.
3. Engaging in 'ghostwriting'.

9. GUIDELINES**9.1. GENERAL****9.1.1. Gifts**

In the course of conducting University business, Covered Individuals may encounter offers of gifts and benefits from vendors. The following guidelines apply:

1. Offers of gifts should be refused.
2. Cash or other monetary equivalents of any kind or amount may never be accepted.
3. The value of any single promotional benefit accepted should not exceed \$25.00. These benefits include: pens, note pads or other items with corporate imprints. However, these items can never be accepted in return for a business favor.
4. Covered Individuals, directly or indirectly, involved in a proposal review may not receive gifts, entertainment, meals, travel, lodging or any other favor during the review process or thereafter.
5. If a Covered Individual is offered anything from a vendor and is uncertain about accepting the offer, the Covered Individual should politely refuse the offer. The Covered Individual's direct supervisor

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should be notified of any such offer. If the offer is received during a bidding cycle or contract period, the Director of Contract Administration and Procurement Services should be notified immediately. This notification is imperative to ensure other evaluating University members can be notified of possible vendor interference, which could lead to sanctions against the vendor including disqualification from the current purchasing process.

9.1.2. Meals

In conducting University business, a Covered Individual may, from time to time, find it appropriate to do so in conjunction with meal times. Covered Individuals should not regularly plan business meetings around meal times; however, it may be appropriate at times for Covered Individuals to accept meals from vendors. The following guidelines should be followed:

1. Covered Individuals should not regularly plan business meetings around meal times.
2. University business must be conducted at the meal.
3. Covered Individual's business judgments and decisions will not be influenced by the meal or the expense involved in the meal, which should not exceed GSA Domestic Per Diem Rates.
4. Covered Individuals should never participate in business meals with an interested vendor while in the process of making a purchasing decision through a RFP/B, Purchase Order, ProCard or any other University payment method.
5. Covered Individuals, who are authorized, should occasionally pay for meals, at the University's expense.
6. Covered Individual's direct supervisor should review any offer for a vendor provided business meal.

9.1.3. Sole Source

It may be necessary to purchase from a Covered Individual if the product or service is not available from any other source and is needed for the benefit of the University. If this is the case, prior to engaging for goods and services, the purchase should first be reviewed and approved by the Director of Contract Administration and Procurement Services or Office of the Controller, based upon approved criteria. Payment for these situations should be made using an Extra Payment form for an amount not to exceed the invoiced amount. Grossing up an invoice for services provided to the University to cover payroll taxes is not permitted.

9.2. CLINICAL SPECIFIC TO HEALTH SCIENCES CAMPUS

9.2.1 Vendor appointments/meetings

Covered Individuals may meet by appointment with vendors, as described in the established guidelines of the appropriate Division or Department. These scheduled meetings can be used for updates on new products, education regarding existing products, discussions of support for unrestricted education grants, and supply of pharmaceutical samples, competitive selection by clinical committees for new products, services, or devices, and in-service training for products to Covered Individuals that have been duly deliberated upon and selected for use at U of L Health Care.

9.2.2. Vendor credentialing

Covered Individuals must request that vendors, who each must be credentialed with U of L Pharmacy or Operating Room, as applicable, register with the inpatient pharmacy or the operating room scheduler's desk prior to all U of L visits and be issued an appropriate ID badge.

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9.2.3. *Unrestricted educational grants & Continuing Medical Education*

Unrestricted educational grants from pharmaceutical companies and medical equipment companies are allowed for the purchase of educational needs as warranted for patient and medical education and patient care, either in an open (unspecified) manner or with acknowledgement that it is focused on a specific area of educational focus. Additionally, these grants can be used for educational related expenses (e.g., staff, resident, faculty lunch-based presentations).

Continuing Medical Education (CME) symposia may not involve marketing, detailing, or advertising of brand names or products, and the granting companies may not select paid lecturers or require the inclusion or exclusion of medications purchased for patient care. These symposia will comply with all CME regulations. CME symposia (i.e., Accreditation Council for Graduate Medical Education (ACGME) accredited and in compliance with ACGME guidelines) may provide food purchased with these grants.

