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Individual Outside Interest Policy

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Responsible University Officials: Vice President of University Compliance and Ethics, Jessica Evenson; Vice President for Research, Ken Olliff; Vice President for Medical Affairs and Dean of the School of Medicine, Robert Wilmott, M.D.

Policy Owner: Manager of Financial Conflict of Interest in Research, Libby Tempel

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1.0 Reason for Policy

Saint Louis University, including its researchers, health professionals, and institutional officials, must balance many competing interests. The University and its members engage in relationships with a variety of external entities that may lead to individual financial benefit. Individual benefits include compensation, business ventures, royalty payments, and equity from licensing intellectual property. Such relationships with external entities are expected and add value to the University's educational, research, and business activities. However, in some cases, an individual outside interest may overlap with institutional responsibilities, and this overlap creates a conflict of interest (COI). The intent of this policy is not to prohibit or discourage individual outside interests, but, as much as possible, to ensure transparency and promote objectivity by managing any COI. This ensures conflicts of interest do not compromise the integrity of the University's primary missions, including the safety and integrity of its research, education, clinical care, and business activities.

2.0 Policy Statement

The University shall identify and respond to conflicts of interest through a process of disclosure of outside

interests, review of outside interests, and resolution of conflicts of interests.

Disclosure of Outside Interests

Covered individuals (CIs) must disclose their own outside interests, as well as outside interests of their immediate family, that reasonably appear to be related to the covered individual's institutional responsibilities. These Outside Interest Disclosures (OIDs) must be submitted upon request from the University and updated by the covered individual within 30 days of a change.

Review of Outside Interests

OIDS will be reviewed and outside interests will be classified as follows:

- A. Below threshold for Individual Outside Interest (IOI) review: Outside interests with income below \$5,000 per calendar year or publicly-held equity valued at less than \$5,000 will be acknowledged. No further review will be required unless the outside interest involves a fiduciary role.
- B. Thresholds for Significant Interests (SIs):
 - 1. For researchers with grants or contracts funded by PHS agencies (or sponsors following the PHS COI regulations), SIs include outside interests with income between \$5,000 and \$9,999 per calendar year or publicly-held equity valued between \$5,000 and \$9,999.
 - 2. For all CIs, SIs are outside interests involving equity valued at \$10,000 or more, \$10,000 or greater of income per calendar year, any non-publicly held equity, fiduciary responsibility, or any income from intellectual property.
- C. IOI administrative offices will refer SIs that have potential overlap with the CI's institutional responsibilities to the Committee on Outside Interests (the Committee) for COI evaluation:
 - 1. SIs with income less than \$40,000 per calendar year or publicly-held equity can be reviewed by the Committee, a subcommittee, or the Committee Chairperson.
 - 2. SIs with income of \$40,000 or more per calendar year, any non-publicly held equity, fiduciary responsibility, or any income from intellectual property will require greater scrutiny by the Committee.

Resolution of Conflicts of Interest

If a COI exists, the Committee will discuss methods to reduce, manage, or eliminate the COI. The covered individual will be contacted within 30 days after the Committee's decision with a proposed resolution. In the case of research projects, all COIs must be resolved prior to the expenditure of funds or within 60 days after the identification of the conflict of interest.

- A. Monitoring: If a COI management plan is required, the University will monitor the plan.
- B. Notification: If a COI exists, the University will notify the sponsor as required.
- C. Termination of a management plan: The management plan will be in effect from the date of agreement by the covered individual until the plan is terminated per the procedures.
- D. Dispute resolution: If the covered individual disagrees with the Committee's determination or resolution strategy, they may dispute per the procedures.

Records

- A. Records request: The University shall ensure public accessibility of information about conflicts of interest related to sponsored research as required by sponsor regulations.
- B. Record retention: The University will maintain records of all outside interest disclosures and all actions it takes with respect to each COI resolution for at least three years from the date of completion of the institutional responsibilities to which they relate.

3.0 Scope

This policy applies to all individuals performing institutional responsibilities, regardless of their compensation terms, including those related to the Saint Louis University Madrid Campus.

4.0 Procedures

[Link out to procedures](#)

5.0 Sanctions

Individuals who fail to comply with this policy and the procedures associated with it may be subject to disciplinary actions guided by the University's *Staff Performance Management Policy*, *SLU Faculty Manual (St. Louis Campus)*, or *Student Handbook*. Non-compliance with this policy may result in disciplinary action, up to and including separation from the University.

6.0 Responsibilities

Covered Individual: The covered individual (CI) is responsible for submitting an Outside Interest Disclosure (OID) upon request within the prescribed time frame. The CI will satisfy required training expectations at least once every four years. The CI will cooperate with the development of a management plan in those instances where the Committee has determined that a COI exists. The CI will comply with the terms and conditions of management plans, including providing required reports in a timely manner and updating information as needed. Regardless of the Committee determinations, the CI is responsible for fulfilling the disclosure guidelines of all other agencies, including journals and professional organizations.

Academic Units: The chair or comparable administrator has responsibility for compliance of all covered individuals within their unit, including external collaborators, subcontractors, and other downstream entities. They may intervene to enforce policy and improve procedures, and will report through their dean to the

Committee.

Deans: The deans (or their designated representatives) have responsibility for enforcing policy and supporting timely collection of disclosures. The deans assure the overall integrity of institutional responsibilities.

Executive Leadership: Executive Leadership is responsible for interpreting and overseeing implementation of and compliance with this Policy. The Vice President for Medical Affairs provides oversight for health professionals. The Vice President for Research provides oversight for researchers. The Vice President of Compliance and Ethics provides oversight for institutional officials. Executive leadership reports to the University's Board of Trustees through the Audit and Legal Committee of the Board.

