SCOPE:
The MCH department listed above, including all employees and contractors or any and all personnel providing services.

PURPOSE:
This standard operating procedure (SOP) outlines the process for identifying, managing, and minimizing institutional conflicts of interest in research.

DEFINITIONS:
1. **Institution or Institutional**: refers to Miami Children’s Hospital (MCH) and all of its owned or operated facilities, including, but not limited to, hospital, ambulatory centers, physician practices and all departments contained therein.

2. **Conflict of Interest**: a situation in which a significant financial interest may compromise, or have the appearance of compromising a Covered Individual’s professional judgment in conducting research including interest in the sponsor, product or service being tested, or a financial interest in the competitor of the sponsor held by the individual or the individual’s immediate family, including conflicts related to inventions and intellectual property.

3. **Controlled Entity**: any corporation, organization, or partnership (other than MCH or any related entity) of which a Covered Individual is an executive, officer, director, or partner (or has responsibilities or influence over the organization as a whole that is similar to an officer, director or trustee), or is owner of 5% or more of any class of equity securities; any trust or other estate in which a Covered Individual has a substantial beneficial interest or as to which a Covered Individual serves as trustee or in a similar fiduciary capacity.

4. **Covered Individual**: an MCH Official, their Immediate Family member or a Controlled Entity of the MCH Official or their Immediate Family Member.

5. **Immediate Family**: Spouse/domestic partner and dependent children

6. **Institutional Financial Interests**: Institutional financial interest include: Licensing, technology transfer, patents, investments of the organization, gifts to the organization when the donor has an interest in the research and the financial interest of senior administrators. An Institutional Financial Interests (“IFI”) occurs when one or more of the following circumstances exists related to MCH research, where “related to MCH research” means that the financial interest is in a sponsor of MCH research, in a competitor of a sponsor of MCH research, in a product or service being tested at MCH.
POLICY DESCRIPTION: Institutional Financial Conflict of Interest Disclosure - Research

where:

- MCH holds an intellectual property interest (e.g., patent or copyright) related to MCH research.
- MCH holds any equity in a non-publicly-traded entity related to MCH research.
- MCH Holds equity exceeding $100,000 in a publicly traded entity related to MCH research, or
- An MCH Official, Immediate Family member or Controlled Entity, (whether or not Participating in MCH research), has a Significant Financial Interests related to MCH research.

7. MCH Official: Means a person with influence over MCH affairs if that person:

- Serves on the governing body of MCH and is entitled to vote on matters over which the governing body has the authority to vote;
- Is the President, Chief Executive Officer, or Chief Operating Officer of MCH or an affiliate or otherwise has or shares ultimate responsibility for implementing the decisions of the governing body or supervising the management, administration, or operation of MCH or an affiliate;
- Is the Treasurer or Chief Financial Officer or otherwise has the responsibility for managing MCH’s or an affiliate’s financial assets;
- Has a material financial interest in a provider sponsored organization in which the MCH participates; or
- Is otherwise treated as having substantial influence over the affairs of the MCH under section 4985 of the Internal Revenue Code.

8. Significant Financial Interest: Any of the following interests of the Covered Individual:

- Ownership interest including, but not limited to stocks and options or royalties in the amount of $5,000 or more for publicly-traded stocks when aggregated for the immediate family, exclusive of interests in diversified mutual funds.
- Other equity or royalty interests of any value for non-publicly traded interests, or any other interests related to the research that may be affected by the outcome of the research.
- Compensation of $5,000 or more in the preceding twelve months when aggregated for the immediate family including, but not limited to honoraria, consultant fees, royalties, or other income related to the research.
- Proprietary interest such as intellectual property related to the research including, but not limited to, patents, trademarks, and copyrights or licensing agreements.
- Board, fiduciary or executive relationship related to the research, regardless of compensation.
- Reimbursed or sponsored travel by an entity other than a federal, state, or local government agency, higher education institution or affiliated research institute, academic teaching hospital, or medical center.

