Mercy Health Cincinnati LLC ("Mercy")
Financial Conflicts of Interest Policy- Research

1. Purpose

1.1 The purpose of this policy is to set forth the framework for identifying, evaluating, and managing any potential or real financial conflict of interest in order to promote objectivity in research and to minimize the risk of bias resulting from Investigator financial conflicts of interest (and/or of the Investigator's spouse and/or dependent children). In addition, this policy is meant to comply with Federal regulations (42 CFR, Part 50, Subpart F; 21 CFR, Part 54; 45 CFR, Part 94).

2. Applicability

2.1 This policy will be interpreted broadly to accomplish its purpose. It will be construed to apply to all entities and locations of Mercy that engage in research activities.

2.2 This Policy applies to Investigators (including principal Investigators, co-principal Investigators, and sub investigators[1]) who are participating in, or planning to participate in the design, conduct, or the reporting of research regardless of the funding source. This policy does not apply to Phase I applications and awards supported under the Small Business Innovation Research/ Small Business Technology Transfer Research programs ("SBIT/SBTTR").

(a) Sub-contractors, sub-recipients, and collaborators must either comply with this policy or provide a certification to Mercy that their institutions are in compliance with pertinent federal policies and that they in turn are in compliance with their own institutional policies.

3. Definitions[2]

3.1 *Financial conflict of interest ("FCOI")* – a significant financial interest that could directly and significantly affect the design, conduct, or reporting of research.

3.2 *Financial interest* – anything of monetary value, whether or not the value is readily ascertainable.

3.3 *Institutional Official* – An individual responsible for the oversight of research and IRB functions and who has the legal authority to act and speak for the institution. The institution's President/CEO may serve as the Institutional Official or he/she should appoint or delegate the appointment of the individual. If the CEO does not function as the Institutional Official, the person appointed should be the equivalent of the director of research and development, a dean or assistant dean, or hospital administrator. The person in this position may have the additional responsibility of selecting the chair of the IRB.

3.4 *Institutional Responsibilities* – an Investigator's professional responsibilities on behalf of Mercy, and as defined by Mercy 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 or Data and Safety Monitoring Boards.

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[1] This policy applies to all individuals listed on the IRB application form including all subsequent filings with the IRB.
[2] The definitions in this section are, in substantial part, as set forth in 42 CFR §50.603.

3.5 *Investigator* – the project director or principal Investigator and any other person, regardless of title or position, who is, or proposed to be, responsible for, the design, conduct, or reporting of research, which may include, for example, collaborators or consultants.

3.6 *Research* – a systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (*e.g.,* a published article, book or book chapter) and product development (*e.g.,* a diagnostic test or drug). This term includes, but is not limited to, funding from a PHS[3] Awarding Component through a grant or cooperative agreement whether authorized under the PHS act or other statutory authority.

3.7 *Senior/key personnel* – the project director or principal Investigator and any other person identified as senior/key personnel by Mercy in a grant application, progress report, or any other report submitted to the PHS by Mercy pursuant to 42 CFR Part 50, Subpart F.

3.8 *Significant financial interest ("SFI")-*

(1) 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) Remuneration received from any publicly traded entity in the previous 12 months and the value of any equity interest in the entity, 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 measures of fair market value;

(ii) Remuneration received from any non-publicly traded entity in the previous 12 months, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest; or

(iii) Intellectual property rights and interests (*e.g.,* patents, copyrights), upon receipt of income related to such rights and interests.

(2) 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. <u>This applies only to PHS-funded Investigators</u>. (See also Section 5.2 of this policy).

(3) The term *significant financial interest* **does not** include the following types of financial interests:

(i) Salary, royalties, or other remuneration 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; income from investment vehicles, as long as the Investigator does not directly control the investment decisions made in these vehicles.

[3] "PHS" means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the NIH.

(ii) 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.

(iii) Income from service on 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) Travel by a PHS-funded Investigator that is reimbursed or 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.

4. Process

4.1 Financial Conflict of Interest in Research Disclosure Form.

(1) Each Investigator must complete a FCOI in Research Disclosure Form as follows:

(i) At the time of proposal submission;
(ii) Annually;
(iii) When added as an Investigator to an ongoing project;
(iv) Prior to participation in any PHS-funded research;
(v) Update within 30 days in the event of a new SFI or changes in previously reported SFI.

(2) Investigator reporting of a SFI includes those of him/herself, his/her spouse and dependent children.

(3) The principal Investigator is responsible for ensuring that all Investigators or sub-investigators involved in the study for which the Investigator is the lead, comply with this policy disclosure requirements.