Vendors may restrict the educational grant to cover specific educational topics (e.g., breast cancer or heart disease) so long as the above listed requirements are met. Recognition of these grants may consist of attribution (e.g., in brochures for conferences, graduation event agenda, acknowledgement slides in presentations, and wall plaques of thanks) for contributions received.

Funds designated to specific units will be kept in designated unit accounts through the Assistant Vice President for Finance, U of L Executive Vice President for Health Affairs (EVPHA) office, with these funds channeled through a central administrative account, but with separate accounts kept for each unit. Individual Departments on the Health Sciences Campus will administer these grants and will be responsible for their collection and expenditure. Annual reporting of the receipt of such grants and their expenditures will be provided to the Dean of the Schools of Medicine, Dentistry, Public Health or Nursing as appropriate. Any perceived violation of the conditions outlined above will be reported to the appropriate Dean.

General grants (i.e., non-unit or topic specific) will be placed in trust within the Assistant Vice President for Finance, U of L EVPHA office, and administered as deemed appropriate under the supervision of a Faculty Oversight Committee elected from the faculty of the respective School.

9.2.4. *Pharmaceutical samples*

Covered Individuals may receive pharmaceutical samples at U of L Health Care clinical sites. Acceptable sample medications will be articulated in a formulary in each department as approved by each in consultation with U of L Pharmacy Services. Delivery of sample medications may not be accompanied by any form of detailing or gifting.

9.2.5. *Educational programs regarding Vendor marketing*

Education programs for students, trainees, staff, and faculty should be developed and implemented by U of L-HSC schools and by individual departments on vendor marketing, as well as the subtle influences that such promotion has on physician decisions. If desired, one educational option is to have a vendor provide an interpretation of educational material on products, which would then be discussed and critiqued by a faculty member. Students may interact with vendors only in educational forums, and only when accompanied by faculty supervision.

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10. PROCEDURES

This procedure governs conflicts of interest and applies to situations involving Covered Individuals. Covered individuals at the University of Louisville must comply with Board of Trustees Policy: Individual Conflict of Interest and all applicable federal and state laws and contractual terms related to conflict of interest. This procedure covers academic, business, clinical and research and scholarly activities conducted under the auspices of and / or for the benefit of the University of Louisville.

10.1. DISCLOSURE

This section includes the general disclosure requirements pursuant to the Individual Conflict of Interest Policy. The sections included below covering procedures for academic, business, clinical and research and scholarly activities may also include additional disclosure requirements.

10.1.1. Attestation and Disclosure Form

External interests and activities are reported on the Attestation and Disclosure Form (ADF). The ADF is located at: <https://iris.louisville.edu>. Covered individuals holding any of the following roles are required to complete the ADF annually, throughout their Term of Appointment:

- Faculty
- Institutional Officials
- individuals participating in sponsored programs under the auspices of UofL
- individuals who have the authority to approve personnel and/or financial transactions for the institution

Term of Appointment means the duration of an individual's University employment, status as student or affiliation with the institution. Special circumstances also exist which might require the filing of an updated ADF during the course of the year. The updated ADF must be filed within 30 calendar days of a change. The reporting period for the ADF includes the previous 12 months and the coming 12 months. 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 procedure or as individually determined to be involved in research by principal investigators, the chair or unit head -- and that all such Covered Individuals complete the ADF in a timely manner (within 30 days of hire and on an annual basis thereafter). 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 ADFs are submitted and forwarded as required by this procedure. In the case of a chair or unit head, the responsibility of ensuring the submission of the ADF will rest with the individual at the next higher level in the administration.

10.1.2. General

Off campus, non-University commitments, such as lectures, speaker bureaus, or consulting activities for external entities that result in personal benefit or compensation are to be disclosed. Covered Individuals who are speakers for external entities, as well as researchers compensated by any external entity will:

1. Fully disclose their engagement with the external entity during presentations and interactions.
2. Disclose any potential commercial bias at presentations and interactions.
3. Not allow their own relationship to bias the content of the presentations and interactions.

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4. Not accept compensation from an external entity for any such commitment that exceeds fair market value.

