

# SAINT LOUIS UNIVERSITY

## FINANCIAL CONFLICT OF INTEREST IN RESEARCH POLICY

**Policy Number:** RC001

**Version Number:** 4.2

**Classification:** Research Compliance

**Effective Date:** November 1, 2013

**Responsible University Office:** Vice President for Research

### 1.0 INTRODUCTION

An integral part of the Mission Statement of Saint Louis University (hereinafter “the University” or “SLU”) is to seek excellence in the fulfillment of research. In support of this important goal, the University encourages and supports innovative and effective scholarship, research, and teaching in all fields, including the humanities; the natural, health, and medical sciences; the social sciences; law; business; aviation; and technology.

In recent years, corporate organizations have played an important role in research at universities as industry partners. Corporate involvement benefits research in many ways; however, financial incentives accompanying this involvement have the potential to lead to conflicts of interest. Financial conflicts of interest have the potential to bias research endeavors, which may compromise or appear to compromise research integrity. Such conflicts of interest may also affect or appear to affect research-related administrative duties, including the selection of equipment and supplies on sponsored research projects and the involvement of students and staff in sponsored projects. Such conflicts of interest may have the negative consequence of reducing public trust in the integrity of university research.

To protect against the potential risks involved with financial conflicts of interest in research and to comply with federal regulations, the University has developed this Financial Conflict of Interest in Research Policy. The University believes that establishing clear guidelines and principles for disclosing and managing potential, actual, and apparent conflicts of interest will assist in ensuring that the highest level of integrity is maintained in the University’s research endeavors. The existence of a financial conflict of interest does not indicate wrongdoing on the part of the investigator. However, if a conflict exists, it must be reduced, managed, or eliminated.

### 2.0 PURPOSE

This policy is intended to assist investigators, as that term is defined in this Policy, in structuring their relationships with industry and other outside entities in ways that will

not compromise their regular University duties or research obligations. This policy is also intended to maintain public trust in the University's research and to support institutional compliance with the Public Health Service (PHS) regulations contained in "Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought," 42 CFR part 50, subpart F, as revised by NOT-OD-11-109, "[Issuance of the Final Rule - Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors](#)"; and the National Science Foundation (NSF) requirements for conflict of interest policies; NSF Proposal and Award Policies and Procedures Guide at IV.A.; and other relevant government regulations.

### 3.0 APPLICABILITY

This policy applies to all personnel, whether or not SLU employees (including faculty members, adjunct instructors, research associates, research assistants, professional staff members, administrators, consultants, contractors, students, and others) participating in the design, conduct, and reporting of research and research-related educational activities. Questions about the applicability of the Policy or the requirements imposed by this Policy should be referred to the Manager of Responsible Conduct of Research, Fusz Hall, 2<sup>nd</sup> Floor, 314-977-7047.

### 4.0 GOVERNMENT RULES AND REGULATIONS

The Public Health Service (PHS), which includes the National Institutes of Health (NIH), requires institutions seeking PHS funding for research to maintain a written, enforced policy on conflict of interest that complies with applicable PHS regulations. The purpose of the PHS conflict of interest regulations is to "promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under PHS grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest." The National Science Foundation (NSF) also requires that each grantee institution employing over fifty persons maintain an appropriate written and enforced policy to ensure that research is not biased by an investigator's financial interests. Furthermore, other federal agencies also maintain similar guidelines regarding conflicts of interest.

### 5.0 DEFINITIONS

The following definitions apply to this Policy:

**5.1 Awarding Component** means the organizational unit of the federal agency or other sponsor that awarded the funds contributing to the subject research or educational activity.

**5.2 Business** means any corporation, partnership, firm, or other legal entity, whether for-profit or non-profit, whether publicly or privately held, but excluding the University.

**5.3 Financial Conflict of Interest (FCOI)** means a financial interest of an investigator that could directly and significantly affect the design, conduct, or reporting of the investigator's research or research-related educational activities.

5.3.1 **Financial Interest** means anything of monetary value, whether or not the value is readily ascertainable.