(4) All Investigators are required to complete the annual disclosure form even if they have no financial interests to report.

(5) Investigators will be required to verify that they have a current FCOI in Research Disclosure Form on file at the time of application to the Institutional Review Board ("IRB").

(6) Investigators conducting clinical trials for the U.S. Food and Drug Administration ("FDA") applications for a human drug, biological product or device must also comply with the FDA requirement that require financial disclosure to be updated both during the course of the study and for one year following the completion of the study.

(7) The financial disclosure forms will be submitted to and maintained by the office of the General Counsel.

4.2 Review of Financial Conflict of Interest in Research Disclosure Forms.

(1) A research oversight committee will review the disclosure forms to determine whether an Investigator's disclosed SFI could directly and significantly affect the design, conduct or reporting the research, and would therefore constitute a FCOI.

(2) At the discretion of the research oversight committee, the Investigator may be included in making the determination. The research oversight committee may request additional clarifying information from the Investigator which will be treated in a confidential manner to the extent allowed by law.

4.3 Management of Financial Conflict of Interest.

(1) If a FCOI is identified for an Investigator conducting a PHS-funded research project, the research oversight committee shall request that the Investigator submit a proposed conflict management plan that details steps that could be taken to manage, reduce, or eliminate the FCOI. The research oversight committee will review the proposed conflict management plan and approve it or add conditions or restrictions to ensure that any conflict is managed, reduced, or eliminated to ensure that the design, conduct or reporting of research is free from bias or the appearance of bias. A draft of the management plan will be provided to the Investigator for review and comment before it is finalized. Conditions or restrictions may include, but are not limited to, the following:

(i) Public disclosure of FCOI (*e.g.,* when presenting or publishing the research);
(ii) Monitoring of research by independent reviewers;
(iii) Modification of the planned activities (possibly subject to sponsor approval);
(iv) Disqualification from participation in all or part of the project;
(v) Divestiture of SFI;
(vi) Severance of relationship(s) creating conflict;
(vii) For research involving human subjects, disclosure of FCOI directly to research subjects.

(2) FCOI for Investigators conducting non-PHS-funded research will be evaluated on a case-by-case basis. The research oversight committee may request that the Investigator develop and implement a management plan as needed.

(3) If Mercy identifies a SFI that was not disclosed or reviewed in a timely manner, it will be reviewed within 60 days from the date the SFI was identified to determine if the SFI is actually a FCOI. An interim management plan will be implemented when necessary.

(4) This policy applies to all types of research conducted at Mercy; however, special precautions must be taken to protect human subjects who participate in research at Mercy. If a FCOI is identified for an Investigator, the Investigator will need to provide a compelling justification for his/her participation in the research. Compelling justification includes factors such as unique Investigator expertise, unique institutional resources, unique access to particular patient populations, nature of the science, level or risk to human subjects, and the degree to which the financial interest and research are linked. The FCOI and the compelling justification will be reviewed by the research oversight committee to determine if a management plan is appropriate, or if the Investigator will be prevented from participating in the research. Mercy legal counsel will be consulted as needed.

(5) Research will not begin until the appropriate management plan or actions have been taken by the research oversight committee to mitigate or eliminate the FCOI, and any other necessary actions, such as IRB approval or the clinical trial contract has been fully executed.

4.4 Management of FCOIs.

(1) Investigator compliance with management plans will be monitored by the research oversight committee. The frequency of monitoring will be dictated by sponsor/agency requirements and management plan provisions.

4.5 Appeals.

(1) Investigators may appeal a research oversight committee decision in writing within 15 days of receipt of management plan or other decision related to FCOI. The written appeal should be directed to the designated Institutional Official, and should include details regarding the Investigator's concern and/or compelling circumstances which support the request for a proposed revision to a research oversight committee decision. The Institutional Official, who will consult with the Investigator, the research oversight committee, and the Chief Academic Officer (if the Chief Academic Officer is not also serving as the Institutional Official), will make a final determination. Final appeal determinations will be reported to the IRB.

4.6 Compliance.

(1) As part of the FCOI in Research Disclosure Statement, each Investigator must certify that if Mercy determines a FCOI exists, the Investigator will adhere to all conditions or restrictions imposed upon the project and will cooperate fully with the individuals(s) assigned to monitor compliance.

4.7 Records.

(1) Mercy will maintain records of all disclosures and associated activities securely and confidentially.

(2) Records will be maintained for three (3) years following termination or completion of a study, submission of the final expenditures report, or the date of final resolution of any investigation, audit, or similar action involving the records.

4.8 Enforcement.

(1) Failure to comply with this policy to properly disclose relevant financial interests or to adhere to conditions or restrictions imposed by Mercy will be considered a deviation from accepted standards of conducting research at Mercy.

