



DEPARTMENT: ADMINISTRATION

NUMBER: C-27

Management Policy And Procedure

EFFECTIVE DATE: 10/2012

**SUBJECT: Financial Conflict of Interest (FCOI)
and Objectivity in Research**

SUPERSEDES: 8/2002,12/2006

PURPOSE:

Individuals conducting research at St. Luke's, including employees of St. Luke's as well as those requesting Protocol Review by the St. Luke's Institutional Review Board, must do so in compliance with applicable federal and state laws related to conflict of interest and objectivity in research.

This policy will set forth the principles for identifying the potential for conflicts and the procedures for reviewing and addressing those potential conflicts that do occur to assure that they do not improperly affect research and other activities.

Application: This policy applies when employees are responsible for, or in a position to influence the design, conduct or reporting of research or other scholarly activity.

POLICY STATEMENT:

Employees conducting research at St. Luke's must comply with all applicable state and federal laws and regulations, including those related to conflict of interest and objectivity in research. These laws include, but are not limited to, Federal Public Health Service (PHS) Regulations 42 CFR, part 50, subpart F (grants and cooperative agreements); and 45 CFR, part 94 (contracts) as revised on August 25, 2011 and effective no later than August 24, 2012 and provide that PHS sponsored investigators shall be subject to specific requirements regarding the disclosure and management of conflicts of interest with regard to research in order to provide a reasonable expectation that the design, conduct and reporting of PHS-sponsored research will be conducted free of bias resulting from Investigator financial conflicts of interest.

These regulations require that all organizations that receive PHS awards maintain a written policy on conflict of interest disclosure. As a participant in federal cooperative group studies St. Luke's is party to cooperative agreements and must comply with these regulations and will do so for all sponsored research endeavors.

St. Luke's shall post on the Clinical Research section of its Web site, this FCOI policy and prior to expenditure of funds, shall post on the Clinical Research section of its Web site certain information concerning FCOI's held by senior/key personnel to be updated annually and within 60 days of identifying new FCOI's.

St. Luke's will require FCOI training of all Investigators and research staff. It will accept evidence of previous training from outside investigators as well as new St. Luke's investigators and staff.

Investigators and Staff must make FCOI declaration according to St. Luke's policy. Whenever an FCOI is not identified or managed in a timely manner, including failure by the Investigator to disclose an SFI, failure by St. Luke's to review or manage an FCOI, or failure to comply with the management plan, St. Luke's shall complete and submit a retrospective review, according to federal guidelines, of the Investigator's activities and the project to determine bias in the design, conduct or reporting of such research.

DEFINITIONS:

1. Investigator – Project Director or Principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.
2. Institutional Responsibilities – means an Investigator's professional responsibilities on behalf of the institution, and as defined by the Institution in its policy on financial conflicts of interest, which may include for example: activities such as research, research consultation, teaching, professional practice, institutional committee memberships and service on panels such as Institutional Review Boards.
3. Significant Financial Interest (SFI) –
 - A. A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's Institutional responsibilities:
 - (i) With regard to any publicly traded entity, a *significant financial interest* 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. For purposes of this definition, 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 measure of fair market value;
 - (ii) With regard to any non-publicly traded entity, a *significant financial interest* 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 or dependent children) holds any equity interest (e.g., stock, stock options, or other ownership interest); or
 - (iii) Intellectual property rights and interests (e.g., patents copyrights), upon receipt of income related to such rights and interests.
 - B. Investigators 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 excluded sources provided in regulation.

C. SFI Exclusions –

- (i) Salary royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution;
- (ii) Intellectual Property Rights assigned to the Institution and agreements to share in royalties related to such rights;
- (iii) Any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization;
- (iv) Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;
- (v) Income from seminars, lectures, or teaching engagements sponsored by a federal, state or local government agency, and 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
- (vi) Income from service on advisory committees or review panels for a federal, state or local government agency, 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.

4. Sponsored Research – research projects involving funds, materials, or other compensation from outside sources under agreements that contain any of the following: The agreement binds St. Luke's or an affiliated institution to a line of scholarly or scientific inquiry specified to a substantial level of detail; a line-item budget is involved; financial reports are required; the award is subject to external audit; unexpended funds must be returned to the sponsor at the conclusion of the project; or the agreement provides for the disposition of either tangible or intangible properties that may result from the activity.

SUBJECT KEY WORDS:

Research, Financial Conflict of Interest

PROCEDURE:

1. Any time an employee plans to initiate an activity that has the potential for conflict of interest, the relevant business or significant financial interests must be disclosed before beginning the activity. Disclosure is required as described in the SFI definition above.

