

**MERCY MEDICAL CENTER IRB
CONFLICTS OF INTEREST IN RESEARCH POLICY**

**Effective: June 4, 2013
Revised: May 14, 2019**

I. PURPOSE:

The purpose of this policy is to ensure the objectivity and integrity of research conducted at Mercy Medical Center (“MMC”) or by Mercy Health Services (“Mercy”) employees and authorized agents¹ and to support MMC’s institutional compliance with the U.S. Public Health Service (“PHS”) regulations on Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 C.F.R. Part 50, Subpart F), Responsible Prospective Contractors (45 C.F.R. Part 94), Financial Disclosures by Clinical Investigators (21 C.F.R. Part 54) and other applicable regulations. This policy also promotes transparency of relationships between Mercy, its affiliates, and its employees with outside entities and individuals as they relate to the research conducted by Mercy or at MMC. Investigators who conduct research at MMC often have meaningful relationships and partnerships with outside entities that contribute to the production of knowledge and technology that benefit society by advancing the science of medicine. At times, these relationships may create, or appear to create, conflicts of interest. To maintain transparency, and ensure the integrity of the research process, these conflicts must be reviewed and managed accordingly. This policy, which provides for mandatory disclosure of financial interests by Investigators, explains how Mercy identifies, screens, and manages actual and potential conflicts to ensure that research is objective and free of outside bias.

II. SCOPE:

This policy applies to Investigators who are Mercy employees or authorized agents when they are engaged in Research regardless of the location or funding source of the Research. In addition, this policy applies to Investigators who are non-Mercy employees or agents when they are conducting Research at MMC regardless of the Research funding source.

III. DEFINITIONS:

- A. **“Conflict of Interest Official” (“COIO”)** means the individual identified by MMC who shall be responsible for overseeing the implementation and enforcement of this Policy. The Senior Vice President of Medical Affairs is designated as the COIO for MMC. The COIO or his or her designee is responsible for soliciting and reviewing disclosures of SFI (defined below) from each Investigator participating in Research at Mercy. The COIO also shall be responsible for ensuring MMC’s compliance with all federal regulations and requirements concerning conflicts of interest, including, but not limited to: monitoring compliance with FCOI Management Plans,

¹ Mercy employees and authorized agents includes employees and authorized agents of any subsidiaries and affiliates of Mercy Health Services, Inc., including, but not limited to, Mercy Medical Center, Inc., St. Paul Place Specialists, Inc., and Maryland Family Care, Inc.

enforcement of sanctions for noncompliance with this Policy and/or federal regulations, and maintenance of all records relating to disclosures and FCOI management.

- B. **“Conflict of Interest Committee” (“COI Committee”)** means a committee consisting of the COIO, the MMC IRB Chairperson, and a representative of the Mercy Corporate Compliance Department. The COI Committee shall assist the COIO, as needed, with determining whether an SFI is Related to the Research. If an SFI is Related to the Research, the COI Committee shall assist the COIO with determining whether an SFI constitutes an FCOI, developing an FCOI Management Plan, and implementing appropriate disciplinary actions in the event of any noncompliance with this Policy.
- C. **“Entity”** means any domestic or foreign, public or private, for-profit or not-for-profit, business, organization, or association; including but not limited to, a sole proprietorship, partnership, corporation, limited liability company (excluding U.S. Federal, state and local government agencies).
- D. **“Equity Interest”** means any ownership interest in an Entity, including but not limited to, stock or stock option, or partnership interest, as determined through reference to public prices or other reasonable measures of fair market value.
- E. **“Financial Interest” (“FI”)** means anything of monetary value, whether or not that value is readily ascertainable.
- F. **“Financial Conflict of Interest” (“FCOI”)** means a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of Research.
- G. **“Institutional Responsibilities” (“IR”)** means an Investigator’s professional responsibilities on behalf of Mercy or the Investigator’s employer. Examples of an IR include, but are not limited to:
 - (1) providing clinical or other professional services to patients of Mercy or the Investigator’s employer;
 - (2) serving on any boards or committees, including the IRB;
 - (3) providing teaching services; and
 - (4) performing research, including the Research described herein.
- H. **“Investigator”** means the project director or principal investigator and any other person, regardless of his or her title or position, who is responsible for the design, conduct, or reporting of research subject to this policy, including but not limited to collaborators and consultants.
- I. **“Key or Senior Personnel”** means the principal investigator or any other person identified as senior or key personnel in an application for grant funding to a federal

agency, progress report, or any other report required to be submitted by law or regulation, or any personnel considered to be essential to work performance and identified as key personnel in a contract proposal or contract with the Federal Government.