Administrative Offices: The Compliance Office and the Research Integrity and Safety Group in the Office of the Vice President for Research share in responsibility for obtaining information through the disclosure process, compiling disclosed information for review and deliberation by the Committee, and issuing the management plan. Other University offices will provide information upon request for IOI review (e.g., personnel information, protocols, contracts, agreements). The two IOI administrative offices will oversee enforcement as directed by executive leadership and the Committee. The IOI administrative offices will maintain records of all disclosures, review, COI, and actions taken by the Committee. The IOI administrative offices will create training and website content as directed by the Committee and administer the reporting obligations.

Committee: The Committee on Outside Interests (the Committee) is responsible for evaluating disclosures and institutional responsibilities and determining whether a COI exists. They will resolve the COI in collaboration with the covered individual and the appropriate administrative office. They will monitor and enforce management plans and notify sponsors as required. The Committee will oversee COI education and ensure that this Policy complies with federal and state laws. The Committee reports to executive leadership.

7.0 References

University Policies Including But Not Limited to:

[*Policy on Authorship for Scientific and Scholarly Publications*](#), RC-005:

[*Private Use of Saint Louis University Research Facilities Policy*](#)

[*SLU Faculty Manual \(St. Louis Campus\)*](#)

External Resources Including But Not Limited to:

[*Medicare, Medicaid, Children's Health Insurance Programs, 42 CFR Parts 402 and 403: Transparency Reports and Reporting of Physician Ownership or Investment Interests \(Sunshine Act\)*](#)

National Science Foundation Policies, [*NSF Proposal and Award Policies and Procedures Guide*](#), NSF 19-1 February 25, 2019, Chapter IX. – Grantee Standards, Section A. COI Policies. Check NSF website for latest edition.

[*Public Health Service Regulations, 42 CFR Part 50, subpart F, Promoting Objectivity in Research: and 45 CFR Part 94, Responsible Prospective Contractors.*](#)

8.0 Definitions

Committee on Outside Interests (the Committee): University committee committed to advancing research and fostering an entrepreneurial spirit at the University while maintaining objectivity and integrity in institutional responsibilities. The Committee provides oversight for COI education, recommends policy, and oversees the disclosure process. If a COI arises, the Committee will consult with the covered individual as needed reduce, manage, or eliminate the conflict of interest.

Conflict of Interest (COI): Any interaction with an external entity by a covered individual that could directly and significantly affect one's primary institutional responsibility to serve the best interest of the University, and/or its students, patients, trainees, research subjects, and the academic community.

Covered Individual (CI): Individual who is a health professional, institutional official, and/or a researcher.

External Entity: Any corporation, partnership, firm, or other legal entity, whether for-profit or non-profit, whether publicly or privately held, but external to the University. This includes their respective representatives, which investigate, develop, produce, market, and sell treatments, goods, or services.

Health Professional: Individual involved directly or indirectly in patient care on behalf of the University.

Immediate Family: Includes any spouse, dependent children, and any other person(s) residing in the covered individual's household.

Institutional Official: Individuals who influence the strategic direction of the University as determined by the University's executive leadership and the Committee.

Institutional Responsibilities: An individual's professional responsibilities on behalf of the University, including research, education, clinical, business transactions, or other activities.

Management Plan: A formal plan of action designed for mitigating the risks associated with an identified COI.

Outside Interest (OI): A covered individual's relationship with an external entity.

Outside Interest Disclosure (OID): A formal statement that identifies relevant information about outside interests that reasonably appear related to the individual's institutional responsibilities. The statement is completed by covered individuals and submitted to the University through a web-based disclosure platform.

Research: A systematic investigation, study or experiment designed and conducted to develop or contribute to generalizable knowledge. Research includes but is not limited to basic and applied research, clinical research, and product development, but does not include confidentiality and non-disclosure agreements (CDAs) and master and service agreements as defined in the procedures.

Researcher: The principal investigator, co-investigator, and/or any other person(s) regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by an external sponsor, or research that is proposed for such funding. For this policy, Researchers will always include Senior/Key Personnel and all members of the IRB protocol research team.

Senior/Key Personnel: Principal investigator, co-investigator(s), program director or any other persons who contribute to the scientific development or execution of a project in a substantive, measurable way.

Significant Interest (SI): An outside interest that exceeds \$10,000 per calendar year, includes non-publicly held equity, or includes any income from intellectual property. For researchers with grants or contracts funded

by PHS agencies (or sponsors following the PHS FCOI regulations), outside interests between \$5,000-\$9,999 are also considered SIs.

Sponsor: An external entity providing financial support or other items of financial value (whether or not the value is stated) for research, educational activities, or travel. This includes all federal and private entities.

9.0 History

This policy replaces and merges:

- Financial COI in Research Policy, Version 4.1, dated February 28, 2019.
- Institutional Conflicts of Interest Policy, Version 1.0, dated August 2, 2016.
- Policy on Composition and Operation of the Saint Louis University COI in Research Committee, Version 2.1, dated February 28, 2019.
- Policy on Medical Center Conflicts of Interest in Patient Care and Service, Version 2014.07.17, dated September 17, 2014.

Attachments

[Outline of IOI Procedures](#)

Approval Signatures

Approver	Date
Michael Reeves	pending
Elizabeth Tempel	4/22/2020
Michael Reeves	4/16/2020

Applicability

SLUCare, Saint Louis University