(2) The research oversight committee will investigate alleged violations of this policy and will make recommendations for action to the Institutional Official. Breaches of policy include, but are not limited to: failure to file the necessary disclosure statements; knowingly filing incomplete, erroneous or misleading disclosure forms; or failure to comply with procedures prescribed by Mercy.

(3) Failure to comply with this policy may result in disciplinary actions and/or sanctions, including but not limited to, formal reprimand; a letter to the Investigator's file; non-renewal/termination of the Investigator's ability to participate in clinical trials. Reports to sponsor(s) and the Department of Health and Human Services will be filed as required.

5. <u>PHS Funded Research</u>. The following <u>additional</u> requirements apply to all research funded by the PHS and any PHS Awarding Component including the National Institute of Health ("NIH").

5.1 Reporting.

(1) Mercy will provide the PHS Awarding Component a FCOI report as outlined in the regulations:

(a) *<u>Initial Reports During an Ongoing NIH-Funded Study</u>* – Prior to expenditure of any funds under a NIH-funded research project, Mercy will provide to the NIH a FCOI report regarding any Investigator SFI found by Mercy to be a FCOI. Mercy will also provide a FCOI report whenever an Investigator does not timely disclose a SFI or whenever Mercy, for whatever reason, does not review a disclosed SFI and Mercy then determines that a FCOI exists.

(i) Mercy will provide a FCOI report within 60 days after its determination that a FCOI exists for an Investigator who is newly participating in the study, for an existing Investigator who discloses a new SFI, or when Mercy identifies a FCOI not previously disclosed.

(ii) Whenever an Investigator does not disclose timely a previously existing SFI or Mercy fails to review a previously existing SFI during an ongoing NIH-funded project, Mercy's designated official(s) will, within 60 days: review the SFI; determine whether it is related to the NIH-funded research; determine whether a FCOI exists. If so, Mercy will implement, on at least an interim basis, a management plan that will specify the actions that have been, or will be, taken to manage the FCOI going forward and submit a FCOI report to the NIH.

(iii) In addition to the FCOI report, Mercy will, within 120 days of its determination of noncompliance, complete a retrospective review of the Investigator's research activities and the NIH-funded research to determine whether any NIH-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct or reporting of such research.

(iv) Based on the results of the retrospective review, if appropriate, update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward.

(v) If bias is found, Mercy will notify the NIH promptly and submit a mitigation report that includes the key elements documented in the retrospective review and a description of the impact of the bias on the research project and Mercy's plan of action or actions taken to eliminate or mitigate the effects of the bias. Thereafter, Mercy will submit FCOI reports annually.

(b) If FCOI reports required in 5.1(1)(a) above, Mercy will include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the FCOI and to assess the appropriateness of Mercy's management plan. Elements of the FCOI report shall include, but are not necessarily limited to, the following:

- Grant/contract/project number
- PD/PI
- Name of Investigator with FCOI
- Name of entity with which the Investigator has a FCOI

- Nature of the FCOI (*e.g.,* equity, consulting fees, travel reimbursement or honoraria)
- Value of the financial interest or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value
- Description of how FCOI relates to PHS-funded research and the basis for the determination that the financial interest conflicts with such research
- Description of the key elements of the management plan

(c) For any FCOI previously reported by Mercy, Mercy will provide an annual FCOI report that addresses the status of the financial interest and any changes to the management plan. Annual FCOI reports will specify whether the FCOI is still being managed or explain why the FCOI no longer exists. Annual FCOI reports must be submitted to the NIH for the duration of the project period.

5.2 Travel. PHS funded Investigators 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 his/her Institutional Responsibilities and that are not reimbursed or sponsored by a federal, state, or local government agency, an Institution of higher educations, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education. This disclosure requirement also applies to the Investigator's spouse and dependent children. The travel disclosure must include at least the following:

- Purpose of the trip
- Identity of the sponsor/organizer
- Destination
- Duration of trip
- Monetary value, if known

Travel disclosures will be reviewed by the research oversight committee to determine whether additional information is needed in order to determine whether the travel constitutes an FCOI with the PHS-funded research. Disclosure of travel must occur no more than 30 days after the last day of the trip.

5.3 Public Accessibility.

(1) This policy will be posted on Mercy's publicly accessible web site. In addition, Mercy will ensure public accessibility by a written response to any requestor within 5 business days of receipt of a request by the research oversight committee for information concerning any SFI disclosed to Mercy that meets the following criteria:

- The SFI was disclosed and is still held by the research oversight committee as defined by this policy;
- Mercy determines that the SFI is related to PHS-funded research; and
- Mercy determines that the SFI is a FCOI.