- J. **“MMC Institutional Review Board” (“IRB”)** means the board established by MMC that is charged with protecting the rights and welfare of human research subjects participating in research activities conducted at MMC or by Mercy employees or agents. Responsibilities of the IRB, for the purposes of this Policy, shall include reviewing FCOI Management Plans and consulting with the COI Committee, as needed, to ensure the safety and welfare of human subjects is protected.
- K. **“PHS-funded Research”** means any Research which is funded by PHS, including any component or agency of PHS. PHS includes, but is not limited to, the following agencies: the National Institutes of Health, the U.S. Food and Drug Administration, the Substance Abuse and Mental Health Services Administration, the Agency for Healthcare Research and Quality, the Centers for Disease Control and Prevention, and the Health Resources and Services Administration.
- L. **“PHS Regulations”** means the PHS regulations promoting objectivity in research (set forth at 42 C.F.R. Part 50, Subpart F and 45 C.F.R. Part 94), as they may be amended or replaced from time to time.
- M. **“Research”** means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge. The term encompasses basic and applied research that may or may not be published in an article, book or book chapter and product development (e.g., a diagnostic test or drug).
- N. **“Significant Financial Interest” (“SFI”)** means a FI consisting of one or more of the following interests of the Investigator (and those of the Investigator’s spouse and dependent children) that reasonably appear to be related to the Investigator’s Institutional Responsibilities:
 - (1) **For publicly traded Entities**, an SFI exists if the value of any Remuneration received from the Entity in the twelve months preceding the disclosure combined with the value of any Equity Interest of the Investigator in the Entity as of the date of disclosure, when aggregated, exceeds \$5,000. Remuneration includes salary and any payment for services not otherwise identified as salary, including but not limited to consulting fees, honoraria, and paid authorships.
 - (2) **For non-publicly traded Entities** (including but not limited to private “start-up” companies, closely held corporations, partnerships or sole proprietorships), an SFI exists if either:

- the value of any Remuneration received from the Entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or
 - the Investigator, or the Investigator's spouse or dependent children, holds any Equity Interest in the Entity;
- (3) Intellectual property rights and interests (e.g., patents, copyrights) upon receipt of income related to such rights and interests (including but not limited to royalties, or licensing revenues); or
 - (4) All reimbursed or sponsored travel that is paid on behalf of the Investigator and not reimbursed to the Investigator related to the Investigator's Institutional Responsibilities; however, for the purposes of this definition, 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 is not an SFI.

The term SFI does NOT include the following types of FI:

- (1) salary or other remuneration paid by Mercy or the Investigator's employer, if the Investigator is currently employed or otherwise appointed by Mercy or the Investigator's employer, including intellectual property rights assigned to Mercy or the Investigator's employer and agreements to share in royalties related to such rights;
- (2) 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;
- (3) income from seminars, lectures or teaching engagements sponsored by a Federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education; or
- (4) income from service on an advisory committees or review panels for a Federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

IV. POLICY:

A. Investigator Training:

Investigators must complete Mercy's Research Conflicts of Interest Training prior to engaging in Research at Mercy, at least once every four (4) years, and immediately upon the occurrence of one of the circumstances listed below:

- (1) When Mercy makes revisions to this Policy that impact an Investigator's responsibilities under this Policy;
- (2) When an Investigator is a new Investigator at Mercy; and
- (3) When Mercy finds that an Investigator is not in compliance with this Policy or with his/her FCOI Management Plan.

Training or access to training shall be provided by Mercy through NetLearning and shall include information regarding this Policy, Investigators' responsibilities under this Policy, and the PHS Regulations. Investigators must submit a certificate of completion for such training through IRBNet with each new study submission and as otherwise specified by Mercy.

B. Investigator Disclosure of SFIs:

Each Investigator, including principal investigators, project directors, and any other person who is responsible for the design, conduct or reporting of the Research, shall disclose all SFIs:

- (1) Upon submission of a new Research proposal to the IRB, prior to submission of an application for Research funding, or when otherwise required by an agency or Entity sponsoring the Research;
- (2) At least annually on or before each July 1; and
- (3) Within thirty (30) days of the discovery or acquisition (e.g., through purchase, marriage, or inheritance) of a new SFI.