**5.4 Significant Financial Interest (SFI) means** a financial interest consisting of one or more of the following interests that reasonably appears to be related to the Investigator's institutional responsibilities and/or sponsored activities:

5.4.1 With regard to any publicly traded entity, an SFI exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000 to the Investigator, including the Investigator's spouse and dependent children. Remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); 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;

5.4.2 With regard to any non-publicly traded entity, an SFI exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse and dependent children) holds **any** equity interest (i.e., stock, stock option, or other ownership interest) regardless of the value; or

5.4.3 Intellectual Property rights and interests of the Investigator, including the Investigator's spouse and dependent children (e.g., patents, copyrights), upon receipt of income related to such rights and interest.

5.4.4 Investigators, including the investigator's spouse and dependent children, also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

5.4.5 Significant Financial Interest does not include the following types of financial interests:

- Salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights;
- Any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization;
- Income from seminars, lectures, or teaching engagements sponsored by a federal state, or local government agency, an Institution of higher education as defined at 20 U.S.C. § 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or
- Income from service on advisory committees or review panels for a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. § 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

**5.5 Investigator** means the principal investigator, co-investigator, and/or any other person(s) regardless of title or position, who have the potential to influence the design, conduct, or reporting of research or educational activities funded by a federal government agency or other external sponsor, or research that is proposed for such funding. In general, undergraduate students are not to be designated as “investigators” unless there is an expectation that they could significantly influence the design, conduct, or reporting of the subject research or educational activity.

**5.6 Senior/Key Personnel** means the 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. This does not include undergraduate students unless there is a reasonable expectation that they will contribute significantly to the scientific development or execution of a project.

**5.7 Significant Contributor** means an individual who commits to the scientific development or execution of the project, but does not commit any specified measurable effort to the project. Individuals with measurable effort may not be identified as Significant Contributors but rather should be considered Key Personnel.

**5.8 Research** means a systematic investigation, study or experiment designed and conducted to develop or contribute to the body of knowledge. Research includes basic and applied research as well as product development. This includes but is not limited to research grants, career development awards, center grants, individual fellowship awards, infrastructure awards, institutional training grants, program project, or research resources awards.

**5.9 Clinical Research** means any research or procedure involving human subjects or the use of human samples in the development, implementation, and evaluation of patient therapies, including drug therapies, diagnostic tests, and medical devices. This term includes clinical trials.

**5.10 Conflict of Interest in Research Committee (COIRC)** means the University committee committed to advancing research and fostering an entrepreneurial spirit at Saint Louis University while maintaining objectivity and integrity in research. The COIRC provides oversight for conflict of interest education, recommends policy, and reviews Conflict of Interest Disclosures. If a conflicting situation arises that will require management, the COIRC will consult with the investigator as needed to develop and implement an appropriate management plan.

**5.11 Disclosure** means a formal written statement of relevant information about financial interests related to the investigator's sponsored research or educational activities. Saint Louis University requires that disclosures are made on-line using the University's eRS (Electronic Research Services) system. Annual disclosures are required, as well as *ad hoc* disclosures when changes to annual disclosures occur. Investigators who have not submitted an annual disclosure must do so prior to submitting a proposal for submission to an external funder.

**5.12 Public Health Service (PHS)** means the operating division of the U.S. Department of Health and Human Services and any components of the PHS to which authority may be delegated.

**5.13 Health and Human Services (HHS)** means the United States Department of Health and Human Services and any components of HHS to which authority may be delegated.

**5.14 National Science Foundation (NSF)** refers to the independent agency of the federal government responsible for the promotion of progress in science and engineering by supporting programs in research and education.

**5.15 Sponsor** means an 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.

**5.16 Sponsored Travel** means reimbursed or compensated travel which is paid to the Investigator (including the investigator's spouse and dependent children), to the University, or paid on behalf of the Investigator, even in cases where the exact monetary value may not be readily available.

**5.17 Institutional Responsibility** as applied to Investigators, means all professional activities an Investigator provides to the University within his/her appointment including instruction, research, clinical (service), and administration.