(2) The information that Mercy will make available via a written response to any requestor within 5 business days of receipt of a request will include at least the following:

- Investigator's name;

- Investigator's title and role with respect to the research study/project;
- Name of the entity in which the SFI is held;
- Nature of the SFI;
- Approximate dollar value of the SFI using dollar ranges or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.
- That the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60 days of the Mercy's identification of a new FCOI, which should be requested subsequently by the requestor.

(3) This information will remain available for 3 years from the date the information was most recently updated.

5.4 Financial Conflict of Interest Training Requirements.

(1) Each Investigator must complete training prior to engaging in NIH-funded research and at least every 4 years, and as soon as reasonably possible under the following circumstances:

- Mercy's FCOI policy changes in a manner that affection Investigator requirements;
- An Investigator is new to Mercy;
- Mercy finds that an Investigator is not in compliance with Mercy's FCOI policy or management plan.

Do not submit this page with the form

Mercy Health Cincinnati LLC

Instructions for Completion of the Disclosure Form

Please Note: Forms should be downloaded each time, as they are subject to change.

What is required?

Federal regulations require institutions to have policies and procedures in place that ensure that all Investigators disclose any significant financial interests that may present an actual or potential conflict of interest. Such disclosures must be made at the time of application and institutions must develop specific mechanisms by which conflicts of interest will be satisfactorily managed, reduced, or eliminated. If a new reportable significant conflict of interest arises at any time after submission of the proposal through the completion of the project, a new filing of a disclosure is also required.

Who should complete form?

Any "investigator" participating in research within a Mercy Health Cincinnati LLC entity, including hospitals and physician practice locations. An "investigator" is defined as the principal investigator, co-principal investigator, study coordinator, and/or any other persons at the institution who are responsible for the design, conduct, or the reporting of research or educational activities. "Investigator" includes the Investigator's spouse and dependent children.

What must be disclosed?

Each investigator shall disclose all significant financial interests that would reasonably appear to directly and significantly affect the research activities funded. "Significant Financial Interest" means anything of monetary value, including, but not limited to salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights (e.g., patents, copyrights, and royalties from such rights). The term does not include:

1. Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
2. Income from service on advisory committees or review panels for public or nonprofit entities;
3. An equity interest that when aggregated for the Investigator and the Investigator's spouse and dependent children, meets one or the other of the following tests: does not exceed $5,000 in value as determined through reference to public prices or other reasonable measures of fair market value or does not represent more than a five percent ownership interest in any single entity; or
4. Salary, royalties or other payments that when aggregated for the Investigator and Investigator's spouse and dependent children over the next twelve months, are not expected to exceed $5,000.

Where and how should the form be submitted?

All forms must to be completed and submitted with any new application for research, and updated during the term of the project, either on an annual basis, or as new reportable significant financial interests are obtained, to the Office of the General Counsel. The research oversight committee and the Legal Counsel will handle these forms in a confidential matter for review and determination of conflict of interest.

The forms are available on the Mercy Health portal or paper copy from Mary Lou Sauer at mlsauer@health-partners.org or Vicki Estridge at VLEstridge@health-partners.org. Completed forms should be sent to Cindy Ziglar at 513-981-6342 or CAZiglar@health-partners.org.

Mercy Health Cincinnati LLC

Investigator Significant Financial Interest Disclosure Form

The answer fields are shaded (or).

Name of Sponsor, Clinical Trial Title, Protocol Number:		
Investigator Name:		
Institution/Organization:	Email:	
Department, Section, Unit:	Phone:	Pager:
Address:	Fax:	

I am disclosing the following financial interests (check all that apply) and I am attaching supporting documentation in the attached sealed envelope that identifies the business enterprise or entity involved and the nature and amount of interest:

	Income or other payment for services (e.g., consulting fees or honoraria) > $5,000.00
	Equity interests (e.g., stocks, stock options, or other ownership interests) > $5,000.00
	Intellectual property rights (e.g., patents, copyrights, and royalties from such rights)
	Other significant interest of the Investigator that possibly could affect or be perceived to affect the results of the research.
	I do not have any financial interest to report.

Further I agree to:

- Update this disclosure during the term of the project, either on an annual basis, or as new reportable significant financial interests are obtained. Complete a Financial Disclosure Statement of Additional Payments for Ongoing Clinical Trials when applicable.
- Comply with any conditions or restrictions imposed by Mercy Health to manage, reduce, or eliminate actual or potential conflicts of interests.

Signature: _____ Date: _____