POLICY:

1. Presumption Against Conducting Research When MCH Holds Institutional Financial Interests

The involvement of MCH in the design, conduct or reporting of a research project in which MCH or MCH Official has an Institutional Financial Interest related to the research is subject to the approval of the Audit and Compliance Committee of the Board of Directors ("Audit and Compliance Committee").
Committee”). Potential IFI conflicts will be reviewed and managed by the Audit and Compliance Committee. Approval may be granted if Compelling Circumstances exist that justify MCH’s involvement in conducting the research. Compelling Circumstances are those facts that convince the Audit and Compliance Committee that the research may be conducted at or by MCH without the Institutional Financial Interest directly and significantly affecting the design, conduct, or reporting of the research. The evaluation and management of an Institutional Financial Interest may not vary by funding or regulatory oversight. If the Audit and Compliance Committee determines that Compelling Circumstances exist, the research could be conducted only pursuant to a written management plan approved by the Audit and Compliance Committee and ratified by an Institutional Review Board (“IRB”). No research protocol may be submitted to an IRB until a determination regarding the non-existence of or the existence of a conflict of Institutional Financial Interest has been made if it exist, and an appropriate course of action instituted.

The Audit and Compliance Committee will consult with the Director of the MCHRI to determine whether funding or regulatory agencies require a report of the IFI conflict. The Director of MCHRI, in consultation with the Institutional Officer, will prepare and submit this report to the funding or regulatory agency where required.

**Enforcement and Sanctions:** The Board Directors has broad power under this policy to determine the existence of potential, perceived and actual IFI conflict, to subject relationships to appropriate management and oversight and to impose appropriate sanctions.

- Management and oversight include the impositions of conditions or restrictions intended to manage, reduce or eliminate such conflicts.
- Sanctions for violations of this policy include disciplinary action including suspensions and up to termination, loss of Medical Staff privileges, loss of administrative appointments, cessation of vendor business, liability for damages and other appropriate sanctions.
- **Failure to Disclose:**
  - Shall result in the individual receiving a written notice of said failure. Upon receipt of the notice, the individual has 10 days to respond.
  - Upon confirmation that party failed to properly disclose appropriate disciplinary and corrective action may include but is not limited to exclusion from participating in governing body deliberations, decision making transactions, and/or termination of employment.

2. **Other Reportable Relationships**

The following (referred to as “other reportable relationships”) are not necessarily IFIs but are nonetheless reportable to the Audit and Compliance Committee by any MCH Staff member or administrator who, on MCH’s behalf:

- Participates Significantly in Major or Non-routine Purchases from a Research Sponsor.
- Receives a Substantial Gift or Grant from a Research Sponsor-including equity or partnership interests.
**POLICY DESCRIPTION:** Institutional Financial Conflict of Interest Disclosure - Research

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Reporting to Audit and Compliance Committee

- **Departmental Reporting** - The MCH Chief Financial Officer, the Office of General Counsel, the Research Institute, and the Purchasing Department, must report to the Audit and Compliance Committee the terms of any arrangements or transactions that may create an Institutional Financial Interest or “other reportable relationship” for MCH (or a MCH subsidiary).

- **Disclosures by Officials** - MCH Officials must annually report to the Audit and Compliance Committee (with prompt interim updating) all Significant Financial Interests (“SFIs”) or “other reportable relationships” that they, their Immediate Family members or Controlled Entity have related to MCH research, whether or not they are involved in the research.

- **Other Reportable Relationships** - Any MCH Staff member or administrator who has an “other reportable relationship” should report that relationship to the Audit and Compliance Committee.

### 3. List of Financially Interested Companies

The Audit and Compliance Committee shall periodically evaluate the reports it receives and develop a listing of (institutionally) Financially Interested Companies and provide that listing to the Chief Financial Officer, the Office of General Counsel, the Office of Ethics and Compliance, and the other MCH departments shown above.

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**PROCEDURE:**

1. **MCH Board of Directors (Board), Officials, Administrators Responsibilities**

   - MCH Officials, Administrative Officers and Department Directors are responsible for knowing and ensuring their employees and contractors know of and comply with this policy. The Board of Directors and/or Management shall take timely action, including remedial action as may be necessary, in response to any matter that arise under this policy.

   - **Duty to Disclose:** In connection with any actual or potential IFI conflict with respect to any particular transaction, any individual covered by this policy must fully disclose the existence and nature of the IFI annually and when circumstances warrant.

