

THE CHILDREN'S MERCY HOSPITAL ADMINISTRATIVE POLICIES MANUAL

TITLE: Reporting and Mitigation of Conflicts of Interest and Conflicts of Commitment Policy

EFFECTIVE: 11/2021

REVISION DATE:

REVIEWED WITH NO CHANGES:

RETIRED:

PURPOSE:

To establish requirements for reporting of relationships and interests that may constitute conflicts of interest or conflicts of commitment and mitigation of identified conflicts.

Note: This document replaces the *Conflict of Interest Policy*.

LOCATION/SCOPE:

This policy applies to all employees of The Children's Mercy Hospital (the "Hospital"). For avoidance of doubt, employees of corporate affiliates of the Hospital, such as Children's Mercy Affiliated Practices are not covered by this policy.

DEPARTMENT(S) RESPONSIBLE FOR POLICY MANAGEMENT AND EXECUTION:

Corporate Compliance

POLICY STATEMENT:

General

Due to the nature of its business, the Hospital must control and mitigate conflicts of interest and conflicts of commitment that may adversely affect its mission, the interests of its patients, the integrity of its research or any other aspect of its business or operations. All employees must report relationships and interests in accordance with this policy. Actual or potential conflicts of interest and conflicts of commitment associated with reported relationships or interests will be managed in accordance with this policy.

Important: Please refer to the [Definitions](#) section at the end of this policy for the meaning of important terms (such as Reportable Relationship/Interest).

Annual Reporting by Designated Employees:

The following employees ("Designated Employees") are required to complete annually a report prescribed by the Corporate Compliance department concerning Reportable Relationships/Interests and proposed Reviewable Relationships/Interests:

- All physicians and other faculty.

- All Investigators and Research Scientists.
- All nurse practitioners and other advanced practice providers.
- All employees assigned to Procurement and Contracting (Supply Chain), Research Administration, Medical Administration contracting, Tech Transfer, or Strategic Planning and Innovation.
- All employees assigned to the Audit and Corporate Compliance department, or the Office of the General Counsel/Risk Management.
- All employees who are members of Decision-Making Committees designated by the Corporate Compliance department.
- All other employees at or above the manager level.

Reporting Requirements for Designated Employees:

For Reportable Relationships/Interests:

- All Reportable Relationships/Interests must be reported annually. Designated Employees involved in research that is subject to the Research COI Addendum must report any Significant Financial Interest (Research) as defined herein. All other Designated Employees must report any Significant Financial Interest (General) as defined herein.
- Newly arising Reportable Relationships/Interests must be reported within the time required by this policy or law, but not later than 30 days after the Reportable Relationship/Interest arises.

For Reviewable Relationships/Interests:

- Prior to commencing a Reviewable Relationship/Interest, an employee must disclose the proposed relationship or interest and receive advance approval.
 - Physicians and other faculty, including Investigators, must comply with the [Outside Professional Services and Activities Request and Approval Policy](#) prior to commencing a relationship to provide Compensable Outside Professional Services as defined in such policy.
 - Any request for approval of a Reviewable Relationship/Interest that does not fall under the [Outside Professional Services and Activities Request and Approval Policy](#) will be reviewed by leadership in the requesting employee's chain of command.

Requirements applicable to all other Employees:

Employees other than Designated Employees are not obligated to complete the annual report. Nevertheless, **all employees are subject to this policy.**

- All employees must report any newly arising Reportable Relationships/Interests within the time required by this policy or law, but not later than 30 days after the Reportable Relationship/Interest arises.
- Any employee who proposes to commence a Reviewable Relationship/Interest, must disclose the proposed relationship or interest and receive advance approval.

