

**THE CHILDREN'S MERCY HOSPITAL
AUDIT AND COMPLIANCE MANUAL
AUDIT AND COMPLIANCE PROCEDURE**

TITLE: Conflict of Interest Disclosure Review Procedure

EFFECTIVE: 10/2009

REVISION DATE: 04/2011, 03/2016, 07/2019

REVIEWED WITH NO CHANGES:

RETIRED:

PURPOSE:

To outline the Corporate Compliance department ("Corporate Compliance") procedure used for the review, approval and storage of conflict of interest disclosure forms, Management Plans and supporting documentation submitted by employees and medical staff (employed and nonemployed).

Note: This procedure replaces the *Outside Professional and Commercial Interests Review Process* document.

LOCATION/SCOPE:

Applies to Corporate Compliance.

DEPARTMENT(S) RESPONSIBLE FOR POLICY MANAGEMENT AND EXECUTION:

Corporate Compliance

PROCEDURE:

The following procedure is used by Corporate Compliance to manage conflict of interest disclosures and accompanying supporting documentation.

I. MyCOI

The Children's Mercy Hospital (the "Hospital") uses MyCOI, a software platform, to manage and retain conflict of interest (COI) disclosures for employees and medical staff. Corporate Compliance only accepts paper disclosures for National Institutes of Health (NIH) subcontractors because an electronic option is not available.

Note: When electronic submission of disclosures becomes available to NIH subcontractors, Corporate Compliance will rescind this exception.

II. Board Member and Captive Conflict of Interest

The processes for board members and captive COI are outlined in the Board of Directors Conflict of Interest Policy and Captive Procedure.

III. Medical Staff Conflict of Interest

A. Employed Medical Staff

Employed medical staff are required to complete the COI disclosure through MyCOI within 30 days of employment and during the annual employee COI completion period (usually July 1 – September 30).

B. Non-Employed Medical Staff

The Hospital does not track COI for non-employed medical staff.

IV. Employee Conflict of Interest

Employees are required to complete a COI disclosure through MyCOI:

- at the time of employment (within 30 days),
- any time the employee's outside relationships change,
- annually during the COI completion period (usually July 1 – September 30), and
- in accordance with the Conflict of Interest Reporting - Public Health Service Funded Research Policy.

V. Compliance Review of Disclosures

- A. If the individual has a possible bias or there is a correlation between Financial Interest disclosures and institutional responsibilities, the Compliance Program Manager will recommend to the individual a Management Plan to mitigate the disclosure.

Routine Management Plans (see [Exhibit A](#)) are determined, selected from a predetermined list of mitigations in the MyCOI system, and then sent to the individual to accept or reject.

Note: If the mitigation is not in the predetermined list of mitigations, it can be added.

- B. If a disclosure cannot be mitigated through a Management Plan or there is a refusal of the individual to accept the proposed Management Plan, the Compliance Program Manager will consult with the COI Committee for resolution.

VI. COI Committee

- A. Disclosures which cannot be remedied by the Compliance Program Manager or for which the Compliance Program Manager requests the COI Committee's input, the COI Committee will be consulted.
 1. The individual disclosing the interest is notified of the escalation to the COI Committee and has the opportunity to present their concerns.
 2. The COI Committee is the final authority regarding COI disclosures.

VII. Monitoring Conflict of Interest Activities

- A. The Compliance Program Manager is responsible for running and analyzing the following reports from MyCOI:
 - Certification reports: Displays all disclosure updates, annual certifications, and research certifications created in the MyCOI system by individual
 - Discloser reports: Provides a list of Hospital employees that have provided a disclosure
 - Disclosure reports: Displays disclosed information provided by Hospital employees
- B. The Compliance Program Manager will monitor and review the reports and, if applicable, develop a plan to address outliers such as non-compliant employees.

VIII. Disclosure Retention and Access

- A. Disclosures, Management Plans and supporting documentation are retained in the MyCOI system.
- B. Access to individual employee disclosures are limited to the Privacy Officer, Compliance Program Manager, Vice President of Audit and Compliance, and the MyCOI IT support staff.
 1. Grants administration has limited access to researchers' COI disclosures. This access is limited to show completed or not completed status and the date of completion.
 2. Problematic disclosures for individuals involved in research activities will be reported to the Institutional Review Board (IRB) in accordance with the Conflict of Interest Reporting - Public Health Service Funded Research Policy.
- C. Corporate Compliance may consult with the Office of the General Counsel/Risk Management regarding information about the employee's duties, decision-making responsibilities and relationships with the Hospital and the reported disclosures as applicable.
- D. In the event that a mitigation of the individual's disclosure cannot be established, and the Office of the General Counsel/Risk Management has determined the individual's

inability to objectively perform their job duties, the individual's manager and the Employee Relations team may be consulted regarding employment concerns.