10.1.3. Academic

The following constitutes interests that must be disclosed:

1. Receiving benefit or the perception of received benefit from the assignment of instructional materials, or selection of a vendor, for University coursework, including instructional materials developed by a supervisor in the Covered Individual's reporting line.
2. Making purchasing and/or contracting decisions with vendors (including potential instructional material vendors) to the University, while maintaining a direct or indirect financial or business interest with that vendor.
3. Accepting any promise, obligation, or contract for a future award from a supplier or instructional material vendor.
4. Making professional referrals to any business while maintaining a direct or indirect financial or business interest with that vendor.
5. Assigning staff, students or faculty to tasks for personal financial or non-financial benefit, rather than for the University, or scholarship or the student's educational needs. Tasks include internships, research, assistantships, and/or employment.
6. Using a University position/role to improperly influence the enrollment, academic progress, or degree confirmation of a student.
7. Entering into a romantic or sexual relationship with a student for which the Covered Individual grades, evaluates, supervises, admits to a degree program, makes an award to, promotes or employs.
8. Serving as an instructor, advisor, or lecturer for a student who is an immediate family member, or otherwise evaluate the student's performance, or make a decision concerning an award or reward, or serve on a scholarship committee.

10.1.4. Business

Covered Individuals participating in a Request for Proposal/Bid (RFP/B) evaluation are required by Purchasing to complete a confidentiality agreement and ADF prior to reviewing any information submitted by vendors. Any external activity/interest will be disclosed to the Conflict of Interest Program for review of the requested exemption and any information will be referred to the CRB, as needed. If, given the time sensitive nature of this process, the issue cannot be resolved within the needed timeframe, the RFP/B reviewer will be replaced.

10.1.5. Research

Certain research and scholarly activities and other supported activities may create the need to file additional or updated information. These situations may include, but are not limited to: substantial changes in external interests and activities; before initiating an activity or external relationship that has a potential for a conflict of interest; when submitting a proposal for supported activities, if the current ADF on file does not reflect the current situation; when receiving a contribution that creates or appears to create a conflict of interest; when involved in review or advisory activities; when involved with technology transfer; when communicating with external entities; or when submitting a paper for publication.

The following constitute external interests in supported activities that must be disclosed (non-exhaustive list):

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1. Covered Individual or immediate family member serving in a fiduciary role (officer, director, or in any other fiduciary role for a financially interested entity, regardless of whether remuneration is received for such service) for a public or private, for-profit or not-for-profit entity;
2. Covered Individual or immediate family member receiving remuneration in connection with the supported activity that is not directly related to the reasonable costs of the supported activity (as specified in the agreement between the entity providing support and the institution), including any bonus or milestone payments to the investigators in excess of reasonable costs incurred;
3. Covered Individual or immediate family member receiving remuneration from any publicly traded entity and the value of any equity interest (other than through purchase of mutual funds) in the entity as of the date of disclosure, when aggregated, exceed \$5,000;
4. Covered Individual or immediate family member receiving any remuneration from any non-publicly traded entity, or the Covered Individual or immediate family member holds **any** equity interest (e.g., stock, stock option, or other ownership interest); and/or
5. Intellectual property rights (e.g., patents, copyrights), royalties from such rights, and agreements to share in royalties related to such rights.

The Office of Technology Transfer (OTT) quarterly will generate a list of companies that pay royalties of \$5,000 or more per year and units and Covered Individuals that receive the revenue. OTT forwards this report to the Conflict of Interest Program, which will compare that list against a database of research sponsors in those units. If the company is on both lists, the Conflict of Interest Program will gather information about the project and forward the matter to the CRB to develop a management plan.

The Sponsored Program Grants Administration and Industry Contracts (SPGA; OIC) may not release for expenditure funds for a supported activity in which a significant financial interest has been disclosed until the interest has been reviewed by the CRB, a determination has been made and a management plan, if required, has been implemented.

Prior to the expenditure of funds, the Institution will report, to the extent required by the entity providing support, the existence of any conflicting interest disclosed and provide assurance that the interest has been managed, reduced or eliminated. If a conflict is identified after this initial report, the covered individual must update the ADF and the Institution will submit a subsequent report in accordance with the requirements of the supported activity

10.1.6. Research & Human Subjects

University of Louisville subcontractors or sub grantees, 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 being included on a proposal. In the case of identified conflicts of interest, the subcontractor/sub grantee must provide the institution with documentation on the conflict of interest and the approved management. On an annual basis, the subcontractor/sub grantee must submit oversight updates to the institution for the duration of the contract period. The institution will report the existence of any conflicts of interest and subsequent management plans as required by sponsors.