Identification and Management of Relationships/Interests that constitute Conflicts of Interest:

All Reportable Relationships/Interests will be reviewed to identify actual or potential conflicts of interest. Where an actual or potential conflict of interest is identified, a management plan will be required to mitigate such conflict. Any required plans will be established and overseen in accordance with procedures maintained by the Corporate Compliance department. If the conflict of interest cannot be appropriately mitigated by a management plan, the employee will be required to discontinue the relationship or divest the interest, as applicable. Significant Financial Interests and FDA-reportable Financial Interests that are subject to the requirements of the Research COI Addendum to this policy, will be reviewed in accordance with such Addendum.

Prohibited relationships: Employees generally are not permitted to engage in or hold the following relationships/interests.

- *Equity Interests:* Employees are not permitted to hold equity interests in organizations who are vendors or potential vendors to the Hospital, or who sponsor research at the Hospital. This restriction generally does not apply to Equity interests that (i) are not acquired by an employee as consideration for or otherwise in connection with a contractual or other arrangement between the employee and the issuer, and (ii) are passive investments representing insignificant holdings in publicly traded companies, exchange traded funds, mutual funds or other similar vehicles. This restriction also generally does not apply to Equity interests held by a spouse, domestic partner or other family member of an employee; provided that any such Equity interest that, if held directly by the employee, may constitute a potential conflict of interest must be disclosed for determination of whether a management plan is necessary. Employees involved in research that is subject to the Research COI Addendum are required to report all Equity Interests that meet the definition of Significant Financial Interest (Research) even if such Equity Interests are permitted by this paragraph.
- *Positions or work related to the Employee's Duties for the Hospital:* Employees generally are not permitted to work in their individual capacity for other organizations if such work is of the same general nature as the employees' job duties for the Hospital. For example, researchers will not in their individual capacity perform research for another institution which is within the scope of research being conducted, or which could be conducted, at the Hospital. This restriction generally does not apply to employees who are not Designated Employees (such as RNs and CAs who are not supervisors and do not otherwise meet the definition of a Designated Employee) who work for other organizations performing duties at or below the level of their duties for the Hospital. Such employees, however, must report their work for other organizations to their supervisors, and they remain subject to all the Hospital policies including confidentiality of the Hospital information.
- *Fiduciary or Managerial Positions:* Employees may not hold positions of trust (officer, director, trustee) or executive or managerial responsibility for any entity engaged in provision of healthcare services, or in research, development, marketing or sale of products or services related to healthcare, medical education or medical research. Executive leadership may authorize exceptions to this rule in cases where the employee is acting as a representative of the Hospital.
- *Other:* The Corporate Compliance department shall identify and post in a document linked to this policy other relationships or interests that are not permitted.

Activities Outside of Scope

The following activities are not within the scope of this policy and do not constitute Reportable Relationships/Interests:

- Participation in United States federal or state government sponsored activities (such as presentations, grant reviews, NIH study sections, NIH, CDC or NSF workshops)
- Lectures or other traditional academic activities within the United States involving receipt of no more than a nominal stipend (\$1000 or less)

Additionally, activities by Hospital employees acting on behalf of the Hospital (as opposed to acting in their individual capacities) under an agreement or contract between the Hospital and a third party are outside of the scope of this policy.

Procedures

The Corporate Compliance department establishes and administers standard operating procedures for the reporting, review and management requirements set forth in this policy. A subcommittee of the Executive Compliance and Risk Committee (ECRC) provides governance oversight for this policy and its application.

Conflicts of Commitment

The Hospital encourages its employees to participate in Outside Activities that are consistent with the Hospital's mission and values. The Hospital recognizes, however, that in addition to creating the potential for a conflict of interest, an employee's participation in an Outside Activity may result in a conflict of commitment. A conflict of commitment occurs when an employee's Outside Activities compromise or may compromise the employee's ability to perform his or her responsibilities to the Hospital. For example, an Outside Activity that requires an excessive amount of an employee's time may compromise the employee's ability to devote the time necessary to perform his or her Hospital job duties.

