



Conflicts of Interest: Organizational Conflicts

Policy

Children's Hospital is sensitive to concerns regarding charitable institutions and their relationships with industry. Children's Hospital is committed to ensuring that its relationship with industry does not result in inappropriate influence, or the perception of such influence. This policy addresses institutional interactions with industry and potential institutional conflicts of interest.

Children's Hospital has several policies and procedures that address conflicts of interest arising from financial interests of the organization or its leaders. This policy refers to those and addresses additional potential concerns. This policy further focuses on the resolution of such conflicts to ensure that they do not influence the Hospital's clinical operations, the conduct of clinical research or the integrity of the Committee on Clinical Investigation or its operations.

Procedure

1. Licensing, Technology Transfer and Patents.

Children's Hospital will from time to time acquire an equity interest or compensation arrangement relating to licensing, technology transfer and patents. These interests are reported and managed in accordance with policies governing these types of interest, including the *Guidelines for Institutional and Investigator Ownership of Equity, Managing Equity Obtained in the Transfer of Hospital Owned Technology in Companies Sponsoring Clinical Research. Conflicts of Interest, Clinical Research* sets forth the policy and procedure related to the Committee on Clinical Investigation's review of and management of the Hospital's participation in clinical trials of a test article sponsored by a licensee in which the Hospital holds license-related equity.

Senior leaders are required to disclose annually whether they personally hold any equity in companies in which the Hospital also holds equity pursuant to intellectual property arrangements. To ensure a robust review of these annual disclosures, Children's Hospital's Technology and Innovation Development Office provides a list of all companies in which the institution holds equity to the Compliance Officer, who reviews all individual disclosures against this list. Any disclosures which reveal the holding of such equity is referred to the Office of General Counsel for further review, and, if necessary management. If the interest could present a conflict with the conduct of research or the Committee on Clinical Investigation or its operations, the General Counsel will work with the Office of Sponsored Research, the Office of Research Compliance, and/or the chair of the institutional review board to ensure a plan is implemented to eliminate or manage the conflict.

2. Investments

Children's Hospital acquires equity and investment interests through the Chief Investment Officer who reports directly to the President. To ensure that investment decisions do not influence or compromise the integrity of its charitable mission, investment decisions are separate from the oversight of its charitable mission. This separation reflects our commitment to our patients, human subjects in research and the integrity of our clinical and research endeavors.

3. Gifts

The Hospital's development unit, the Children's Hospital Trust, reports significant corporate donations and prospects regularly to the Corporate Interests Committee. This committee's membership includes the General Counsel, who monitors such donations for potential conflict with the conduct of clinical research or the Committee on Clinical Investigation and its operations. Consideration will be given to various factors related to the gift, including whether or not the gift is held for the benefit of the unit where the research is conducted, and if any institutional official involved in soliciting the gift has any authority to affect the conduct, review or oversight of proposed research. If any potential conflict is identified the Office of General Counsel will work with senior leaders, including as appropriate, the Office of Sponsored Research, the Office of Research Compliance and/or the chair of the institutional review board to ensure a plan is implemented to eliminate or manage the conflict.

4. Financial Interests of Senior Leaders

As set forth in Children's Hospital *Conflict of Interest Policy*, Hospital senior leaders and others in positions of authority, including those in positions with purchasing authority, are required to disclose annually their outside financial interests. These disclosures are reviewed by the Compliance Officer who refers any potential conflict of interest to the Office of General Counsel for review. Conflicts of interest that may be related to the institution's research endeavors are reviewed by the Office of General Counsel to determine whether any such interests could present a conflict with the conduct of research or with the operations of the Committee on Clinical Investigation. If any potential conflict is identified the Office of General Counsel will work with senior leaders, including as appropriate, the Office of Sponsored Research, the Office of Research Compliance and/or the chair of the institutional review board to ensure a plan is implemented to eliminate or manage the conflict.

Other relevant policies include:

Guidelines for Institutional and Investigator Ownership of Equity, Managing Equity Obtained in the Transfer of Hospital Owned Technology in Companies Sponsoring Clinical Research

Conflict of Interest Policy

Code of Conduct

Policy on Inventions and Intellectual Property

Conflicts of Interest: Procedures for Coordinating Investigations

Conflicts of Interest: Clinical Research

Resolution and Management of Conflicts of Interest.

Potential institutional conflicts of interest are reviewed by the General Counsel's Office who has the responsibility to involve other senior leaders of the institution in the review and management of potential conflicts. This might include the Vice President for Research Administration, the Director of Clinical Research Compliance, the chair of the institutional review board, and other senior leaders from the Children's Hospital Trust or Office of Finance. The financial interest is

reviewed to determine if such interest might potentially effect Children's Hospital's clinical operations or the protection of those involved in our research endeavors.

Once a potential conflict is identified it is the responsibility of the senior leadership to ensure a plan is implemented to eliminate or manage the conflict.

Management strategies might include:

- If an individual conflict, recusing oneself from relevant decision making;
- If an individual conflict, reduce, modify or eliminate the financial interest;
- If a conflict related to the institutional ownership of equity, the decision that the institution will not conduct clinical trials on the technology of the company;
- If a conflict related to a major donation, a separation from those involved in soliciting/managing the gift and those involved in any related research or clinical care;
- Disclosure of the financial interest in publications, presentations, future grant applications and other communications;
- Disclosure of the financial interest to trainees and supervisees;
- If involving human subject research, establishing a monitoring process to protect the integrity of the research and the well-being of human subjects;
- Not proceeding with the activity related to the financial interest.

Management strategies will be structured to address the complexities of each individual potential conflict.

Document Attributes

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