Investigators shall complete the financial disclosure form attached as **Exhibit A** and submit it through IRBNet with any submission of a new Research proposal to the IRB. The COIO or his or her designee shall notify the Investigator if further information is needed in order to determine whether an SFI constitutes an FCOI, and the Investigator shall provide any additional information requested. New Research proposals submitted through IRBNet will not be reviewed by the IRB until all Investigators involved in the Research have submitted, and the COIO or his or her designee has reviewed, the Investigators' financial disclosure forms.

Investigators shall complete the annual financial disclosure form attached as **Exhibit B** and submit it through IRBNet on or before each July 1, regardless of whether an SFI was previously disclosed in an ongoing research study. The COIO or his or her designee shall review such disclosures.

Investigators are also responsible for submitting an updated financial disclosure form (**Exhibit A**) on IRBNet within thirty (30) days of discovery of a new SFI.

C. Review of Disclosures and Determination of FCOIs:

(1) Review of Disclosures

The COIO or his or her designee shall be responsible for the review of all SFIs disclosed in order to determine whether an SFI is “Related to the Research” being conducted by the Investigator. The COIO may convene the COI Committee to assist in making this determination. An SFI will be deemed to be “Related to the Research” if: (1) the SFI could be affected by the Research, or (2) is in an Entity whose financial interest could be affected by the Research. The COIO or his or her designee may seek input from the Investigator to determine whether the SFI is related to the Research.

(2) FCOI Determination

If the COIO or his or her designee determines that the SFI is Related to the Research, the COI Committee shall determine whether the SFI is an FCOI. An SFI shall be treated as an FCOI if the COI Committee determines that the SFI could directly and significantly affect the design, conduct, or reporting of the Research. If it is determined that an FCOI exists, then the COI Committee shall communicate this to the Investigator and determine how to manage or eliminate the FCOI.

(3) SFIs Reported or Discovered During Ongoing Research

If, during the course of ongoing Research, an Investigator who is new to the Research discloses an SFI, an existing Investigator discloses a new SFI, or Mercy identifies an SFI that was not timely disclosed by an Investigator or previously reviewed, the COIO and/or the COI Committee shall, within 60 days of the disclosure, review the SFI and determine whether it is Related to the Research and constitutes an FCOI, and if applicable, implement an FCOI Management Plan and, for PHS-funded Research, submit an FCOI report to the appropriate PHS funding agency.

For any SFIs disclosed or discovered during the course of Research that requires making an FCOI report to a funding agency, Mercy shall also complete a retrospective review (see Section V.B below) to determine whether the Research, or a portion thereof, conducted prior to the identification and management of the FCOI biased the design, conduct, or reporting of such Research. If bias is found, Mercy shall notify the PHS funding agency and submit a mitigation report.

D. Management of FCOIs:

(1) Creation of an FCOI Management Plan

If the COI Committee determines that an FCOI exists, it shall create and document an FCOI Management Plan that specifies the actions that have been and/or shall be taken to manage the FCOI. The Investigator’s input regarding what actions should be included in the FCOI Management Plan shall be considered by the COI Committee. Examples of conditions and

restrictions that may be imposed to manage an FCOI on either an interim or permanent basis include, but are not limited to:

- Public disclosure of the FCOI (e.g., when publishing or presenting the Research);
- If the research involves human subjects, disclosure of the FCOI directly to participants;
- Appointment of an independent monitor capable of taking measures to protect the design, conduct and reporting of the Research against potential bias resulting from the FCOI;
- Modification of the Research plan;
- Change of personnel or personnel responsibilities or disqualification of personnel from participating in all or a portion of the Research, including interim disqualification of personnel from the Research between the date of disclosure and the completion of Mercy's review of the matter;
- Reduction or elimination of the SFI (e.g., sale of an equity interest); or
- Severance of the relationship giving rise to the FCOI.

Once the COI Committee has created and documented an FCOI Management Plan, it shall submit the Management Plan to the IRB and the IRB shall consider the Management Plan during its review of the proposed Research.

