MERCY HEALTH

INSTITUTIONAL POLICY & PROCEDURE
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TITLE: Institutional Review Board Review of Research
RR 400 Investigator and Key Research Personnel Conflicts of Interest

ORIGINATOR: Institutional Official

APPROVAL: _____
Institutional Official

POLICY STATEMENT: It is the policy of the Mercy Health Institutional Review Board (IRB) that all conflicts, potential conflicts or perceived conflicts of interest be reported to the IRB for review to assure protection of the rights and welfare of participants in human subjects research. Conflicts of interest will be eliminated when possible and effectively managed and disclosed when they cannot be eliminated.

GENERAL PROVISIONS:
The purpose of this policy is to promote objectivity in programs and funding that support the research, scholarship and service mission of the Institution. It will do so by establishing standards to ensure there is no reasonable expectation that the design, conduct or reporting of funded research or cooperative agreements with companies or groups will be biased by any conflicting financial interest of research investigators, study staff, students or immediate family members. Complete disclosure and expeditious review of such conflicts or potential conflicts is in the best interest of all of those involved in the research and the administration. As such, the IRB has established the Research Conflict of Interest Committee (RCOIC). The members of the RCOIC will be appointed by the Chairperson of the IRB. The IRB Chairperson will delegate the RCOIC as the group responsible for evaluation of all potential significant conflicts of interest. All completed Research Conflict of Interest Disclosure forms with a box checked "yes", will be provided to the RCOIC for review. The RCOIC will determine if a potential or significant conflict of interest exists. The RCOIC will provide the Office of the IRB with their findings in writing and shall advise the IRB of the steps to be taken to disclose the conflict of interest as necessary. The IRB will review the RCOIC determination and will include in their approval determination letter what action shall be taken to resolve or disclose the conflict.

Required Training

In order to ensure research investigators and their research staff are aware of the required disclosure of potential financial conflicts of interest, an additional required module in the CITI program must be completed every three years or in the event the federal requirements are updated. The completion of the module is referenced in all CITI training certificates. This certificate must be turned into the Office of the SMHC IRB and will be kept on file in the Office of the IRB. If the investigator receives funding through an NIH grant or award, the investigator and all key research personnel will be required to complete the NIH Office of Extramural Research Financial conflict of interest online tutorial in addition to the CITI training modules. The NIH Financial Conflict of Interest Training certificate of completion must be submitted to the Office of the IRB upon completion of training. It must also be submitted with the initial application and continuing renewal documents for IRB review and records for any study that is NIH funded.

The IRB requires each investigator and their research staff update the disclosure form at least annually during the period covered by the grants, research study or project or within 30 days of identifying or acquiring a new significant financial interest and at one year after the study is completed.

Training will be documented by one or more of the following:

1) Submission of the CITI training that includes the specific Financial Conflict of Interest module being printed and provided to the Office of the IRB.
2) Submission of the NIH Financial Conflict of Interest completion training certificate being printed and provided to the Office of the IRB.
3) The printed name, signature and date of an investigator and key research personnel on an Office of the IRB training session attendance record.

Required Actions

As grantees, investigators are responsible to ensure they are compliant with the requirements set forth by any public health service for entering FCOI information into the PHS system provided. Investigators must report and disclose appropriately within the timelines required for each grant project in which they are involved.
Investigators must ensure that they and all key research personnel comply with all required procedures set forth by this policy.

Failure to Comply

The IRB Chairperson will review any instances of non-compliance with this policy and will send those to the Institutional Review Board Committee and/or the Institutional Official for further review and action. Non-compliance with this policy may result in sanctions or disciplinary action, including but not limited to one of more of the following:

- Written reprimand;
- Suspension of project funding;
- Suspension of research study(s)
- Restriction of privileges;
- Suspension without pay;
- Dismissal; and/or
- Other appropriate sanctions or discipline, depending on the severity and nature of the non-compliance.
- Potential notification of non-compliance to the research sponsor.

Existing Mercy Health and Trinity Health policies and procedures, and/or applicable and federal laws shall govern the procedures for imposing sanctions or discipline, and the nature of the sanctions.