2. An employee must disclose relevant business or significant financial interests at the time of application for research support or technology transfer, if the proposal falls under the provisions of this policy. Funding for the project will not be accessible to the employee until the disclosure of financial interest is reviewed and approval is given, and other appropriate measures have been implemented in accord with this policy.
3. An employee must provide disclosure when a contribution is given to St. Luke's or St. Luke's Foundation from a business in which an employee has a business or significant financial interest if:
 - a. The contribution exceeds a value of \$1,000 in a given year, and
 - b. The employee knows or reasonably should know that any portion of the contribution will be used to benefit the employee's teaching, research, outreach, or public service activities.
4. Each Investigator and staff, including collaborators, consultants or subcontractors, must complete NIH-compliant training found at: <http://grants.nih.gov/archive/grants/policy/coi/tutorial/fcoi.htm> and submit the certificate of completion to St. Luke's IRB office. All existing St. Luke's Investigators and staff must complete this initial training by December 31, 2012. New Investigators must complete this training prior to study initiation. Renewal training may be required by St. Luke's in accordance with PHS regulations.
5. Principal Investigators of sponsored research at St. Luke's must complete the Financial Conflict of Interest section of the IRB's Research Application and acknowledge their reading and compliance with this policy C-27, by signature. In addition, if their financial situation changes during the research they are to resubmit the COI section of the Research Application.
6. Employees participating in research at St. Luke's are required annually to complete and submit the St. Luke's Conflict of Interest Statement found with Management Policy C-9, Conflict and Duality of Interest. Whenever changes occur that the employee believes may alter the business or significant financial interests previously disclosed, an updated form must be submitted within 30 days.
7. Employees must disclose relevant business or significant financial interests to sponsors of research and in reporting of research results by written or oral means. When submitting a paper for publication, an employee must disclose to the editor or any business or significant financial interest that may be affected by publication. This provision also applies to release of information to the news media.
 - a. Disclosure of a relevant business or significant financial interest must also be made by an employee who makes an appearance, either in person or by way of a written communication, before any public body, commission, group, or employee, to present facts or give an opinion respecting any issue or matter up for consideration, discussion, or action.
8. When considering approval of or monitoring activities, the St. Luke's senior officer may require the employee to submit additional clarifying information pertinent to the activity

under review. This supplemental information will be treated as nonpublic information to the extent allowed by law.

9. When employees participate in research involving sub-grantees, contractors, or collaborators outside St. Luke's, St. Luke's will take reasonable steps to ensure that investigators working for these outside entities comply with appropriate conflict of interest disclosure and review requirements. These steps may include requiring the investigators to comply with St. Luke's policy or obtaining written assurances from the outside entity that it complies with applicable federal regulations or sponsor policies on conflict of interest.

Review of Potential Conflict of Interest in Research

Review of any potential Conflict of Interest will occur through the same channels as outlined in St. Luke's Policy C-9, Conflict and Duality of Interest, which states: "If resolution of potential conflicts of interest is needed, it will be handled through the chain of command or at the Board of Directors level".

Management of FCOI's

St. Luke's will take necessary actions to manage FCOI's of its Investigators, will develop a management plan and monitor compliance. FCOI's of investigators and staff will be posted on the Clinical Research page of the St. Luke's website according to federal requirements.

If an Institution identifies an SFI that was not disclosed or reviewed in a timely manner, the designated official(s) shall within sixty (60) days review the SFI, determine if an FCOI exists and implement an interim management plan, if needed. St. Luke's shall then, if applicable, within 120 days of the determination of noncompliance, complete and submit a retrospective review, according to federal guidelines (using the federal FCOI electronic module, eRA Commons), of the Investigator's activities and the project to determine bias in the design, conduct or reporting of such research.

Enforcement

Breaches of this policy include, but are not limited to, failure to file, intentionally filing an incomplete, erroneous, or misleading conflict of interest statement, or failing to provide additional information as required by the approving authority. A violation of this policy may be the basis for discipline of an employee. If sanctions are necessary, they will be imposed in accordance with other applicable St. Luke's policies. The potential sanctions may include, but are not limited to:

1. Letter of admonition;
2. Ineligibility of the employee for grant applications, Institutional Review Board approval;
3. Suspension;
4. Dismissal.

FORMS:

None

REFERENCE:

Management Policy C-9, Conflict and Duality of Interest, Conflict of Interest Statement.

COORDINATION:

Director, Whiteside Institute

KEY INVOLVED DEPARTMENTS:

Whiteside Institute
St. Luke's Institutional Review Board
St. Luke's Compliance

APPROVED:

President/CEO