(2) IRB Review of FCOI Management Plan

The IRB shall not render a decision regarding proposed new Research studies until after the COIO or his or her designee has reviewed each Investigator's SFI disclosures. If the COI Committee determines that any Investigator has an FCOI Related to the Research, the IRB shall review the proposed FCOI Management Plan proposed by the COI Committee. Prior to approving the Research, the IRB may propose to the COI Committee that modifications or additional protections be added to the FCOI Management Plan for the protection of human participants. The COI Committee may adopt or reject the IRB's proposed changes to the FCOI Management Plan and resubmit the plan to the IRB for consideration. The IRB has final authority over whether to approve the proposed Research.

(3) Investigator Responsibilities Regarding FCOI Management Plan

The Investigator must agree to abide by the FCOI Management Plan before the FCOI Management Plan may be finalized. Both the Investigator and the COIO shall sign the finalized FCOI Management Plan. If Mercy finds the Investigator is not in compliance with an FCOI Management Plan, the Investigator must comply with all corrective actions, enforcement mechanisms, and/or sanctions imposed by Mercy.

Funding for PHS-funded Research shall not be released unless and until the FCOI Management Plan has been implemented and agreed to by the Investigator. If funds have already been released, the COIO or his or her designee may request the funding to be held

pending the FCOI determination and the Investigator's agreement to the FCOI Management Plan, if any.

(4) Monitoring of FCOI Management Plan

The COIO or his or her designee will monitor Investigator compliance with the FCOI Management Plan on an ongoing basis until the completion of the Research.

E. External Reporting and Access to Information

The COIO shall be responsible for ensuring that all FCOI reports and other required information is submitted to the PHS funding agency for PHS-funded Research in accordance with the PHS Regulations. For PHS-funded Research, FCOI reports must be filed: (1) prior to Mercy's expenditure of funds; (2) within sixty (60) days of discovering any SFI that is an FCOI subsequent to the initial FCOI report during ongoing PHS-funded Research; and (3) annually with respect to any FCOIs previously reported in ongoing PHS-funded Research.

Mercy shall make a copy of this policy available on its website. Mercy shall make available to the public information concerning FCOIs of Investigators in PHS-funded Research that meet the following criteria: (1) the SFI is held by Key or Senior Personnel; (2) Mercy determines the SFI is Related to the PHS-funded Research; and (3) Mercy determines that the SFI is an FCOI. Mercy will make the information required by the PHS Regulations available within five (5) business days of the COIO's receipt of a written request.

F. Subrecipient Investigators:

In the event that Mercy is a primary awardee of PHS-funded Research and intends to carry out any part of the Research through a subrecipient Investigator (i.e., subcontractors, or consortium members), Mercy and the subrecipient shall enter into a written agreement whereby the subrecipient shall: (i) abide by all requirements and procedures established by this Policy; or (ii) abide by the conflicts of interest policy established by the subrecipient.

If the subrecipient will comply with the subrecipient's conflict of interest policy, the subrecipient will certify that that policy complies with the PHS Regulations. If the subrecipient cannot provide such certification, the subrecipient shall be subject to this Policy and shall be responsible for disclosing SFIs that are related to the subrecipient's work for Mercy in accordance with the terms of the written agreement with Mercy.

The COIO shall provide FCOI reports to the PHS funding agency regarding all FCOIs of subrecipients consistent with the PHS Regulations.

G. Record Retention

Mercy shall maintain records relating to Investigator SFI disclosures and Mercy's review and determination related to each disclosure (whether or not a disclosure resulted in a determination of an FCOI) and all actions under this Policy. Mercy shall retain these records for

at least three (3) years following completion/closure of non-PHS funded Research, or for three (3) years from the date of submission of the final expenditures report is submitted to the PHS funding agency for PHS-funded Research.

V. NONCOMPLIANCE:

A. Disciplinary Action:

Any suspected noncompliance with this Policy, including but not limited to an Investigator's failure to disclose an SFI according to this Policy or failure to abide by an applicable FCOI Management Plan, shall be handled by the COIO in accordance with any applicable regulatory requirements and Mercy's policies and procedures, including the IRB's policies on noncompliance. The COIO may convene the COI Committee to assist with determining proper disciplinary action to be taken against the Investigator and corrective actions to be taken by the Investigator. Potential disciplinary actions for noncompliance with this Policy include, but are not limited to, suspension of all the Investigator's Research activities or other disciplinary or employment actions deemed appropriate by the COIO.

In PHS-funded Research, the COIO will promptly notify the appropriate PHS federal agency of the disciplinary or corrective action taken or to be taken. If the funding for Research is made available from a primary awardee (such that the Mercy Investigator is a sub-investigator), such notification shall be made promptly to the primary awardee for reporting to the appropriate PHS federal agency.