## 6.0 POLICY

## 6.1 Guiding Principles

Although the University expects its employees to conduct themselves with the utmost integrity and honor in the engagement of all activities, there are certain activities that require particular sensitivity and attention. The following activities fall within this category:

- **Research.** Decisions concerning the nature and direction of scholarly research at the University should be governed by judgments of scholarly merit and intellectual importance. A faculty member's involvement with, or interest in, outside commercial or professional applications of research should not bias judgment concerning the faculty member's own scholarly research or that of other faculty or students.
- **Publication.** Free and open communication of the results of research is an important and longstanding policy of the University. Involvement in outside professional or commercial activities should not unnecessarily delay or inhibit the publication of scholarly research or the sharing of information derived from such research. Short-term delays in publication for consideration of proprietary information or related to patent applications are sometimes necessary. Investigators are expected to disclose relevant outside consulting arrangements or affiliations in their published scholarly works.
- **Education.** Students, residents, and fellows rely on faculty advice and guidance concerning educational matters within the University, including the nature and direction of research, as well as temporary and career employment opportunities outside the University. Such advice and guidance should always be governed by a student's best interest and should not be made to serve a faculty member's interest in outside commercial and/or professional activities.
- **Clinical Trials.** Faculty assuming the responsibility for the design, conduct, or reporting of clinical trials have a special obligation to avoid bias or the appearance of bias in the conduct of these studies. Clinical trials involving materials, devices, or procedures invented or discovered by faculty members (whether such invention or discovery took place at Saint Louis University or elsewhere) with the intention of commercial development require careful scrutiny. Similar concerns arise when a faculty member has a consulting engagement with a company whose product is the target of the clinical trial.
- **Intellectual Property.** Any research involving patents, materials, devices, or procedures invented or discovered by faculty members (whether such development took place at SLU or elsewhere) with the intention of commercial development requires careful scrutiny.
- **Human Subjects.** Research involving human subjects poses special concerns that require heightened scrutiny. Any possible conflict of interest relating to human subjects in research must be routinely disclosed to the Institutional

Review Board(s) (IRB) as part of the application for approval by the IRB, and disclosed when new conflicts arise.

- **Collaborative Research.** Research with entities external to SLU requires particular scrutiny, as the University is responsible for ensuring that all Key Personnel, including those at other institutions, comply with the PHS guidelines for conflict of interest in research.
- **Office/Laboratory Space and Other Resources.** Faculty members may make reasonable use of their office and office equipment for all activities permitted within the scope of their University employment. University facilities such as laboratories, scientific equipment, University personnel, or students should not be used primarily for the financial benefit of the faculty member or for the benefit of a business with which the faculty member is associated. A faculty member who wishes to use University laboratory space for a commercial project must follow other related policies as applicable, such as the Policy on Private Use of University Research Facilities, Research Facilities Lease Agreement, the Extramural Activities Policy, and the *Faculty Manual*.
- **Startup Companies.** Startup companies provide opportunities for development and commercialization of inventions and technology but also may create conflicts of interest and require a high level of review and management.

## 6.2 Recognizing Conflict of Interest

A conflict of interest exists under this Policy when the COIRC reasonably determines that a significant financial interest of an investigator could directly and significantly affect the design, conduct, or reporting of sponsored research or educational activities. If a conflict of interest is identified, it must be reduced, managed, or eliminated within 60 days of its discovery.

A critical step in handling potential conflicts is full disclosure of significant financial interests and, if a conflict of interest is identified, development and implementation of an appropriate management plan. The COIRC is committed to advancing research and fostering an entrepreneurial spirit at SLU while maintaining objectivity and integrity in research. If a conflicting situation arises that will require management, the COIRC will work in cooperation with the individual to develop and implement an appropriate management plan.

## 6.3 Termination of a Conflict

A conflict affecting a particular study or project continues to exist until the conflicted Investigator from Saint Louis University has completed the project and their portion of any subsequent publications or presentations, understanding that research data may take several years before publication takes place.

