

Definitions for COIC Policy

Actual Conflict. Conflict of Interest or Commitment exists as determined by University. This determination warrants management.

Apparent Conflict. Covered Person's activity or Interest may represent actual or potential Conflict of Interest or Commitment, but needs analysis. If Apparent Conflict is ruled nonexistent, perception may still warrant explanation and documentation.

Appropriate Authority. The Covered Person's direct supervisor. Board of Trustees serves as Appropriate Authority for the President.

Attestation and Disclosure Form (ADF). A Covered Person's annual attestation to the Standards of Conduct and disclosure of external activities and Interests to the University.

Conflict of Interest or Commitment. A situation that influences Covered Person's professional judgment in University teaching, Research, outreach, or public service because of external relationship that affects an external Interest of the Covered Person, a Relative, or an Entity. Term also includes situation in which Covered Person engages in a Non-University Commitment that may interfere with fulfillment of obligations to University. Examples may include outside employment, pro bono or volunteer work, and government service in public interest.

Conflict of Interest and Commitment Office (COIC Office). COIC Office reports to the COIC Officer. COIC Office fulfills the following duties:

- preserve files on all disclosures of significant financial interest at University;
- keep databases for tracking disclosures and disclosure dates;
- keep administrative files for CRB;
- screen disclosures for completeness before starting review;
- act as a resource for Covered Persons on general regulatory information, guidance with forms, and aid in preparing ADF;
- provide reports certifications, and assurances for federal, state, departmental- and unit-wide surveying of disclosure compliance;
- provide sanctioned reports or certifications for external sponsors or agencies, when necessary;
- preserve information on federal regulations about conflicts of interest in research;
- provide education about the COI process and regulations to the University community;
- provide education opportunities to CRB members; and
- conduct quality assurance and quality improvement for the CRB.

Conflict of Interest and Commitment Officer (COIC Officer). The Vice President for Risk, Audit and Compliance, who is responsible for implementation and enforcement of policy and reports directly to President. COIC Officer is responsible for developing and issuing this policy. COIC Officer is responsible for ensuring compliance with all federal, state and local requirements about conflicts of interest. COIC Officer shall report yearly to President and Board of Trustees under this policy. COIC Officer may delegate responsibilities under this policy to COIC Office.

Conflict Review Board (CRB). Panel named by COIC Officer to evaluate potential COIC, review reconsideration requests, and review information about noncompliance. Members include both faculty and administrative staff. The CRB is chaired by the COIC Director (who only votes to break a tie vote).

Covered Person. Covered Person includes all employees¹ and individuals (full or part-time, paid or unpaid) Participating in academic, business, clinical, and Research or scholarly activities for University.

Entity. Any domestic or foreign, public or private business, organization, corporation, partnership, proprietorship, limited liability company, or firm, regardless of whether organized for profit or as a nonprofit entity. The term does not include University, University Research Foundation, or University Athletic Association.

Financial Conflict of Interest (FCOI). Any condition in which an SFI could directly and significantly affect the design, conduct, or reporting of Research.

FCOI Report. A University's report of a financial conflict of interest to a Public Health Service Awarding Component.

Financial Interest (FI). Anything of monetary value including, but not limited to: direct or indirect interest in 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 fund, pension, or other institutional investment fund over which the Covered Person does not exercise control; or receipt of, or the right or expectation to receive, any income in one or more of: consulting fee, honorariums, salary, allowance, forbearance, forgiveness, interest in real or personal property, dividend, royalty gained from licensing of technology, or other processes or products, rent, capital gain, or any other form of compensation. FI may arise from (nonexclusive examples):

- Compensation, including wages, salaries, commissions, professional fees, or fees for business referrals;
- Consulting, including commercial and professional consulting and service arrangements, scientific and technical advisory board memberships, or serving as an expert witness in litigation;
- Services provided in exchange for honorariums including travel expense repayments;
- Research funding or other forms of Research Support;
- Investment in the form of stock or bond ownership, including single sector investment only mutual funds;
- Business ownership or partnership interests;
- Patents, copyrights, and other intellectual property interests;
- Seeking or negotiating for prospective employment or business; or
- Gifts, including travel.