DEFINITIONS:

Financial Interest (FI) means one or more of the following financial interests of an investigator and/or his/her immediate family member received in the 12 months preceding the disclosure which appear to be related to the investigator's institutional responsibilities:

- Payments or remuneration including salary and any non-salary (consulting fees, honoraria, paid authorship)
- Equity interest including stock, stock option or other ownership interest
- Income related to intellectual property rights and interest, such as patents and copyrights • Any reimbursed or sponsored travel related to their institutional responsibilities (sponsor travel that is paid on behalf of the investigators to the Hospital does not require disclosure by the investigator); includes any entity (including non-profits) except 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

Financial Interests do not include the following:

- Salary, royalties, or other remuneration paid by Hospital to the investigator if the investigator is currently employed or appointed by Hospital
- Intellectual property rights assigned to the Hospital and agreements to share in royalties related to such rights
- 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
- Income from seminars, lectures or teaching and service on advisory or review panels for federal, state or local government agencies; institutions of higher education; academic teaching hospitals; medical centers; or research institutes affiliated with an institution of higher education
- Payment made directly to Hospital; however, if payment for services is paid directly to the investigator, the remuneration must be disclosed regardless of whether the money will be turned over to the Hospital or will be used to support the investigator's future research activities

Management Plan means a plan of action to address a financial conflict of interest which can include reducing or eliminating the conflict to ensure – to the extent possible – that the design, conduct and reporting of research will be free from bias.

REQUESTS FOR GUIDANCE REGARDING THIS PROCEDURE:

Requests for guidance regarding this policy will be directed to the Compliance Program Manager.

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:

- Quarterly reporting: Number of hospital-wide management plans and the percentage of total disclosures
- Quarterly reporting: Number of research management plans and percentage of hospitalwide total disclosures
- Quarterly reporting: Top five Management Plan types
- Number of Management Plans escalated to the COI Committee
- Number of individuals non-compliant with completion of annual COI disclosure

RECOURSE FOR NON-COMPLIANCE:

Non-compliance will be addressed in accordance with the Conduct and Discipline Policy.

RELATED POLICIES:

Board of Directors Conflict of Interest Policy

Captive Procedure

Conflict of Interest Policy

Conflict of Interest Reporting - Public Health Service Funded Research Policy

Form 990 Procedure

Solicitation and Distribution Policy

RELATED FORMS:

REFERENCES:

REGULATIONS:

TJC LD 02.02.01 EP 3

KEYWORD SEARCH:

conflict of interest, COI, MyCOI, disclosure, management plan, COI Committee

POLICY CONTENT OWNER(S):

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ADMINISTRATIVE COUNCIL SPONSOR:

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REVIEW PERIOD:

Three (3) years

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FINAL APPROVAL:

Kim Brown

July 8, 2019

Kim Brown, CPA, MBA, CHC
Vice President, Audit and Compliance

Date

EXHIBIT A

The following list outlines recommended Management Plan options:

- Employee and supervisor review the Conflict of Interest Policy and address potential conflict of interest, protection of patient information and proper use of Hospital resources
- Employee and supervisor review Solicitation and Distribution Policy and address prohibition of soliciting/advertising/promoting employee’s outside activities while acting on Hospital’s behalf
- Employee recuses him/herself from participation in discussions or decision-making roles regarding the disclosed entity and/or its competitors
- Employee publicly discloses outside professional and commercial interests (when presenting or publishing research; to staff members working on research project; to the Hospital’s IRB)

- For researchers, modification of research plan including change in principal investigator, change in investigator responsibilities, prohibition of enrolling research participants, analyzing data or assessing adverse events
- Reduction or elimination of outside relationship creating the possible conflict (including sale of equity interest or investment placed in a blind trust)
- Severance of the relationship creating the possible conflict (termination of consulting agreement, speaker bureau contract)
- Other