The conclusion of a conflicted study within the University's system can be determined as follows: (1) For studies involving human subjects, the COIRC will terminate the COI Management Plan when the IRB officially closes the related protocol; and (2) For research not involving human subjects, the COI Committee will terminate the COI Management Plan when the Office of Sponsored Programs officially closes the fund on the University's financial reporting system.

## **7.0 RESPONSIBILITIES**

### **7.1 University Responsibilities**

The University has the following responsibilities under this Policy, in order to fully comply with the requirements of federal regulations:

1. Maintaining on a publicly accessible Web site, an up-to-date, written, enforced policy on financial conflicts of interest that complies with federal regulations.
2. Informing each investigator and other covered persons of this Policy and reporting obligations under this policy, including relevant time frames;
3. Requiring each investigator to submit an updated disclosure of significant financial interests within 30 days of discovering or acquiring a new significant financial interest.
4. Requiring each investigator to complete training regarding this policy prior to engaging in research related to any PHS-funded grant and at least every four years, and immediately when any of the following occur:
  - a. The University revises this policy or procedures in ways that affect the requirements of investigators.
  - b. An Investigator is new to an Institution; or
  - c. The University finds that an Investigator is not in compliance with the University's financial conflict of interest policy or management plan.
5. Identifying and approving the Conflict of Interest Officer or Manager of Responsible Conduct of Research, who is responsible for soliciting and reviewing Conflict of Interest Disclosure Forms as specified in Section 8.0 of this Policy, and providing guidelines consistent with federal regulations to determine whether an investigator's SFI represents a financial conflict
6. Ensuring that all sub-grantees, subcontractors, and collaborators of federally funded research and educational activities comply with federal requirements regarding financial conflict of interest by either requiring investigators working for those entities to comply with this Policy or by requiring the entity to provide an assurance to the University that will enable the University to comply with federal regulations.

7. Providing initial and on-going FCOI reports to awarding agencies. Reporting the existence of any FCOI by University investigators or subrecipients to the appropriate sponsoring entity and assuring that they have been managed, reduced, or eliminated. For PHS-funded research, prior to expending any sponsored funds, the institution must report an FCOI to the PHS-awarding component and must report any interest identified as conflicting subsequent to the initial report within 60 days of that identification. For PHS funded research, this is accomplished through the eCommons website.

Information to be reported initially includes the following:

- Grant/Contract Number;
- Project Director/Principal Investigator or Contact PD/PI;
- Name of Investigator with Financial Conflict of Interest;
- Whether FCOI was managed, reduced, or eliminated;
- Name of the entity with which the Investigator has a FCOI;
- Nature of FCOI, (e.g., equity, consulting fees, travel reimbursement, honoraria);
- Value of the financial interest (0-4,999; \$5K – 9,999; \$10K – 19,999; amounts between \$20K and \$100 K by increments of \$20K; amounts above \$100K by increments of \$50K or statement that a value cannot be readily determined);
- A description of how the financial interest relates to PHS-funded research and the basis for the University’s determination that the financial interest conflicts with such research; and
- Key elements of the University’s management plan.

In addition, an Annual Report will be filed noting the status of the FCOI, and any changes to the management plan.

8. Promptly notifying federal sponsors and, where required by the funding agreement, private sponsors, if the failure of any investigator to comply with this Policy has, in the opinion of the COIRC, biased the design, conduct, or reporting of the sponsored research or educational activity.
9. Maintaining records of all financial disclosures and all actions taken by the University with respect to each conflicting interest in accordance with Section 12.0 of this Policy.

10. Overseeing the establishment of adequate enforcement mechanisms to promote conformance with this Policy and sanctions, as appropriate, against investigators who fail to comply with this Policy.
11. Making information available, upon request, to federal sponsors, regarding all disclosures of financial interests and the University's review of, and response to, such disclosures, whether or not the University determined that it resulted in a financial conflict of interest.
12. Making information available, upon request, to federal sponsors, regarding all conflicting interests identified by the University in research or educational activities sponsored by the entity in which the conflict exists and how those interests have been managed, reduced, or eliminated to protect the objectivity of the research activity.
13. Requiring investigators involved in a PHS-funded project of clinical research to disclose a conflicting interest in each public presentation of the results of clinical research, the purpose of which is to evaluate the safety or effectiveness of a drug, medical device, or treatment that has been determined by HHS to have been designed, conducted, or reported by an investigator with a conflicting interest that was not disclosed or managed.
14. Certifying in each application for funding sought from the PHS that the University has in effect an up-to-date, written, and enforced administrative process to identify and manage financial conflicts of interest with respect to all research project for which funding is sought or received from the PHS.