B. Retrospective Review:

For PHS-funded Research, if the COIO or his or her designee determines that an FCOI was not identified or managed in a timely manner, including when an Investigator fails to disclose a SFI or fails to abide by an FCOI Management Plan, the COIO or his or her designee shall complete a retrospective review. The COIO may convene the COI Committee to assist with this retrospective review. This retrospective review must commence within 120 days of Mercy's determination of noncompliance with this Policy, and shall focus on determining whether the Research conducted during the period of noncompliance was biased in the design, conduct or reporting of the Research.

This retrospective review will be completed in the manner and within the time frame established by the PHS Regulations. If bias is found, the COIO will promptly notify the PHS funding agency and submit a mitigation report in accordance with the PHS Regulations. Mercy shall document the retrospective review in accordance with the PHS Regulations.

The COIO shall update any previously submitted FCOI report to the applicable PHS funding agency or to the primary awardee relating to the Research, specifying the actions that will be taken to manage any newly identified FCOI going forward.

In the event that the U.S. Department of Health and Human Services, or one of its agencies, determines that PHS-funded Research whose purpose is to evaluate the safety or

effectiveness of a drug, medical device, or treatment has been designed, conducted or reported by an Investigator with an FCOI that was not managed or reported by Mercy as required by the PHS Regulations, Mercy shall require the Investigator involved to disclose the FCOI in each public presentation regarding the Research results and to request an addendum to previously published presentations.

VI. INVESTIGATOR DISCLOSURES FOR FDA-REGULATED RESEARCH

The Food and Drug Administration (“FDA”) Financial Disclosure by Clinical Investigators regulation (21 C.F.R. Part 54) requires applicants who submit marketing applications for human drugs, biological products, or devices or who submit covered clinical studies to the FDA, to submit information regarding the compensation to, and financial interests and arrangements of, any Clinical Investigator conducting covered clinical studies. The FDA requires the applicant to certify the absence of certain financial interests or to disclose those financial interests and arrangements and identify any steps taken to minimize the potential for bias. The applicant must provide this certification or disclosure for each “Clinical Investigator,” which means “a listed or identified investigator or subinvestigator who is directly involved in the treatment or evaluation of research subjects” and the Clinical Investigator’s spouse and dependent children. The certification or disclosure statements shall include complete and accurate information regarding any financial interests, as defined by 21 C.F.R. § 54.2, held by a Clinical Investigator who participates in a covered clinical study.

Any Clinical Investigator who participates in an FDA covered clinical study shall provide to the sponsor of the covered study sufficient accurate financial information to allow the sponsor to complete the required certification or disclosures described in this Section. The Clinical Investigator shall update this information if any relevant changes occur in the course of the Research, or during the one year following completion of the study.

REFERENCES:

- Title 42 Code of Federal Regulations (“CFR”), Part 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought
- Title 45 CFR, Part 94, Responsible Prospective Contractors
- Title 21 CFR, Part 54, Financial Disclosures by Clinical Investigators

ATTACHMENTS:

- **Exhibit A: Investigator Financial Interests Report**
- **Exhibit B: Annual Investigator Financial Interests Report**

APPROVED BY:

Wilma Rowe, M.D.
SVP of Medical Affairs

Ralph Lebron, M.D.
IRB Chairperson

Exhibit A

Investigator Financial Interests Report

This Report is submitted pursuant to the requirements of the MMC IRB Conflicts of Interest in Research Policy.

SECTION 1: INVESTIGATOR INFORMATION

Investigator Name:	
Investigator Phone and Email:	
Investigator Role:	<input type="checkbox"/> Principal Investigator <input type="checkbox"/> Sub-Investigator <input type="checkbox"/> Research Coordinator <input type="checkbox"/> Data Collection <input type="checkbox"/> Other _____
Financial Disclosure for:	<input type="checkbox"/> Initial/New Study <input type="checkbox"/> Amendment/Update

SECTION 2: STUDY INFORMATION

Protocol Title/Name:	
PI Name:	
PI Affiliation/Employer:	
Study Sponsor(s)/Funding Source(s):	
If funded through a sub-contract awarded to Mercy, list the primary awardee and original funding agency (e.g., NIH):	

SECTION 3: FINANCIAL INTERESTS AND/OR RELATIONSHIPS

Indicate you and your Immediate Family’s financial interests and relationships that are Related to the Research:

For the purposes of this Report:

- “**Immediate Family**” means spouse, domestic partner, or dependent children.
- “**Related to the Research**”* means any compensation from or interest in the sponsor, product, or service being tested, or compensation from or interest in a competitor of the sponsor, held by the Investigator or the Investigator’s Immediate Family.