2. **Board, Ethics and Compliance, Legal and Research Administration Responsibilities**

   - Review disclosures that indicate a potential IFI related to the research. (Director MCHRI)

   - Review financial disclosure forms against List of Financially Interested Companies to determine whether any significant financial interest related to research has been disclosed. (Director MCHRI)

   - If a form indicates that a potential financial interest related to the research is present, the MCHRI Institutional Official (or their designee) will conduct a preliminary review and provide a synopsis to the Sr. Vice President of Ethics & Compliance for additional investigation (if appropriate) and presentation to the MCH’s Board of Directors’ Audit & Compliance Committee. (Director MCHRI)
• Working with the Audit & Compliance Committee as necessary, judge whether any financial interests require management’s intervention such as: (Sr. Vice President of Ethics & Compliance; MCH Legal Counsel; MCH Board of Directors Audit & Compliance Committee)
  ▪ Given the fact-specific nature of many these issues, they are resolved on a fact-sensitive, case-by-case basis that is consistent with applicable laws, regulations, and policies
  ▪ Relevant factors for the committee to consider are:
    a. whether a IFI or the appearance of a IFI actually exists or has potential to exist
    b. the current or potential size of the financial interest and any other relevant terms
    c. risks to the institution
    d. risks to patients or research subjects
    e. the importance of the proposed activity
    f. whether the conditions of the relationship have changed since the last disclosure statement was filed
    g. whether the IFI is unavoidable
    h. necessity and/or feasibility of IFI avoidance, elimination, or management
  ▪ When a IFI or appearance of a IFI, as defined by this policy is identified, the Audit and Compliance Committee shall recommend to the proper institutional officials that an appropriate course of action be taken to avoid, manage, or eliminate such conflicts. Recommended courses of action may include but are not limited to:
    a. Complete nonparticipation in a research project, or partial nonparticipation in specific aspects of the project
    b. Public disclosure of the financial interests.
    c. Disclosure of the financial interests to subjects.
    d. Additional disclosure
    e. Monitoring of activities by independent parties
    f. Modification of research plan
    g. Elimination of the IFI through divestiture or independent management of financials interests
    h. Cessation of specific activities that create actual or potential IFI
    i. Allowance of specific activities for a limited time period
    j. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research.
    k. Severance of relationships that create financial conflicts.
    l. Involvement of external individuals in key portions of the protocol.
    m. Use of an external IRB.
    n. A retrospective review.
    o. A mitigation report.
    p. A plan to monitor and enforce the implementation of the management plan.
• Notify the IRB of any financial interests requiring management, as well as the management plan. (Sr. Vice President of Ethics & Compliance; Director of MCHRI)
  ▪ MCH grants the IRB the final authority to decide whether the interest and its management, if any, allow the research to be approved.
  ▪ The IRB will review MCH’s findings and determine the adequacy of the plan in accordance with IRB policies and procedures.

• Report, as required, the existence of an IFI in research that has been approved by the Audit and Compliance Committee. (Director MCHRI)

• All disclosure forms and the actions taken to eliminate or manage the IFI shall be maintained for at least three years beyond the termination or completion of the grant and/or study, or until the resolution of any action involving a Public Health Services (PHS) entity, whichever is longer. The Public Health Services (PHS) entities/agencies include but is not limited to the National Institutes of Health (NIH), Centers for Disease Control (CDC), Food and Drug Administration (FDA), AHRQ, HRSA, HIS. (Sr. Vice President of Ethics & Compliance)

REFERENCES:
• General Responsibilities of Investigators; 21 CFR 312.60
• 46DHHS Part 46 Protection of Human Subjects; 45 CFR 46
• Subpart E Responsibilities of Investigators; 21 CFR 812
• ICH Good Clinical Practice: Consolidated Guideline (E6 4.2.4) May 1997
• FDA Internal Compliance Program Guidance Manual for Clinical Investigators: 7348.811 September 1993
• NIH Notice OD-00-029: Required Education in the Protection of Human Research Participants June 2000
• Clarification on June 5, 2000 Notice (OD-00-39) September 2000
• Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors. Federal Register, Vol. 76, No. 165 August 2011