## **7.2 Investigator Responsibilities**

The effectiveness of this Financial Conflict of Interest in Research Policy relies upon the accurate and timely reporting of the Investigators. Investigators have the following responsibilities under this Policy:

1. Electronically completing and submitting, through the University's eRS system, an annual Conflict of Interest in Research Disclosure Form, as specified in Section 8.1 of this Policy, within thirty days of receiving the Form. The Investigator is also responsible for updating the Disclosure Form to account for changes in his/her financial interests that render the annual disclosure inaccurate or incomplete, also within thirty days of identifying the change. Investigators who have not previously completed the disclosure form must do so prior to submission of any proposal for external funding.
2. Cooperating with the COIRC in the development and verification of a management plan in those instances where the COIRC has determined that a conflict of interest exists that must be managed, reduced, or eliminated.

3. Complying with the terms and conditions of management plans, including providing required reports in a timely manner and updating information as needed.
4. Informing co-investigators, staff, students, other individuals, and personnel at institutions external to SLU who are involved in the design, conduct, or reporting of the investigator's externally sponsored research projects of their obligation to comply with this Policy, in accordance with any management plans.  
Undergraduate students are exempted from the policy unless they are significant contributors to the project and could influence the design, conduct, and reporting of the externally funded project.
5. Ensuring that external collaborators/subcontractors have submitted evidence of compliance with their institution's Conflict of Interest in Research policy, or, if none exists, ensuring that any external collaborators certify that they will comply with this policy. This includes projects for which no monetary value is placed on the collaborative effort (e.g., a no-cost consulting arrangement). SLU Principal Investigators have the same responsibility for these collaborators as they do for any SLU collaborators or Key Personnel.
6. If SLU researchers commit to a project for which the prime awardee is not SLU, and request no monetary compensation or other items of value, those researchers are not covered under SLU's Conflict of Interest in Research Policy and will not be certified by SLU as such. Such collaborative effort is considered to be the researcher's responsibility and should not involve SLU resources (e.g., laboratories, personnel, etc.).
7. Participating in required financial conflict of interest training within 30 days of the issuance of this original policy (August 24, 2012), and at least once every four years thereafter.
8. The Investigator is responsible for the accuracy of Conflict of Interest references in all grant-related documents submitted both within the Institution and outside the Institution.

### **7.3 Departmental Chair Responsibilities**

Each Department Chair and Division Head has the following responsibilities under this Policy:

1. Ensuring that investigators under their supervision are aware of this policy and their obligation to electronically submit the annual Conflict of Interest Disclosure Form and complete required training under this Policy.
2. Working with the COIRC and individual faculty in developing and implementing management plans to address any identified conflicts of interest.

3. Helping to determine whether a violation of this Policy has occurred.

## **8.0 PROCEDURES FOR DISCLOSURE AND REVIEW**

### **8.1 Annual Disclosure**

Each investigator engaged in or applying for externally sponsored research is required to complete an annual electronic Conflict of Interest in Research Disclosure Form using the eRS system. The Disclosure Form requires the investigator to list: (1) current and proposed sponsored research and educational activities; (2) all significant financial interests, as well as those of investigator's spouse and dependent children and, (3) an explanation of the connection, if any, between the sponsored activities and the significant financial interests.

Annual Disclosure Forms shall be submitted electronically through eRS. The Manager of Responsible Conduct of Research will triage the disclosures for review by the COIRC. Positive disclosures will be shared with the department chair or division head and the appropriate Dean. In matters where there are positive disclosures from Deans, they will be shared with the appropriate Vice President.

