



SAINT LOUIS UNIVERSITY

POLICY ON THE COMPOSITION AND OPERATION OF THE SAINT LOUIS UNIVERSITY CONFLICT OF INTEREST IN RESEARCH COMMITTEE

Policy Number: RC002

Version Number: 2.0

Classification: Research Compliance

Effective Date: November 14, 2011

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 Conflict of Interest in Research Policy (RC001). The COIRC reports to the Vice President for Research and is guided by a chairperson appointed by the Vice President for Research. Perceived or actual 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 sponsor research at SLU. It is the responsibility of the COIRC to review all financial disclosures related to research projects that may indicate a conflict; to assist faculty in ensuring that actual or perceived financial conflicts of interest are minimized, eliminated, or otherwise managed; and to make recommendations to the Vice President for Research when management of a conflict is not possible.

In addition, the COIRC will develop guidance for 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 actual or perceived 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 Vice President for Research;

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

Of the nine voting members of the COIC, 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 also may be asked to serve as non-voting consultants to the COIRC as it considers complex issues (e.g., Institutional Review Board, Research Development and Services). The COIRC may develop sub-committees consisting of its members and other appropriate personnel to address specific issues.

4.0 FREQUENCY OF MEETINGS

The COIRC will meet monthly during the academic year, unless more frequent meetings are necessary in order to comply with federal conflict of interest reporting requirements. During the months of June, July, and August, the COIRC will meet as needed.

5.0 COMMITTEE RESPONSIBILITIES

The COIRC with assistance from the Division of Research Services shall:

1. solicit, receive, and review conflict of interest disclosures annually from faculty and other employees engaged in research at SLU and make final determinations as to whether a financial conflict exists;
2. receive and review ad hoc disclosures, including disclosures related to submission of proposals to external agencies;
3. advise faculty and other research employees of action required due to positive COIR disclosures.
4. ensure that management plans are appropriate and complete and are designed to reduce, manage, or eliminate financial conflicts;
5. work with the Office of the General Counsel to monitor and enforce management plans;
6. report to federal agencies as required when a conflict of interest exists for funded researchers;
7. provide oversight for conflict of interest education, including training programs for University personnel;
8. recommend additional policies for addressing conflict of interest consistent with this Policy;
9. ensure that the University's Conflict of Interest in Research policies and procedures remain in accordance with federal and state laws;

10. make recommendations to the 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 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 COI disclosures and all other confidential information related thereto.

6.0 PROCEDURES

All disclosure forms are launched from the University's electronic Research System (eRS) by the Manager of Responsible Conduct of Research on an annual or ad hoc basis.

Disclosure forms with no actual or apparent conflict of interest will undergo an expedited review by the Manager of RCR.

Disclosure forms where the potential for an actual or apparent conflict of interest exists will undergo a full review by the COIRC. Positive disclosures will be reported to the department Chair/Division Head and Dean of the School or College to whom the affected individual reports.

When necessary, the COIRC will discuss the disclosure with the individual involved and may also consult with others who may have relevant information. The affected individual 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 conflicting interest. In making these determinations, the COIRC will be guided by the principles discussed in Section 6.3 of the 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 individual, the Department Chair or Division Head, and the School or College Dean.

The affected individual may appeal the COIRC's decision to the 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 Conflict of Interest in Research Policy, including the requirements of disclosure. Individuals who deliberately or repeatedly fail to disclose fully and truthfully conflict of interest situations or fail to comply with any stipulated plan for managing the disclosed conflict 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 Vice President for Research with recommendations for appropriate disciplinary actions which may include cessation of research or other sanctions as noted in this section. The 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 liability 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 this 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

St. Louis University's Conflict of Interest in Research Policy, RC001.

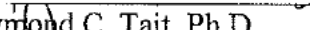
Public Health Service Regulations, 42 CFR Part 50, subpart F and 45 CFR Part 94.

National Science Foundation Policies, NSF Proposal and Award Policies and Procedures Guide

Saint Louis University Faculty Manual

9.0 APPROVAL SIGNATURES

The Policy has been approved by:


Raymond C. Tait, Ph.D.
Vice President for Research

Date: 11/14/2011

REVISION HISTORY		
EFFECTIVE DATE	REVISION NUMBER	MODIFICATION
June 1, 2009	1.0	New Document
November 14, 2011	2.0	Revision