

THE CHILDREN'S MERCY HOSPITAL ADMINISTRATIVE POLICY

TITLE: Outside Professional and Commercial Interests (Replaces Policy previously titled Conflict of Interest)
EFFECTIVE: 2/23/96
REVISION DATE: 9/26/96, 11/2/98, 12/03, 06/09
REVIEWED WITH NO CHANGES: 12/28/01
RETIRED:

PURPOSE

The purpose of this policy is to provide appropriate guidelines and oversight for the disclosure of and elimination or management of conflicts of interest on the part of Hospital Staff so that such conflicts are not detrimental to the interests or integrity of the mission, goals and objectives of the Hospital.

POLICY

The Hospital recognizes that there are many opportunities to develop relationships with outside entities and engage in other activities that enhance one's professional competency, render valuable service to the community, and benefit the individual and Hospital. In addition, the Hospital recognizes the necessity and importance of academic achievement as being critical to its continued evolution as an academic pediatric medical center. As a result of these activities, CMH recognizes that the relationships between Hospital Staff, private industry, federal and state governments, and the non-profit sector have grown increasingly complex.

Some activities and relationships may appear to pose a conflict of interest; therefore, it is critical that such relationships and activities be approached in a manner consistent with Hospital codes and policies in order to eliminate or manage potential conflicts.

For the purpose of protecting the integrity and objectivity of its staff in the performance of their Hospital obligations, it is the policy of the Hospital that conflicts of interests should be avoided where possible, or disclosed and managed so as to avoid violation of state and federal laws and the CMH Code of Conduct. Since the existence of a conflict of interest is not always easily determined, Hospital Staff are required to disclose those relationships so that a reasonable determination can be made regarding the conflict and, if needed, the appropriate management of such conflict.

Upon disclosure, it is the responsibility of the Hospital Staff's supervisor/manager or Section Chief to review and address any potential conflicts of interest. The Compliance Department is responsible for providing support and additional guidance regarding possible conflicts as well as assisting in the administration of Hospital's policies. In the event a proposed remedy is not put forth, or there are concerns about the proposed remedy, the matter will be reviewed by the Compliance Committee. All information disclosed by Hospital Staff for the purposes of this policy will be kept strictly confidential and will only be shared with those Hospital Staff responsible for the administration of this policy.

DEFINITIONS

Conflict of Interest: A situation in which Hospital Staff have financial or other personal considerations that may compromise or have the appearance of compromising their professional judgment in conducting his/her duties for the Hospital, conducting or reporting research, teaching, or performing other obligations as Hospital Staff.

Financial Interest: 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. stock, stock options or other equity ownership interests), and intellectual property rights (e.g. patents, copyrights and royalties from such rights) regardless of the dollar amount. This **does not** include interest arising solely by reason of investment by a mutual fund, pension, or other institutional investment fund or blind trust.

Hospital Staff: All CMH employees, including but not limited to, administrative staff, managers, employees, dependent and independent allied health care professionals, Medical Staff members, residents and fellows.

Hospital: The Children's Mercy Hospital, including any partially or wholly owned subsidiary.

Immediate Family: In accordance with IRS guidelines, this includes spouse, ancestors, children, grandchildren, great-grandchildren, siblings (whether by whole or half blood), and the spouses of children, grandchildren, great-grandchildren, and siblings. For the purposes of this policy, it is irrelevant whether these family members live in the same household.

Prohibited Activities: Activities undertaken by a Hospital Staff member which are violations of Hospital policy.

ACTIVITIES REQUIRING DISCLOSURE

General

Hospital Staff must disclose outside professional activities that the individual should reasonably believe involves responsibilities that have the potential to interfere with the performance of the member's administrative, teaching, research, or clinical service obligations to the Hospital. Examples of such activities are as follows:

1. Directorship, managerial or consultant services to, agreements with, or as an employee or agent of, any outside concern that does business with or competes with the services of the Hospital (i.e. drug or device manufacturers, providers of medically related good and services, medical institutions, etc.).
2. Any involvement, written agreements or business dealings with for-profit or not-for-profit organizations which may be perceived to compete, compete with or do business with the Hospital.
3. Financial Interests in, or relationships with, any company with whom the Hospital does business with or competes with the services of the Hospital.

4. All written agreements or business dealings with any supplier, research sponsor, corporation or other entities or persons with whom the Hospital does business with or competes with services of the Hospital.
5. Any outside employment or moonlighting.
6. Professionally-related activities such as consulting, speaking engagements and/or speaker's bureaus, advisory board services, and review panel participation.
7. Expert witness testimony and/or services.
8. The undertaking of research when the Hospital Staff member or an Immediate Family Member has a Financial Interest in either the sponsoring entity or in the entity producing the product to be evaluated.
9. The publication or presentation of research results in which the presenter has a Financial Interest in the entity producing the product to be evaluated or in a competing entity.
10. Any payments that represent a Financial Interest which are made by the sponsor of a study to an investigator or to CMH to support activities of the investigator (ex: grants to support investigator-initiated research, payments for educational activities and/or staff development, equipment, and consultancy or honoraria payments) that are external to the costs of conducting a sponsor-initiated clinical trial.
11. Any other arrangement entered into between Hospital Staff and any corporate entity which could influence the outcome of a research study.