### **8.2 Travel Disclosures**

Investigators, including investigator's spouse and dependent children, also must disclose the occurrence of any reimbursed or Sponsored Travel. However, this disclosure requirement does not apply to travel that is reimbursed or sponsored by a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. § 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

Such disclosure will include the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. Further information may be requested to assist in the determination of whether or not a financial conflict of interest exists.

### **8.3 Ad Hoc Disclosures**

In addition to the annual disclosures, in each of the following circumstances, investigators are required to electronically file an ad hoc Conflict of Interest Disclosure Form through the eRS system: (1) the investigator did not submit a disclosure at the time of the annual disclosure and is planning to file an application for external funding with PHS, NSF, or any other external sponsor or to engage in such research prior to the next annual disclosure form submission or (2) significant financial interests of the investigator have changed, making the prior annual disclosure inaccurate or incomplete.

Ad hoc disclosures shall be submitted through the eRS system and will be reviewed in the same manner as the annual disclosures.

## 9.0 MANAGEMENT OF CONFLICTS OF INTEREST

If it is determined that an actual or apparent conflict of interest exists, the COIRC, in collaboration with the conflicted individual, will prepare a management plan to ensure the reduction, management, or elimination of the conflict. The input of the affected individual will help in devising an appropriate management plan. In addition, the Manager of Responsible Conduct of Research will notify the Dean of the School or College in which the affected individual works that a positive disclosure was made. The Research Compliance Officer of the Office of the General Counsel will be responsible for monitoring compliance with management plans. Non-compliance will be reported to the COIRC who will recommend further action to the Vice President for Research.

Examples of conditions or restrictions that might be imposed to manage, reduce, or eliminate actual or potential conflicts of interest include, but are not limited to:

- public disclosure of relevant significant financial interests;
- disclosure of financial interests to research subjects, co-investigators or students involved in the research;
- monitoring of the design, conduct, and reporting of the research by independent reviewers;
- modification of the research plan;
- disqualification of the conflicted individual from participation in any portion of the activity that would be affected by the significant financial interests;
- reduction or elimination of significant financial interests; or,
- severance of the relationships that create actual or potential conflicts.

## 10.0 SANCTIONS FOR NONCOMPLIANCE

Individuals are expected to comply fully with this Policy, including the requirements of disclosure. Investigators 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 as prescribed in the Saint Louis University *Faculty Manual* or other appropriate University guidelines, up to and including termination. The COIRC will report in writing to the Vice President for Research, those individuals who do not cooperate fully with the COIRC.

The COIRC will recommend to the Vice President for Research actions which may include, but are not limited to, the following:

1. Specific training for the investigator and/or members of the research team. Formats of such training could be on-line or face-to-face training sessions specifically designed for the identified transgression.
2. Increased frequency of disclosure, such as requiring the investigator to submit monthly reports or attend face-to-face meetings informing the Committee of any disclosure updates.
3. Heightened scrutiny on an investigator's disclosure, such as requiring the researcher to submit documentary evidence of the disclosure items. Examples include supporting tax documents, such as a 1099-DIV or Schedule K-1, bank statements, equity schedules, licensing agreements, etc.
4. Collaborative support from the investigator's department, such as requiring both the investigator and his/her department chair to participate in face-to-face meetings with the COI Committee to ensure disclosure accuracy and effective conflict management.
5. Freezing of externally sponsored funds.
6. Barring investigators from applying for future research.

In consultation with the appropriate Chair and Dean, the Vice President for Research will impose penalties or disciplinary actions that s/he 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 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, including loss of funding, fines, and/or debarment, may be assessed at the discretion of the agency.

## **11.0 NOTICE TO EXTERNAL SPONSORS**

### **11.1 Notification to PHS**

Prior to the expenditure of any funds under a PHS award, the University will report to the PHS Awarding Component within 60 days of its discovery the existence of any conflicting interest related to the specific PHS award that was identified by the University under the procedures set forth in this Policy. The University will report on that information regarding the conflict as required by agency guidelines. The notification will include an assurance that the conflict of interest has been managed, reduced, or eliminated.

