SAINT LOUIS UNIVERSITY

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

Policy Number: RC002
Classification: Research Compliance
Responsible University Office: Provost’s Office

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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 for the betterment of mankind, and to ensure integrity in research, has established a Conflict of Interest Committee in Research (COICR) to oversee compliance with the University’s Conflict of Interest in Research Policy (RC001). The COICR reports to the Provost and is guided by a chairperson appointed by the Provost. Perceived or actual conflicts of interest on the part of SLU faculty are often complicated. Conflicts may 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 COICR to review all financial disclosures related to research projects and to assist faculty in ensuring that actual or perceived financial conflicts of interest are minimized, eliminated, or otherwise managed.

In addition, the COICR 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 Committee in Research (COICR), its membership, and its 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 COICR is charged with ensuring compliance with federal and University policies, regulations, and guidelines regarding financial conflicts of interest.

3.0 COMMITTEE MEMBERSHIP

The COICR consists of nine voting members, including:

1. at least one tenured or tenure-track member of the faculty appointed by the Executive Committee of the Faculty Senate;
2. at least two tenured or tenure-track faculty members from the University appointed by the Provost;
3. at least two tenured or tenure-track members from the Medical Center appointed by the Provost; and
4. a tenured Chairperson of the COICR appointed by the Provost. 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 Provost's Office will serve as ex officio non-voting COICR members. Other members of the University administration and faculty also may be asked to serve as non-voting consultants to the COICR as it considers complex issues (e.g., Institutional Review Board; Research Services). The COICR may develop sub-committees consisting of its members and other appropriate personnel to address specific issues.

4.0 FREQUENCY OF MEETINGS

The COICR 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 COICR will meet as needed.

5.0 COMMITTEE RESPONSIBILITIES

The COICR 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 conflicts 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 Provost 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 sent by the Department Chair or Division Head to the Manager of Responsible Conduct of Research for review by the COICR. Disclosure forms with no actual or apparent conflict of interest will undergo an expedited review.

Disclosure forms for which the COICR has determined that an actual or apparent conflict of interest exists will undergo a full review by the COICR. Positive disclosures will be reported by the Manager of Responsible Conduct of Research to the Dean of the School or College to whom the affected individual reports.

When necessary, the COICR will discuss the disclosure with the individual involved and may also consult with others who may have relevant information. These conversations will be confidential. The affected individual is entitled to meet with the full COICR if s/he wishes.

The COICR will determine whether a conflict of interest exists, and, if so, will develop a management plan with the input of the conflicted individual to effectively reduce, manage, or eliminate the conflicting interest. In making these determinations, the COICR will be guided by the principles discussed in Section 6.3 of the Conflict of Interest in Research Policy. Final approval of management plans rests with the COICR. If the COICR prescribes monitoring of the activity, it will describe specifically how the monitoring shall be performed, any reports that will be due, and what records are to be kept.

The COICR 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.

If the COICR determines that a financial conflict cannot be managed, reduced, or eliminated, the COICR chair, with consensus from the committee, will make recommendations to the Provost for action to be taken, which may include prohibiting the individual from doing research for which the conflict exists. The affected individual may appeal the COICR’s decision to the Provost, whose decision is 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. The COICR will report to the Provost in writing those individuals who do not cooperate fully with the COICR. The COICR will make recommendations for appropriate disciplinary actions which may include cessation of research or other sanctions as noted in this section and in the University’s Conflict of Interest in Research Policy (RC001). The Provost will impose any penalties or disciplinary actions that s/he deems
necessary, in accordance with University policy and depending on the severity of the non-compliance.

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 HHS determines that a PHS-funded project of clinical research whose purpose is 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, at a minimum, to disclose the conflicting interest in each public presentation of the results of the research. Other sanctions or penalties may be assessed at the discretion of the agency.

8.0 REFERENCES

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


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

Saint Louis University Faculty Manual

9.0 APPROVAL SIGNATURES

This policy has been prepared by:
Carole Knight, Ph.D., Associate Vice Provost for Research

The Policy has been approved by:

[Signature]
Manoj Patankar, Ph.D.
Interim Provost
Saint Louis University

DATE: Aug 1, 2009

Revision History

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