Employees shall not engage in Outside Activities if such activities are likely to, or will, result in a conflict of commitment. Employees are responsible for reporting Outside Activities that may result in conflicts of commitment to their supervisors. In most cases, such reporting should always include any employment or contracting relationship of an employee with another party, and in the case of employment or contracting with another healthcare provider the employee must always report such Outside Activity to his or her supervisor. To the extent any question arises regarding a possible conflict of commitment, the affected employee and the employee's supervisor shall promptly address and resolve the issue with leadership in such employee's chain of command.

The restrictions on conflicts of commitment set forth herein are in addition to the restrictions on conflicts of interest, including the prohibition of certain relationships and activities. An Outside Activity that does not constitute a conflict of commitment may nevertheless constitute a conflict of interest under this policy.

DEFINITIONS:

Company: Any corporation, limited liability company, partnership, entity, proprietorship, association, or other enterprise, whether owned by one or more than one individual. A Company may be a U.S. domestic enterprise or a foreign enterprise.

Decision-Making Committees: Internal Hospital committees that make decisions concerning transactions or relationships with outside parties. The Corporate Compliance department will determine which committees are Decision-Making Committees.

Employee: Any employee of the Hospital and such employee's spouse or domestic partner and dependent children.

Equity: Any ownership interest in a for-profit entity, including shares of equity securities (stock), options to purchase stock, securities that are convertible into equity interests, stock appreciation rights, or other rights the value of which are a function of equity value.

Financial Conflict of Interest:

- *Research:* Significant Financial Interests that may affect research will be reported and reviewed in accordance with the Research COI Addendum.
- *Non-research:* The determination of Financial Conflict of Interest will be based on whether the interest could affect the employee's ability to make decisions and otherwise act in the best interests of the Hospital.

FDA-Reportable Financial Interest: Financial interests of employees acting as clinical investigators for clinical studies to be used for purposes of FDA approvals of human drugs, biological products, or devices as defined in the FDA disclosure regulations set forth in 21 CFR Part 54. FDA-Reportable Financial Interests are addressed in the Research COI Addendum.

Foreign Entity: (i) Any company that is not a United States domestic entity; (ii) any government or subdivision of a government other than the governments of the United States, the states, territories, commonwealths or other political subdivisions of the United States, and any municipal or other local subdivisions, agencies or other instrumentalities of the foregoing; or (iii) any natural person who is not a citizen or permanent resident of the United States.

IP Right: Any rights or interests in intellectual property, including intellectual property created by the employee. "Intellectual Property" shall have the meaning set forth in the [Intellectual Property Policy](#).

Investigator: A program director/principal investigator and any other person, regardless of title or position who is responsible for the design, conduct, or reporting of research funded by PHS or any Company or Other Organization, or a proposal for such funding (which may include, for example, collaborators or consultants).

Non-Financial Potential Conflict of Interest: Without regard to financial value, the employee holds a position or otherwise has a relationship with a third party that could affect the employee's ability to make decisions and otherwise act in the best interests of the Hospital. Examples of Non-Financial Potential Conflict of Interest include holding a position of influence (officer, member of the board of directors, trustee, or other fiduciary position) with a third party

with whom the Hospital has a business relationship, such as a vendor (goods and/or services), a payor or another healthcare system.

Other Organization: Any public or private organization, including any government or government agency, foundation, college, university or other educational institution, research institution, or any other organization that is not a Company.

Outside Activities: Any work (including employment or contracted services), business activities, professional endeavors, public service, service on boards of directors or advisory groups or other work performed outside of Hospital employment.

Private Company: Any Company that is not a Public Company.

Public Company: A Company which has any equity securities (such as shares of stock) or debt securities (such as bonds) that are traded on any exchange, over the counter, or by any listing service.

Reportable Relationship/Interest: Any relationship with or interest in a Company or Other Organization that constitutes (i) a Significant Financial Interest (General) or a Significant Financial Interest (Research), whichever is applicable, or (ii) a Non-Financial Potential Conflict of Interest.