DEFINITIONS:

Research/Conducting Research: "Research" shall mean any organized program of scientific inquiry. "Conducting Research" includes designing research, directing or serving as an investigator, performing laboratory experiments, having a role in soliciting informed consent from research subject or making decisions related to the eligibility of patients to participant in research, analyzing or reporting research data, or submitting manuscripts or abstracts concerning the research for publication.

Individual Conflict of Interest: A circumstance such that any action or decision in which an individual is substantially involved with the research may have direct or predictable effect on a financial interest of the individual, spouse, domestic partner, minor child, or organization in which the individual serves as an officer, trustee, partner or employee.

Key Research Personnel: The term investigator means the project director or principal investigator or any other person regardless of title or position, who is responsible for the design, conduct or reporting of research to be done at Saint Mary's Health Care.

Immediate Family Member: Spouse, domestic partner, or minor child.

Significant Financial Interest: Any of the following financial interests of any key research personnel, or his or her immediate family, in aggregate. (The thresholds described below apply to the aggregate ownership of a key research personnel and his / her immediate family. For example, if an Investigator, his/her spouse, domestic partner and dependent children own together $5,000 worth of equities in the sponsor and/or its affiliated companies). The thresholds do not apply to the combined ownership of all Investigators or Key Research Personnel.

1. Income in excess of $5,000 from a publicly-traded entity (a company whose stock is available for purchase by general public) during past 12 months.

2. Stock values in excess of $5,000 at the time of disclosure in a publicly traded entity.

3. A combination of the above two items (stock and income) that exceeds $5,000.

4. Any amount of equity (stock, stock options, or other ownership interest) in a non-publicly traded entity (such as a start-up company).

5. Compensation that exceeds $5,000 from a non-publicly traded entity in the past 12 months.

6. Income related to intellectual property rights paid by any source other than the investigators or Key Research Personnel's current institution.

7. Any reimbursed or sponsored travel paid by an entity, including non-profit organizations, but excluding travel sponsored by or reimbursed by a government agency, a U.S. institution or higher education or a research institute affiliated with such, a medical center or an academic teaching hospital. The specific details that must be disclosed are: the name of the entity sponsoring the travel and purpose, destination, and duration of the travel.

8. Any other interests required under the Institutional policy.

REFERENCES:

- 21 CFR 46.103, 107
- 21 CFR 56.107
- 21 CFR 54
- 45 CFR Part 50 subpart F
- 45 CFR Part 94
- 45 CFR 74.14, 74.62 and 92.43
- FDA Information Sheets, FAQ's, Section II, question 12
- OHRP Guidance on Financial Relationships
- CITI Financial Conflict of Interest: Overview of Investigator Responsibilities and COI Rules
- NIH Financial Conflict of Interest http://grants.nih.gov/grants/policy/coi/
- FDA Financial Disclosure by Clinical Investigators Guidance for Industry http://www.fda.gov/RegulatoryInformation/Guidances/ucm126832.htm
- Saint Mary's Health Care Policy, "Conflicts of Interest Policy" IP 02-104
- Trinity Health Conflict of Interest Policy 8-20
- Trinity Health Annual Conflict of Interest Disclosure Form
- Saint Mary's Health Care Annual Financial Disclosure Form
- HHS Final Rule August 25, 2011
- 42 CFR pts 50 & 94
- National Institute of Health Financial Conflict of Interest Online Research Tutorial http://grants.nih.gov/grants/policy/coi/tutorial/fcoi.htm
- Transparency Reports and Reporting of Physician Ownership or Investment Interests, 76 Fed Reg. 78742 (December 19, 2011) proposed rule. Section 6002 (Sunshine Law)
- Patient Protection and Affordable Care Act, Pub. L No 111-148, 124 Stat. 119 amended by Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 (herein after cited as PPACA) § 6402.

ATTACHMENT:
RR 400-A Investigator and Key Study Personnel Conflict of Interest Disclosure Form

PROCEDURE: All Mercy Health Campuses

RESPONSIBILITY	ACTION
Investigator Responsibilities.	1. Investigators, including their immediate family, must disclose to the Saint Mary's Health Care IRB (IRB) who has delegated authority to members who will serve as the Research Conflict of Interest Committee (RCOIC) for all conflicts/ potential conflicts of interest in association with the human subjects research project under review. This includes assuring that all Key Study Personnel conflicts are disclosed and reported as well. 2. Written disclosures must be performed and submitted:

A. With the initial IRB application using the IRB application form;
B. At each continuing review of the project using the continuing review form; and
C. Within 10 days of becoming aware of any change and/or previously undisclosed significant financial interest using the "Request for Modification Form" (IRB Form).