In addition, if a financial conflict of interest is identified subsequent to the University's report to PHS as specified above, the University will notify the PHS Awarding Component of the existence of the conflicting interest and implement a management plan to manage, reduce, or eliminate the interest within 60 days of its identification.

If an investigator fails to comply with this Policy and has a financial conflict of interest in research funded by PHS that was not identified or managed in a timely manner due to noncompliance, the University will conduct a retrospective review of the Investigator's activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct or reporting of such research. The University will notify the PHS awarding agency within 120 days of the corrective action taken or to be taken by the University.

A copy of all notifications to PHS under this section will be kept in the office of the Manager of Responsible Conduct of Research and in the grant files to which the notifications pertain.

### **11.2 Notification to NSF**

In the event that the University is unable to satisfactorily manage, reduce, or eliminate a conflict of interest related to an NSF award, the University will notify NSF of the situation using the NSF FastLane System.

### **11.3 Notification to Other External Sponsors**

For external sponsors other than PHS and NSF, the University will notify the sponsor of identified conflicting interests when specifically required to do so by the sponsoring agency or in the funding agreement.

## **12.0 RECORD RETENTION**

### **12.1 PHS-Funded Research**

The University will maintain records of all financial disclosures and all actions it takes with respect to each conflicting interest in connection with PHS-funded research for at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 C.F.R. § 74.53(b) for different situations.

### **12.2 NSF-Funded Research**

The University will maintain records of all financial disclosures and of all actions taken to resolve conflicts of interest related to NSF-funded research and educational activities for at least three years beyond the termination or completion of the activity to which they relate, or until the resolution of any NSF action involving those records, whichever is longer.

### 12.3 Other Externally Sponsored Research Activities

For all other externally sponsored research activities, the University will maintain records of all financial disclosures and all actions it takes with respect to each conflicting interest for at least three years from the completion of the research activities to which they relate.

## 13.0 ACCESS TO RECORDS

The University will make information available, upon request, to HHS, NSF, and any other federal sponsors regarding all conflicting interests identified by the University that relate to research funded by the federal sponsor and how those interests have been managed, reduced, or eliminated to protect the sponsored research from bias.

Prior to expenditure of any funds under a PHS-funded research project, the University shall ensure public accessibility, via a written response to any requestor within five business days of a request, of information concerning any significant financial interest of senior/key personnel disclosed to the University that meets the following three criteria:

- (A) The significant financial interest was disclosed and is still held by the senior/key personnel;
- (B) The Institution determines that the significant financial interest is related to the PHS-funded research; and
- (C) The Institution determines that the significant financial interest is a financial conflict of interest.

This information will include the Investigator's name, title, and role with respect to the research project; the name of the sponsor in which the significant financial interest is held; the nature of the significant financial interest; and the approximate dollar value of the significant financial interest or a statement that the value of the interest cannot be readily determined.

## 14.0 REFERENCES

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

*NOT-OD-11-109, "Issuance of the Final Rule – Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is South and Responsible Prospective Contractors," issued August 22, 2011*

*National Science Foundation Policies, NSF Proposal and Award Policies and Procedures Guide at IV.A*

Saint Louis University Policy on Authorship for Scientific and Scholarly Publications, RC005

**APPROVAL SIGNATURES**

This policy has been approved by:

Signed by Raymond C. Tait, Ph.D.

October 24, 2013

\_\_\_\_\_  
Raymond C. Tait, Ph.D.  
Vice President for Research  
Saint Louis University

Date: \_\_\_\_\_

<b>REVISION HISTORY</b>		
<b>EFFECTIVE DATE</b>	<b>REVISION NUMBER</b>	<b>MODIFICATION</b>
February 13, 2003	1.0	New Document
March 1, 2006	2.0	Policy revision
August 1, 2009	3.0	Policy revision
August 24, 2012	4.0	Policy revision
October 29, 2012	4.1	Policy revision (clarification)
November 1, 2013	4.2	Policy revision (clarification)