*If you have any question or uncertainty about whether a financial interest or relationship is Related to the Research, you should disclose it.

Yes	No	1. Compensation. Have you or your Immediate Family received compensation Related to the Research in <u>any amount</u> including, but not limited to: <i>honoraria, gifts, consultant fees, speaker fees, expert witness fees, sponsored or reimbursed travel expenses, advisory board membership, or any other income?</i>
Yes	No	2. Equity. Do you or your Immediate Family have any equity interest Related to the Research of <u>any value</u> including, but not limited to: <i>stock or stock options with a publicly-traded or privately owned entity?</i>

Yes	No	3. Role. Do you or your Immediate Family have any board or executive relationship Related to the Research (regardless of whether you receive any compensation for such role) including, but not limited to: <i>Data Safety Monitoring Board or Scientific Advisory Board membership; service as a Director, Trustee, Officer or other key employee in a for-profit corporation, partnership, business, or other entity outside of the Mercy?</i>
Yes	No	4. Proprietary interest. Do you or your Immediate Family have any proprietary interest Related to the Research of <u>any value</u> , including, but not limited to: <i>rights, royalties, patents, copyrights, licensing agreements, and trademarks, but excluding academic or scholarly works?</i> You do NOT need to include intellectual property owned or managed by Mercy or the Investigator's employer.

If you answered **YES** to any of the questions above, fill out Section 4 below and attach additional sheets as necessary to describe the financial interest or relationship.

SECTION 4: INFORMATION ON FINANCIAL INTERESTS AND/OR RELATIONSHIPS

You have indicated that you have a financial interest or relationship with a sponsor or other entity that is Related to the Research. Please provide more information about this interest/relationship below. If you have an interest or relationship with more than one sponsor or entity that is Related to the Research, fill out a separate table for each Entity.

Name of the Entity:				
Entity's business and its relationship to the research:				
	Reporting For?		<u>\$ Value in Prior 12 Months?</u>	<u>Anticipated \$ Value in Next 12 Months?</u>
	Yourself	Immediate Family Member		
Lectures, Speaker Fees				
Consulting, Advising				
Scientific Advisor, Scientific Advisory Board				
Data Safety Monitoring Board				
Management or Executive Position				
Board Member, Officer, Director				
Provide Education, CME, develop educational materials				
Employment, Independent Contractor				
Intellectual Property Rights (personal ownership)				
Royalties				
Gifts > \$250 in Value				
Sponsored or Reimbursed Travel				
Other				
Stock Ownership, Business				

Ownership				
For stock, stock options, and/or business ownership, provide you or your Immediate Family's aggregated interests:				
#Stock Shares: _____				
# Stock Options: _____				
% Business Ownership: _____				
Describe how you or your Immediate Family's financial interests and/or relationships might have the potential to affect, or be affected by, this proposed research:				

Certification:

By submitting this Report, I certify the following:

- I have read and understand that I am responsible for complying with the Mercy Medical Center IRB's policy on Conflicts of Interest in Research;
- The information provided in this Report is true and correct to the best of my knowledge;
- If required, I will comply with any conditions or restrictions imposed by Mercy or the IRB to manage any real or perceived conflicts in the Research; and
- If my financial or managerial interests, or those of my Immediate Family, change in a way that result in different answers to any of the questions asked in this Report, I agree to submit an amended report within thirty (30) days of the change in interest.

Date

Signature

INTERNAL USE ONLY	
<input type="checkbox"/>	No Financial Interest
<input type="checkbox"/>	Financial Interest not directly Related to Research; no further action required
<input type="checkbox"/>	Financial Interest appropriated managed, reduced, or eliminated; no further action required
<input type="checkbox"/>	COI determined to be too severe; research not approved

Exhibit B

Annual Investigator Financial Interests Report

This Annual Report is submitted pursuant to the requirements of the MMC IRB Conflicts of Interest in Research Policy. This Annual Report is due on or before July 1 of each year.