Full-time University Employee. Means 80% or more full-time equivalent and for which employment continues for six months or more.

Ghostwriting. Means person qualifies for authorship but not listed as an author or recognized on a publication. Ghostwriting occurs when a commercial entity writes an article or presentation and a Covered Person is named as an author. This includes papers or presentations featuring data that were simply presented to the named author (without the opportunity for that person to analyze, directly, perform calculations, review or question the data).

Gift Authorship. Means person does not qualify for authorship but named as an author.

Gift. Anything Covered Person receives while not giving equal or greater consideration within 90 days. Term² includes, not limited to,

- food or drink,
- membership dues,
- plants, flowers, floral arrangements,
- transport and lodging, a preferential rate,

¹ University faculty, administrators, staff

² Term does not include salary associated with private employment, an award, plaque, certificate, or similar personalized item for service, gifts from an Honorarium, or an expense related to an Honorarium event paid to a person or the person's spouse, or gifts from Relatives.

- use of property,
- forgiveness of a debt,
- entrance fees, admission fees or tickets to events, performances, or facilities,
- charged services provided free, or
- other similar service having an attributable value not already provided for in this definition.

Honorarium. Anything of value given to Covered Person for speech or written item³. Term does not include payments for outside employment or payments for Covered Person's public duties. Term does not include payment of reasonable transport, lodging, registration fee, or food and drink expenses for Covered Person and spouse at honorarium event.

Institutional Conflict of Interest (ICOI). A condition compromising or seemingly compromising Institutional Official or University's decision making. ICOIs may arise when (non-exhaustive list):

- Institutional official with significant financial interest in business entity is in position to act for University that may benefit business entity;
- University licenses invention to business entity and holds royalty or equity interests in entity;
- Vendor gives a gift to the University;
- University holds investments in business entity that has financial or business affiliation with University;
- University enters commercial transaction compromising or seemingly compromising University's missions, or institutional reputation; or
- University has significant financial interest in business entity with commercial interests affected by research conducted at University.

Institutional Financial Interest. Institutional Financial Interests includes, but not limited to:

- Royalty arrangements: payments, including royalty payments and licensing fees, resulting from technology transfer, licensing, and business activities that exceed \$100,000 in the preceding twelve month period⁴;
- Non-publicly traded equity⁵;
- Publicly-traded equity⁶; and
- Gifts above one million dollars from for-profit entity or philanthropic unit associated with for-profit entity⁷.

³ other than a book, intended to be published

⁴ from a single entity

⁵ equity and ownership interests of any amount in any for-profit entity that is not publicly traded

⁶ equity and ownership interests valued at greater than \$100,000 in the preceding twelve (12) month period in any publicly-traded, for-profit entity, except for equity held in the University's endowment

⁷ Certain other payment or financial benefits: from time to time, the University enters into contractual relationships with outside parties which include a payment or other financial benefit to the University from the contracting party that are based on factors outside the course of business between the University and the contracting party (e.g., number of units sold or new accounts established, philanthropic support for the University). The University recognizes that certain types of these contracts, if not properly managed or disclosed by the University, and which because of the University's unique position and relationships, may create the perception that the University was improperly influenced to enter into the contract or endorses the contracting party as a "preferred provider" or may improperly influence consumer choices by third parties, in particular University students.