ACTIVITIES NOT REQUIRING DISCLOSURE

Hospital Staff are encouraged to become involved in community service, civic affairs, and political activities. Hospital Staff are reminded that according to the CMH Code of Conduct, Hospital resources should not be used to support these activities. These activities may include, but are not limited to:

- a. serving on civic boards, boards of learned societies and/or editorial boards of professional journals, engaging in governmental, political, community, or charitable activities.
- b. engaging in family, religious, or other personal activities.

PROHIBITED ACTIVITIES

1. Payment of bonuses and/or the offering of incentives, made by research sponsors, whether made directly to the individual or to the Hospital, for accelerated or increased enrollment in clinical research protocols.
2. Use of confidential information for personal financial gain.
3. Compensation, through financial interest, for conducting research where payment is affected by the outcome of the research (e.g. higher compensation for a favorable outcome).
4. Use of human and/or material resources of the Hospital for non-Hospital purposes (for example, not related to the employment/academic expectations for a given Hospital Staff member).
5. Activities conducted on Hospital time or using Hospital resources which are not for purposes related to the mission of the Hospital.
6. Any activities prohibited by law.
7. Arrangements with outside organizations which have not received approval as required by this policy.

PROCEDURE

1. Hospital Staff will be required to complete an Outside Professional and Commercial Interests Disclosure Form (Attachment A): 1) upon employment or affiliation with the Hospital; 2) as a part of the annual performance evaluation process (if applicable); 3) at least one time annually; and 4) any time the Hospital Staff's professional or commercial relationships change. Hospital Staff who have completed a Disclosure Form in the last 12 months and need to update their information due to a change in a professional or commercial relationship, Hospital Staff may complete an abbreviated Disclosure Form marked "Amendment". Amendments will be attached to the existing Disclosure Form. However, a full disclosure of all activities must be submitted at least once annually.
2. Hospital Staff have a continuing duty to update their information within a reasonable amount of time, should he/she engage in any new activity or position that is reportable. In addition, department managers/chairs or Section Chiefs may request that a Hospital Staff member within their area complete the Outside Professional and Commercial Interests Disclosure Form as circumstances arise.
3. Hospital Staff shall obtain the approval of their department managers/chairs or Section Chief of the Hospital prior to engaging in any activity on Hospital time which will result in payment (apart from hospital salary) or other form of compensation to a Hospital Staff member.
4. If a Hospital Staff member has doubt as to whether an outside activity involves a conflict of interest, the Hospital Staff member should consult with his or her supervisor, department manager/chair, Section Chief or the Corporate Compliance Manager to seek advice on whether disclosure is necessary.
5. Hospital Staff who fail to disclose or resolve a conflict of interest will be subject to counseling, up to and including termination of employment or affiliation with the Hospital. By signing the Outside Professional and Commercial Interests Disclosure Form, Hospital Staff are certifying that (1) they have read and understand the Hospital policy; (2) all required disclosures have been made; and (3) they will comply with any conditions or restrictions imposed by the Hospital to manage, reduce or eliminate conflicts of interest.

REVIEW PROCESS

1. The Outside Professional and Commercial Interests Disclosure Form must be reviewed and signed by the applicable department manager/department chair or Section Chief.
2. Any identified issue that represents a potential conflict will be addressed by the department manager/chair or Section Chief to propose an appropriate resolution and/or remedy.
3. The applicable department manager/chair or Section Chief will work in collaboration with the affected Hospital Staff in an effort to resolve the issue.
4. The department manager/chair or Section Chief will forward the Disclosure Form to the Corporate Compliance Manager, or the Medical Staff Office when applicable, noting whenever any potential conflicts exist, including the appropriate resolution, remedy or notification that the conflict cannot be resolved.
5. All forms will be reviewed by the Corporate Compliance Manager or a designated Compliance department employee in his/her absence.

6. If the Corporate Compliance Manager concurs that no conflict exists or that the proposed remedy is appropriate, he or she will sign the Disclosure Form and forward it for retention purposes.
7. In the event that the applicable department manager/chair or Section Chief and the affected Hospital Staff are unable to provide a proposed remedy, or if the proposed remedy does not meet the intent of this policy as determined by the Corporate Compliance Manager, the issue will be forwarded to the Corporate Compliance Committee for review and resolution. The process for such review and resolution will be determined by the Corporate Compliance Committee.
8. In addition to the reporting requirements outlined in this policy, Hospital Staff involved in the conduct of research are also responsible for providing disclosure of conflicts of interest on IRB application forms, on Medical Research Administration Approval Forms and to industry sponsors (when required).

