



Policy on the Composition and Operation of the Saint Louis University Conflict of Interest in Research Committee

Policy Number: RC-002

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Classification: Research Compliance

Effective Date: February 28, 2019

Responsible University Office: Vice President for Research

1.0 INTRODUCTION

Saint Louis University (hereinafter “the University” or “SLU”), in support of its mission to seek excellence in the fulfillment of research, to encourage research to the betterment of mankind, and to ensure integrity in research, has established a Conflict of Interest in Research Committee (COIRC) to oversee compliance with the University’s *Financial Conflict of Interest in Research Policy* (RC-001). The COIRC reports to the Vice President for Research and is guided by a chairperson appointed by the Vice President for Research. Conflicts of interest on the part of SLU faculty are often complicated, and may also exist when faculty or faculty members’ spouses and/or dependent children have financial interests in entities that are related to research at SLU. It is the responsibility of the COIRC to review all financial disclosures related to research projects where a conflict may exist; to assist faculty in ensuring that financial conflicts of interest are minimized, eliminated, or otherwise managed; and to make recommendations to the Associate Vice President for Research when the management of a conflict is not possible. The COIRC will assess compliance with disclosures and management plans and refer non-compliance to the Associate Vice President for Research.

In addition, the COIRC will develop guidance for the University investigators that, upon review by the appropriate University signatories, will serve as University policy on conflicts of interest in research.

2.0 PURPOSE

The purpose of this policy is to define the composition of the Saint Louis University Conflict of Interest in Research Committee (COIRC); its membership, responsibilities, and functions to support research at the University; and to assist investigators to reduce, manage, or eliminate any financial conflicts of interest. The COIRC is charged with ensuring compliance with federal and University policies, regulations, and guidelines regarding financial conflicts of interest.

3.0 COMMITTEE MEMBERSHIP

The COIRC consists of at least nine voting members, including:

1. At least one tenured or tenure-track member of the faculty recommended by the

Executive Committee of the Faculty Senate and appointed by the Associate Vice President for Research;

2. At least two tenured or tenure-track faculty members from the University (non-Medical Center) appointed by the Associate Vice President for Research;
3. At least two tenured or tenure-track members from the Medical Center appointed by the Associate Vice President for Research;
4. A tenured Chairperson of the COIRC appointed by the Associate Vice President for Research; and
5. Additional volunteers appointed by the Associate Vice President for Research to reach at least nine faculty members.

Of the voting members of the COIRC, at least three must be full-time, tenured faculty engaging in sponsored research activities.

Members of the Committee will be appointed for renewable three-year terms and will represent schools/colleges and departments across the campus, particularly those with faculty who have significant activity in sponsored research and relationships with external entities. Representatives from the Offices of the General Counsel and the Vice President for Research will serve as *ex officio* non-voting COIRC members. Other members of the University administration and faculty may also be asked to serve as non-voting consultants to the COIRC as it considers complex issues (e.g., Institutional Review Board, Research Strategy Group, GO Centers). The COIRC may develop sub-committees consisting of its members and other appropriate personnel to address specific issues.

The quorum for Committee decisions is four, which must include the Chairperson and three additional Committee members. The Manager of Conflict of Interest in Research (COIR) or designated backup must also be present during the vote.

4.0 FREQUENCY OF MEETINGS

The COIRC usually meets monthly. If there is no business to discuss, the meetings may be cancelled. Additional meetings, phone/e-conference meetings, or e-mail votes may be requested as needed to review situations where quick turn-around is required.

5.0 COMMITTEE RESPONSIBILITIES

The COIRC with assistance from the Office of the Vice President for Research shall:

1. Solicit, receive, and review Outside Interest Disclosure (OID) Forms annually from faculty and other individuals engaged in research at SLU, and make final determinations as to whether a financial conflict of interest in research exists;
2. Receive and review *ad hoc* OIDs, including disclosures related to submission of proposals to external agencies;
3. Advise faculty and other researchers of action required due to determination of COIR .

4. Ensure that management plans are appropriate and complete and are designed to reduce, manage, or eliminate financial conflicts of interest in research;
5. Work with the Office of the General Counsel to monitor and enforce management plans;
6. Report to federal agencies as required when a financial conflict of interest in research exists for funded researchers;
7. Provide oversight for conflict of interest education, including training programs for University personnel;
8. Recommend additional policies for addressing conflicts of interest consistent with this Policy;
9. Ensure that the University's *Financial Conflict of Interest in Research Policies* and procedures remain in accordance with federal and state laws;
10. Make recommendations to the Associate Vice President for Research of appropriate disciplinary action to be taken in the case of non-compliance related to this Policy and the University's *Financial Conflict of Interest in Research Policy*, as specified in Section 7.0 of this Policy; and
11. Maintain strict confidentiality of annual or *ad hoc* OID Forms and all other confidential information related thereto.

6.0 PROCEDURES

All annual OID Forms are launched from InfoEd Global by the Manager of COIR in collaboration with the other Conflict of Interest Offices (e.g., Institutional COI and Patient Care/Clinical COI).