Institutional Financial Interest shall also mean the following non-exhaustive financial or business interests of Institutional Officials (and those of the Institutional Official's spouse or partner):

- Equity or ownership interests in publicly-traded, for-profit entities if the value exceeds \$25,000 in the preceding twelve (12) month period. Not included are equity or ownership interests in mutual funds and retirement accounts⁸;
- Equity (including stock, options, warrants), ownership, or founders' interests of any amount in non-publicly traded entities;
- Income, including royalties, equity, consulting fees, honorariums and gifts or other payments, from for-profit entities that, in the aggregate, exceed \$25,000 from entity in preceding twelve-month period;
- Fiduciary role with for-profit entity, regardless of compensation or income, such as service on the board of directors, management role in company or partnership (for example, President, CEO, COO, CRO, CSO or Treasurer).
- Fiduciary role with nonprofit entity that could reasonably lead to potential ICOI.

Institutional Official (IO). Means people with direct authority over faculty and staff appointments, salaries, promotions, signatory authority, or division of institutional resources, such as assignment of graduate students or other trainees, progress or promotion of students, funding or space, for faculty who are conducting research. Term includes anyone holding administrator positions, even temporarily. Term includes, but not limited to individuals serving as: Deans, Associate Deans, and Assistant Deans; Institute and Center Directors; University 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; Department Heads; Directors of Sponsored Programs, Technology Transfer, Research Integrity, Human Subjects Protection; and chairs of the Institutional Review Board, Institutional Biosafety Committee, Institutional Animal Care and Use Committee, Conflict Review Board, and other similar committees created in the future.

Interest. A Covered Person's direct (ownership) or indirect (receipt by Covered Person of direct financial) gain, benefit, monetary value, right, claim, or share.

Instructional Materials. Includes textbooks, software, courseware, and laboratory equipment.

Investigator. Means person, regardless of title, position, pay, role, or responsibilities, with ability to decide independently design, conduct, or reporting of University Research. Term does not include people who perform only incidental or isolated tasks related to project.

Manage. Means taking action to address COIC. Term includes reducing or removing the COIC, to ensure that affected activity is free from bias.

Management Plan. Means written plan for management, reduction, or elimination of identified COIC. Management Plan shall contain provisions for purposes intended (for example management, reduction, or elimination of conflict), for identity, nature and any monetary amount of conflict.

Mitigation Report. Means written report filed by University when results of Retrospective Review show bias occurred because of unreported or unmanaged FCOI. Mitigation Report includes

- Findings of Retrospective Review;
- Description of impact of bias on Research; and

⁸ as long as the University Official does not directly control the investment decisions made in these investment vehicles

- University's plan of action or actions taken to remove or mitigate effect of bias⁹.

Non-University Commitment. Means outside (non-University) consulting or other activity, paid or unpaid, beyond work assignment of Covered Person's University Responsibilities or employment.

Organizational Conflict of Interest. Means person cannot give unbiased aid or advice to the Government, or the person's objectivity in performing the contract work is, or might be, otherwise undermined, or a person has an unfair competitive advantage.

Participate. To be part of the University activity in any capacity, including, but not limited to, serving as the PI, co-investigator, Research collaborator, or provider of direct services or patient care. Term does not apply to Covered Persons who provide mainly technical or advisory Support and have no direct access to data or control over its collection or analysis. Term also does not apply to study participants, unless they are in position to influence study's results or have privileged information about results.

Personal (or Private) Gain or Benefit. To use University resources for personal or private purposes or personal or private financial or nonfinancial benefits. Personal or private benefits may include, but not limited to, cash, profits, securities, Gifts, performed work, or sex.

Qualifying Adult. Means person over 18 years old, and, if blood Relative (or Relative by adoption or marriage) must be of same or younger generation as Covered Person (as used in KRS 391.010), and, must be living in Covered Person's household (for at least 12 months), and financially interdependent (for example, have a joint checking account or a joint mortgage) for 12 months or longer, and be unmarried.

Relatedness. Means directly and significantly associated with Covered Person' Research associated with Research based on topic, use of products, potential for an increase in the value of SFI, or company in which SFI is held.