SECTION 1: INVESTIGATOR INFORMATION

Investigator Name:	
Date (month/day/year):	
Investigator Phone and Email:	
Investigator Role (check all that apply):	<input type="checkbox"/> Principal Investigator <input type="checkbox"/> Sub-Investigator <input type="checkbox"/> Research Coordinator <input type="checkbox"/> Data Collection <input type="checkbox"/> Other _____

SECTION 2: FINANCIAL INTERESTS AND/OR RELATIONSHIPS

Indicate you and your Immediate Family’s financial interests and relationships that are Related to any ongoing Research that you are engaged in:

For the purposes of this Annual Report:

- “**Immediate Family**” means spouse, domestic partner, or dependent children.
- “**Related to Research**”* means any compensation from or interest in the sponsor, product, or service being tested, or compensation from or interest in a competitor of the sponsor, held by the Investigator or the Investigator’s Immediate Family.

*If you have any question or uncertainty about whether a financial interest or relationship is Related to Research, you should disclose it.

Yes	No	1. Compensation. Have you or your Immediate Family received compensation Related to Research in <u>any amount</u> including, but not limited to: <i>honoraria, gifts, consultant fees, speaker fees, expert witness fees, sponsored or reimbursed travel expenses, advisory board membership, or any other income?</i>
Yes	No	2. Equity. Do you or your Immediate Family have any equity interest Related to Research of <u>any value</u> including, but not limited to: <i>stock or stock options with a publicly-traded or privately owned entity?</i>
Yes	No	3. Role. Do you or your Immediate Family have any board or executive relationship Related to Research (regardless of whether you receive any compensation for such role) including, but not limited to: <i>Data Safety Monitoring Board or Scientific Advisory Board membership; service as a Director, Trustee, Officer or other key employee in a for-profit corporation, partnership, business, or other entity outside of the Mercy?</i>
Yes	No	4. Proprietary interest. Do you or your Immediate Family have any proprietary interest Related to Research of <u>any value</u> , including, but not limited to: <i>rights, royalties, patents, copyrights, licensing agreements, and trademarks, but excluding academic or scholarly works?</i> You do NOT need to include intellectual property owned or managed by Mercy or the Investigator’s employer.

If you answered **YES** to any of the questions above, fill out Section 3 below and attach additional sheets as necessary to describe the financial interest or relationship.

SECTION 3: INFORMATION ON FINANCIAL INTERESTS AND/OR RELATIONSHIPS

You have indicated that you have a financial interest or relationship with a sponsor or other entity that is Related to Research. Please provide more information about this interest/relationship below. If you have an interest or relationship with more than one sponsor or entity that is Related to Research, fill out a separate table for each Entity.

Name of the Entity:				
Entity's business and its relationship to the research:				
	Reporting For?		<u>\$ Value in Prior 12 Months?</u>	<u>Anticipated \$ Value in Next 12 Months?</u>
	Yourself	Immediate Family Member		
Lectures, Speaker Fees				
Consulting, Advising				
Scientific Advisor, Scientific Advisory Board				
Data Safety Monitoring Board				
Management or Executive Position				
Board Member, Officer, Director				
Provide Education, CME, develop educational materials				
Employment, Independent Contractor				
Intellectual Property Rights (personal ownership)				
Royalties				
Gifts > \$250 in Value				
Sponsored or Reimbursed Travel				
Other				
Stock Ownership, Business Ownership				
For stock, stock options, and/or business ownership, provide you or your Immediate Family's aggregated interests:				
#Stock Shares: _____				
# Stock Options: _____				

% Business Ownership: _____				
Describe how you or your Immediate Family's financial interests and/or relationships might have the potential to affect, or be affected by, this research:				

Certification:

By submitting this Annual Report, I certify the following:

- I have read and understand that I am responsible for complying with the Mercy Medical Center IRB's policy on Conflicts of Interest in Research;
- The information provided in this Annual Report is true and correct to the best of my knowledge;
- If required, I will comply with any conditions or restrictions imposed by Mercy or the IRB to manage any real or perceived conflicts in the Research; and
- If my financial or managerial interests, or those of my Immediate Family, change in a way that result in different answers to any of the questions asked in this Annual Report, I agree to submit an amended Financial Interests report within thirty (30) days of the change in interest.

Date

Signature

INTERNAL USE ONLY	
	No Financial Interests
	Financial Interests not directly Related to Research; no further action required
	Financial Interest appropriated managed, reduced, or eliminated; no further action required
	COI determined to be too severe; research not approved