Disclosure forms with no apparent financial conflict of interest in research will undergo an expedited review by the Manager of COIR (or a RIS Group designated backup individual). The Manager of COIR and RIS Group designated backup are delegated to decide when no COIR exists between disclosed financial interests and particular research project(s).

Disclosure forms where a possible conflict of interest exists will be reviewed by the COIRC Chairperson. If the situation is substantially similar to a previous review, the COIRC Chairperson can make the final decision about whether or not the situation constitutes a FCOIR. If the situation is new, it must undergo a full review by the COIRC.

1. For the purposes of this policy, substantially similar means either:
 - a. The investigator's financial interest has already been reviewed by the full COIRC related to another research project; the COIRC has determined a COIR exists and has developed a management plan; and the new review is a similar project that will be added to the existing management plan, or
 - b. The investigator's financial interest has already been reviewed by the full COIRC related to another research project; the COIRC has determined a COIR does not exist; and the new review is a similar project.

2. If the COIRC Chairperson makes a determination, his/her review will be reported to the COIRC at the next regularly-scheduled COIRC meeting.

When necessary, the COIRC will discuss the disclosure with the investigator involved and may also consult with others who may have relevant information. The investigator is entitled to meet with the COIRC if he or she wishes.

The COIRC will determine whether a conflict of interest exists, and, if so, will vote to approve a management plan to effectively reduce, manage, or eliminate the conflict of interest. In making these determinations, the COIRC will be guided by the principles discussed in section 6 of the *Financial Conflict of Interest in Research Policy*. If the COIRC prescribes monitoring of the activity, it will describe specifically how the monitoring shall be performed and what records are to be kept.

The COIRC will attempt to conclude its review within six weeks after the matter is referred, and will communicate its decision in writing to the investigator, the Department Chair or Division Head, and the School or College Dean.

The affected individual may appeal the COIRC's decision to the Associate Vice President for Research, whose decision will be final.

7.0 SANCTIONS

Individuals are expected to comply fully and promptly with this Policy and the University's *Financial Conflict of Interest in Research Policy*, including the requirements of disclosure. Individuals who deliberately or repeatedly fail to fully and truthfully disclose conflict of interest situations or fail to comply with any stipulated plan for managing the conflict of interest will be subject to the applicable University disciplinary processes and those prescribed in the Saint Louis University Faculty manual, up to and including termination. Those individuals who do not cooperate fully with the COIRC will be reported in writing to the Associate Vice President for Research with recommendations for appropriate disciplinary actions which may include cessation of research or other sanctions noted in the Conflict of Interest in Research Policy. The Associate Vice President for Research will impose any penalties or disciplinary actions that he/she deems necessary.

Individuals may also be subject to criminal sanctions or civil liabilities under federal or state law.

Violations of full and prompt disclosure may result in the loss of grant funding and sanctions regarding future funding from federal agencies.

In addition, if the federal department of Health and Human Services (HHS) determines that a Public Health Service (PHS)-funded project of clinical research to evaluate the safety or effectiveness of a drug, medical device, or treatment, was conducted by an investigator with a conflict of interest that was not disclosed or managed, as required by the Policy, the investigator will be required to disclose the conflicting interest in each public presentation of the results of the research. Any publications or presentations prior to the discovery of the non-disclosed conflict may need to be amended, retracted, or revised.

8.0 REFERENCES

- 8.1 *Saint Louis University's Financial Conflict of Interest in Research Policy, RC-001*, available under "F", at the following link: <http://www.slu.edu/research/faculty-resources/research-policies.php>
- 8.2 *Public Health Service Regulations, 42 CFR Part 50, subpart F*. See link: <https://www.ecfr.gov/cgi-bin/text-idx?rgn=div5&node=42:1.0.1.4.23#sp42.1.50.f>
And *45 CFR Part 94*, available at the following link: <https://www.ecfr.gov/cgi-bin/text-idx?SID=45d72cc56b4f3554cff69d63f17ab1ea&mc=true&node=pt45.1.94&rgn=div5>
- 8.3 *National Science Foundation Policies, NSF Proposal and Award Policies and Procedures Guide, NSF 19-1 February 25, 2019, Chapter IX. – Grantee Standards, Section A. Conflict of Interest Policies*. Check NSF website for latest edition. The 2019 guide is available at the following link: https://www.nsf.gov/pubs/policydocs/pappg19_1/pappg_9.jsp
- 8.4 *Saint Louis University Faculty Manual, St. Louis Campus, 2017*. See link: https://www.slu.edu/provost/policies/faculty-manual/faculty-manual_2017.pdf

9.0 RECISSION

Policy on Composition and Operation of the Saint Louis University Conflict of Interest in Research Committee, Version 2.0, dated November 14, 2011.

APPROVAL SIGNATURES

This policy has been approved by:

(Signed Copy on File)
Kenneth A. Olliff
Vice President for Research

Date: March 4, 2019

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