Research COI Addendum: A companion document to this policy, [Conflict of Interest Reporting - Research and Sponsored Projects](#), as published and updated by Research Administration.

Research Scientist: An individual who works under the supervision of an Investigator(s), but with independent responsibilities in project/study implementation including supervising research staff, as defined more specifically in the Hospital job description for Research Scientists.

Reviewable Relationship/Interest: A Reportable Relationship/Interest that involves any proposed employment by or contractual relationship (such as a consulting agreement) with a Company or Other Organization that is (i) a present or potential vendor or customer of the Hospital; and/or (ii) engaged in provision of healthcare services, or in research, development, marketing or sale of products or services related to healthcare, medical education or medical research. Without limitation, any proposed relationship to provide Compensable Outside Professional Services as defined in the [Outside Professional Services and Activities Request and Approval Policy](#) is a Reviewable Relationship/Interest. Reviewable Relationships/Interests do not include situations in which employees act on behalf of the Hospital (for example, professional services provided by the Hospital under contract with another healthcare provider or collaborative research conducted by the Hospital under an agreement with another institution).

Significant Financial Interest (General): A consulting or other relationship with or interest in a Company or Other Organization which could adversely affect, or create the appearance of an adverse effect on, the exercise of judgment by an employee in performing his or her duties for the Hospital. Whether an employee has such an interest depends upon the relevant facts and circumstances, and employees are expected to consult with the Corporate Compliance department where there is any question regarding such interests. In considering whether a reportable interest exists, employees should note:

- In all cases, employees may not engage in relationships listed under the section entitled "Prohibited Relationships."

- Any IP Rights relating to healthcare must be reported.
- Any payments regardless of amount (such as awards, prizes, contributions, hospitality, or expense reimbursement) or any in-kind contributions such as materials and/or resources received from any foreign entity must be reported.

Significant Financial Interest (Research): A consulting or other relationship with or interest in a Company or Other Organization which meets any of the following criteria:

- *Interests in Public Companies:* Remuneration received by the employee from the Company during the preceding 12 months plus the value of Equity held by the employee in the Company is greater than \$5,000.
- *Interests in Private Companies or Other Organizations:* (i) Remuneration received by the employee from the Company or Other Organization during the preceding 12 months is greater than \$5,000; or (ii) the employee holds any Equity interest in the Company (regardless of value).
- *IP Rights:* The employee has received any IP Rights from the Company or Other Organization. For avoidance of doubt, any inventor's share of an employee under the [Intellectual Property Policy](#) will not constitute a Significant Financial Interest.
- *Foreign Activity:* Any payments regardless of amount (such as awards, prizes, contributions, hospitality, or expense reimbursement) or any in-kind contributions such as materials and/or resources from any foreign entity.

REQUESTS FOR GUIDANCE REGARDING THIS POLICY:

Requests for guidance regarding this policy will be directed to the VP, Audit and Compliance/Chief Compliance Officer.

BUSINESS CONTINUITY AND DISASTER (BCD) PLAN:

Unless otherwise indicated, requirements in this document remain applicable during a business continuity and disaster (BCD) situation.

MEASUREMENTS/METRICS:

RECOURSE FOR NON-COMPLIANCE:

Non-compliance will be addressed in accordance with the [Conduct and Corrective Action Policy](#).

RELATED POLICIES:

[Conflict of Interest Reporting - Research and Sponsored Projects](#)

[Intellectual Property Policy](#)

[Outside Professional Services and Activities Request and Approval Policy](#)

RELATED FORMS:

[Request for Approval to Provide Outside Compensable Professional Services and Activities](#)

REFERENCES:**REGULATIONS:**

42 CFR Part 50

21 CFR Part 54 (FDA Disclosure Regulations)

KEYWORD SEARCH:

disclosure, conflict of interest, COI, professional interests, commercial interests, financial interests, immediate family, expert witness, moonlighting, employment, compensation, compliance, FCOI, myCOI

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REVIEW PERIOD:

Three (3) years

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