The Outside Professional and Commercial Interests Disclosure Form is available on the CMH Intranet under "Downloadable Forms".

RELATED POLICIES:

Corporate Compliance Plan
Code of Conduct

REFERENCES:

Internal Revenue Service Ruling 69-545, 1969-2 C.B.117
42 CFR § 50, subpart F
45 CFR § 94
21 CFR § 54

WRITTEN BY:

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APPROVED BY:

Medical Staff Executive Committee: 05/06/2009

Administrative Council: 05/28/2009

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Doug Blowey, MD	06/15/2009
Medical Staff President	Date

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Randall L. O'Donnell, PhD	06/16/2009
President/CEO	Date

Frequently Asked Questions: Outside Professional and Commercial Interests

Section 1: Definitions

Q1: Who does the Outside Professional and Commercial Interests Policy apply to?

A1: This policy, previously known as the Conflict of Interest Policy, applies to all Hospital Staff which includes all CMH employees, administrators, managers, dependent and independent allied health care professionals, medical staff members, residents and fellows.

Section 2: Activities Requiring Disclosure

Q2: What am I required to disclose?

A2: The complete list of relationships which would require disclosure can be found in the Outside Professional and Commercial Interests Policy. Some examples of these relationships include consulting agreements, employment with another organization, receiving payment as a result of participation in a speaker's bureau, having a financial interest in a company that does business with CMH, having a financial interest in a company that sponsors research at CMH. Please remember that these activities may not be prohibited, but do require disclosure.

Q3: How frequently must I disclose this information?

A3: All Hospital Staff must disclose their relationships: 1) at the time of affiliation or employment; 2) at the time of Hospital Staff's performance evaluation (if applicable); 3) at least one time annually; or 4) any time the Hospital Staff's professional and commercial relationships change. Hospital Staff who have completed a Disclosure Form in the last 12 months and need to update their information due to a change in a professional or commercial relationship, may complete an abbreviated Disclosure Form marked "Amendment". Amendments will be attached to the existing Disclosure Form. However, a full disclosure of all activities must be submitted at least one annually.

Section 3: Activities Not Requiring Disclosure

Q4: Do I have to disclose my relationships with the local PTA, my church or other non-professionally related affiliations?

A4: No, CMH does not require disclosure for Staff serving on civic boards or engaging in governmental, community, or charitable activities.

Section 4: Prohibited Activities

Q5: What activities are prohibited by the outside Professional and Commercial Interests Policy?

A5: A list of prohibited activities is available in the policy, however, some examples of such activities include using confidential information for personal financial gain, receiving compensation for conducting research where payment is affected by the outcome of the research (e.g. higher compensation for a favorable outcome), or activities

conducted on Hospital time or using Hospital resources which are not for purposes related to the mission of the Hospital.

Sections 5 & 6: Procedure and Review Process

Q6: What happens when I disclose my information?

A6: Hospital Staff's supervisor/manager or Section Chief are responsible for reviewing each Hospital Staff's disclosure form and determining whether the Hospital Staff's outside activities constitute a potential, actual or perceived conflict of interest. If such a determination is made, it is the responsibility of the manager/supervisor or section to develop, document and implement an appropriate plan to manage such a conflict. Once completed, all disclosure forms and management plans are reviewed by the Corporate Compliance Manager.

Q7: What is the process if my supervisor and I disagree about the management of my conflict?

A7: The Corporate Compliance Committee is responsible for assisting in resolving those situations in which a Hospital Staff member and his/her manager are unable to develop or agree on an acceptable management plan. Because each relationship is reviewed based on your role in the organization and the potential risk presented by each potential conflict, you may be asked to provide additional information to the Corporate Compliance Committee to assist in resolution of the case.

Q8: What are the possible solutions to managing a conflict?

A8: Depending on the Hospital Staff's role within CHM and the conflict to be resolved, a number of remedies are available which include, but are not limited to:

- Limiting employee's decision making responsibilities regarding the use of the products or services provided by the entity with whom they have a relationship
- Disclosure of the relationship to research subjects, or in publications and presentations
- Limiting the role of the investigator in research situations
- Reassignment of patients in clinical situations

Q9: Who can I contact if I have questions about this policy?

Q9: Hospital Staff are strongly encouraged to discuss all outside relationships with their supervisor/manager or Section Chief prior to engaging in activities which may present a potential conflict. If you have questions regarding disclosure or potential remedies, the Corporate Compliance Manager is your CMH resource for all conflict of interest questions.

Contact:

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Please be advised that all information disclosed by Hospital Staff for the purposes of this policy will be kept strictly confidential and will only be shared with those Hospital Staff responsible for the administration of this policy.