3. The Investigator must comply with all recommendations of the RCOIC to minimize the conflict.
4. Investigators are to complete the online CITI tutorial module for financial conflict of interest. Once completed the investigators must submit the completion certificate to the Office of the IRB.
5. Investigators are to complete the NIH Financial conflict of Interest training modules if their study is funded by the NIH. Once completed the investigators must submit the completion certificate to the Office of the IRB.
6. As grantees, investigators are responsible to ensure they are compliant with the requirements set forth by any public health service for entering FCOI information into the PHS system provided. Investigators must report and disclose appropriately within the timelines required for each grant project in which they are involved.

IRB Committee.

1. The IRB forwards disclosures of significant financial interest to the designated members of the RCOIC as appropriate.
2. The IRB may approve the research pending review and approval by the RCOIC.
3. The final recommendations of the RCOIC are sent to the IRB Committee Chair for review. If the RCOIC has not imposed any additional criteria that would impact the previously determined risk-potential benefit profile of the study, the Chair or a designated Committee Member may conduct an expedited review of the RCOIC final recommendation. Otherwise the research and the recommendations of the RCOIC are reviewed by the convened IRB.
4. The IRB may choose to accept or not accept the recommendations of the RCOIC. If the IRB does not accept the recommendations of the RCOIC, it will include in its decision and IRB minutes the reasons for non-acceptance in a letter to the RCOIC members and the Investigator.
5. If the IRB determines there is a conflict of interest, when the Investigator is so notified, the following options may exist:
    a. Investigator may submit an action plan of proposed handling of disclosure
    b. Investigator may choose to not do the study
    c. The study informed consent may be revised to include said disclosure
6. The Office of the IRB must provide educational opportunities for initial and continuing education

for investigators and key study personnel with regard to research conflict of interest.

7. The Office of the IRB will maintain the CITI modules and CITI program for research financial conflict of interest training for the institution.
8. The Office of the IRB will provide investigators and key study personnel with proper websites to access for completion of required research conflict of interest training.
9. The Office of the IRB will maintain an education record for the CITI including the module on research conflict of interest training and completion.
10. The Office of the IRB will maintain an education record for the NIH Financial conflict of interest training completion.
11. The Office of the IRB will maintain an education record for any type of research Conflict of Interest training by creating an attendance record and including documentation of the training as was presented.

IRB Specialist/IRB Coordinator

1. The CRA forwards any disclosures of significant financial interests to the RCOIC as applicable for review with a completed "Conflict of Interest Annual Financial Disclosure Form". In the event more information is needed to complete this form or there are additional questions, the CRA contacts the Investigator for more information or clarification prior to forwarding.
2. The CRA makes appropriate database entries assuring documentation of the conflicts of interest and the nature of the conflict in the notes section of the database.
3. The CRA assures that final recommendations from the RCOIC are reviewed by the IRB Chairperson and accepted by the IRB prior to releasing a signed approval letter.
4. The 2012 Financial Conflict of Interest Regulation requires that conflicts of interest policies, as well as any Significant Financial Interest (SFI) determined to be a "financial conflict of interest" or "FCOI", (defined as an SFI that could directly and significantly affect the design, conduct or reporting of PHS-funded research) must be made available on a publicly accessible website maintained by the grantee organization. CRA will assure accuracy of website.
5. The CRA will assist with the maintenance of training records for research conflict of interest.

Institutional Responsibilities

1.The RCOIC reviews all conflicts of interest deemed significant in accordance with Institutional policies and Federal regulations.
2. The RCOIC makes recommendations to the IRB according to IRB policies, as applicable.

3. The IRB is informed in writing of the outcome of the review from the RCOIC.
4. If the Institution's policy on Financial Conflicts of Interest (COI) includes standards that are more stringent than the 2012 FCOI Regulation, the Institution, Investigator and IRB must adhere to its internal policy and provide reports regarding identified interests in accordance with its own standards.
5. Provide educational opportunities for training and information on research financial conflicts of interest and disclosure.

CONCURRENT CONSENTS:

Institutional Official