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The designee of the EVPR serving on the CRB shall be responsible for professional level staff review under this procedure of each ADF submitted to the University by Covered Individuals related to research and scholarly activity, and make appropriate recommendations to the EVPR concerning the development of management plans for the elimination, reduction, or management of any potential conflict of interest in research. The designee of the EVPR shall provide status information regarding research conflict management to the CRB Chair and CRB at convened meetings.

Supported 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, Covered Individuals 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 CRB Chair. The mitigation can involve acceptance or denial of the rebuttable presumption. The CRB Chair 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 Program 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

10.1.7. Exempt from disclosure on the ADF

The following activities do not create a potential conflict of interest and are exempt from reporting on the ADF, but may require disclosure via other methods based upon University policies and procedures:

1. Receiving income from seminars, lectures, or teaching engagements sponsored by a federal, state or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education (as defined at 20 U.S.C. 1001(a));
2. Receiving income by serving as a special reviewer or on a review panel for a federal, state or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education (as defined at 20 U.S.C. 1001(a));
3. Receiving royalties under the University's royalty-sharing policy but not having any other relationship with the royalty-granting entity that could result in a conflict of interest;
4. Ownership of Mutual Funds, of any amount;
5. Salary, royalties, or other remuneration paid by the University to the Covered Individual if the individual is currently employed or otherwise appointed by the University; or
6. Receiving travel, lodging and/or per diem expense for meals as required per University work assignments for serving on (federal, state, local or) peer-review panels or research agencies.

10.2. REVIEW

10.2.1. Conflict of Interest Program

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The COI Program will perform initial review of submitted ADFs and refer appropriate cases to the CRB for review and management determination.

10.2.2. Conflict Review Board

1. 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.
2. In making that determination, the CRB will consider the following issues: the covered individual's institutional responsibilities, 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 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.
3. The CRB will consult appropriate individuals, including the Covered Individual, as needed, to ensure a complete understanding of the relationship and its potential impact on University activities and any appropriate management requirements.
4. Based upon this review, the CRB will issue a recommendation that will be forwarded to the CRB Chair for review and approval.
5. The CRB Chair will review the CRB recommendation and formally approve the recommendation, modify the recommendation or reject the recommendation and approve an alternate management plan.

10.3. MANAGEMENT

10.3.1. Management Plan

1. Based upon the review, the CRB will issue a recommendation, which may include a management plan, which will be forwarded to the CRB Chair for review and approval.
2. The CRB Chair will review the CRB recommendation and formally approve the recommendation, modify the recommendation or reject the recommendation and approve an alternate management plan.

10.4. IMPLEMENTATION

Once a management plan is approved, the Conflict of Interest Program 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 Program 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.

10.5. RECONSIDERATION

Any Covered Individual 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 CRB Chair within ten (10) business 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).

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The CRB Chair 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 within the Request 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 Covered Individual. If a modification is approved, the CRB can accept the resolution proposed by the Covered Individual, or adopt an alternate resolution.

Regardless of the chosen resolution, the CRB will provide the Covered Individual 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.

11. CONFLICT REVIEW BOARD

The Conflict Review Board was 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 (who votes to break a tie vote).

11.1. CRB MEMBERSHIP

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 and Innovation, 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 the Office of Technology Transfer, the Office of Industry Contracts, the Faculty Senate, the Staff Senate and University Counsel will serve as ex-officio members.

11.2. CRB MEETINGS

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.

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.
2. The CRB Chair will recuse him/herself from review and oversight of all potential conflicts of interest involving staff from the Conflict of Interest Program, including the CRB Chair.

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12. ENFORCEMENT

Covered Individuals 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, failing to file a ADF, 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.

To the extent required by a research sponsor, the Institution will notify the research sponsor of the violation and any corrective action taken or to be taken. If a research sponsor should report a case of non-compliance, by a Covered Individual, the Institution will require the Covered Individual to fulfill all reporting requirements, to the extent required by the research sponsor.

13. ASSOCIATED FORM

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

14. CONTACT INFORMATION

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