Relative. Anyone related to a Covered Person in the following ways, and includes those within these categories who are referred to as adopted, step-, foster, grand-, half-, in-law, spouse of, or great-:

- parent
- child or ward
- sibling
- uncle or aunt
- first cousin
- nephew or niece
- spouse, domestic partner, significant other

Remuneration. Means salary or any payment for services not identified as salary¹⁰; 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. A systematic investigation designed to develop or contribute to generalizable knowledge. Term encompasses basic and applied Research, service and testing, and product development that may be published. Term includes any such condition for which Research funding is available through grant, cooperative agreement, or contract, such as Research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or Research resources award or gift. Term also

⁹ (for example, extent of harm done, including any qualitative and quantitative data to Support any actual or future harm; analysis of whether Research is salvageable)

¹⁰ (e.g., consulting fees, honoraria, paid authorship, travel reimbursement)

includes Research activities that are not funded or sponsored. Gifts may be considered Research projects needing COIC management when used for purposes related to Covered Person's Interests.

Retrospective Review. Means review conducted by University when Investigator fails to report SFI in timely manner or when noncompliance with PHS regulation or approved Management Plan is discovered.

Senior or Key Personnel. Means project director or PI and anyone identified as Senior or Key Personnel in grant application, progress report, or report filed by law or regulation.

Significant Financial Interest (SFI). Means FI consisting of one or more of following Interests of Covered Person¹¹ related to University Responsibilities:

1. For publicly traded Entities, value of any Remuneration received from Entity in 12 months preceding disclosure combined with value of Equity Interest in Entity as of date of disclosure, when totaled, exceeds \$5,000;
2. For non-publicly traded Entities (including but not limited to private "start-up" companies, closely held corporations, partnerships or sole proprietorships), if either:
 - a. the value of any Remuneration received from the Entity in the 12 months preceding the disclosure, when totaled, exceeds \$5,000; or
 - b. the Investigator holds any Equity Interest (i.e., there is no de minimis amount for Equity Interests in a non-publicly traded Entity) in the Entity;
3. Income from intellectual property rights and interests (for example, patents, trademarks, copyrights) that exceeds \$5,000 in previous 12 months; or
4. Repaid or sponsored travel exceeding \$5,000 from Entity in 12 months preceding disclosure¹².

Statutory Affiliates. University Research Foundation, and University Athletic Association and any other affiliates added in the future.

Supervisory Relationship. Exists when a Covered Person is directly or indirectly through span of control responsible for supervising, directing, evaluating, or influencing the work activities, or job performance of another Covered Person.

Support. Providing anything of value (for example, funds, supplies, equipment, staff, etc.), regardless of whether restricted or unrestricted.

Term of Appointment. The duration of a Covered Person's University employment, status as a student, or affiliation with the University.

Travel. Repaid or sponsored Travel related to Covered Person's University Responsibilities, when combined with other Remuneration from Entity meets \$5,000 reporting threshold. Covered Persons do not disclose Travel repaid or sponsored by a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), academic teaching hospital, medical center, or Research institution affiliated with Institution of higher education.

University Responsibilities. A Covered Person's duties and responsibilities for the University¹³.

¹¹ (and those of the Covered Person's spouse or partner and dependent child[ren])

¹² however, travel that is reimbursed or sponsored by a federal, state, or local government agency in the United States, an American institution of higher education as defined at 20 U.S.C. 1001(a), an American academic teaching hospital, an American medical center, or a Research institute that is affiliated with an American Institution of higher education does not need to be disclosed as an SFI

¹³ The activities outlined in an Covered Person's annual assignment or position description may include administration, teaching, Research (regardless of whether or not it is funded), Research consultation, and creative

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

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activities, course preparation, curriculum development, lectures, evaluation of student efforts, academic advising, committee meetings and memberships, service on panels such as University review boards or data and safety monitoring boards, public service to include service on advisory committee's or review panels, and any other activity assigned by the Covered Person's Appropriate Authority in accordance with University policies.

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