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Owner Alisia

Lamborghini

Department

Compliance

Applicability

Boston Children's

Hospital-Policies

& Procedures

Chapter /

/ Activities

Tags

outside US, Annual

Disclosure,

Consulting + 17 more



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# **Conflict of Interest and Commitment Policy/Procedure**

# **Internal Approval**

SVP, Chief Compliance Officer

# Scope

This policy applies to all Boston Children's Hospital (BCH) administrative, operational, clinical departments, and hospital licensed locations and all providers and staff (employees, contracted staff, and members of the medical staff, and scientific research staff). The policy also applies to foundation practices leasing space at hospital-licensed locations.

# **Definitions**

Boston Children's Hospital:	The Children's Hospital Corporation d/b/a Boston Children's Hospital, and Children's Medical Center Corporation and any of their respective subsidiaries, and affiliates, including BCH faculty physician foundations.
Business:	Any legal entity organized for profit or non-profit purposes. This term includes, but is not limited to: corporations, partnerships, sole proprietorships, associations, organizations, holding companies, and business or real estate trusts. A Business is considered to be "non-profit" if it is legally organized for charitable purposes (e.g., 501(c)(3) and equivalents), unless it is principally organized, funded, and/or managed by

	one or more for-profit entities engaged in commercial or research activities of a biomedical nature. This term does not include unions or labor organizations.
Company:	Any pharmaceutical or medical device company, or any other person or Business that provides or is seeking to provide goods or services to BCH or that otherwise does business with or is seeking to do business with BCH.
Conflict of Commitment:	An Outside Relationship that creates a risk of undermining a Covered Person's Primary Interest. Generally, Covered Persons who are full-time employees of BCH may not devote more than 20% of their professional time to Outside Relationships.
Conflict of Interest:	An Outside Relationship that conflicts with a Covered Person's Primary Interests that may result in inappropriate influence, or the perception of such influence over the activities of the Covered Person in accordance with all applicable state and federal laws and the standards of business and professional ethics and commitment to the principles stated in the <a href="Code of Conduct">Code of Conduct</a> .
Consulting Agreement:	Any arrangement in which a Business provides anything of value to a Covered Person, department, or foundation in exchange for services. This includes grants and other advisory type payments.
Covered Persons:	Each employee, faculty member, fellow, resident, student, visiting faculty or scientist, consultant, members of the medical or research staff and volunteers of BCH, whether compensated or not, who are involved in any activities supported in whole or in part by funds, personnel, facilities, materials or other resources of BCH or administered by BCH. This policy also applies to members and officers of BCH's governing boards, including elected and ex-officio members, and members of certain BCH standing committees as determined by the Compliance Department.
Executive Position:	Any position that is responsible for a material part of the operation or management of a Business. This term specifically includes, but is not limited to, the following positions: Chief Executive Officer, Chief Operations Officer, Chief Scientific Officer, Chief Medical Officer, Scientific Director, and Medical Director.
Fiduciary Role:	A Fiduciary Role includes but is not limited to members of the fiduciary board of directors, managers of or members of a member-managed limited liability company, and partners in a partnership or limited liability partnership. This definition excludes Scientific Advisory Boards.
Gift:	Anything provided by a Company having monetary value for which no legitimate services are provided by the recipient. Gifts include travel, meals, entertainment, books, etc.
Institutional Conflict of Interest:	An Outside Relationship of BCH or BCH's Senior Leaders that may result in inappropriate influence, or the perception of such influence, over the activities of the institution in accordance with all applicable state and federal laws and the standards of business and professional ethics and commitment to the principles stated in the <a href="Code of Conduct">Code of Conduct</a> .

Meal:	Any food or drink on or off BCH's premises.
Modest Meal:	A Meal with a similar value to what a Covered Person would purchase if dining at his or her own expense.
Outside Relationship:	A relationship with any business entity, or institution of higher learning or foreign institutions) Business. This includes any Business that competes directly or indirectly with BCH in the purchase or sale of any property, goods, or services. This also includes, but is not limited to Businesses that provide direct patient care, conduct biomedical research, produce, provide or market medical services or products, or are vendors of BCH. An Outside Relationship includes a Covered Person's family member's relationship with a Business (spouse, partner, and dependent children).
Primary Interest:	A Covered Person's obligation to BCH (and to Harvard Medical School (HMS), if a member of the HMS faculty) and the sponsors of research at BCH. This includes obligations under BCH's policies, grants, contracts, collaborative agreements, and any agreements with BCH (including a participation agreement concerning ethical conduct, conflicts of Interest, intellectual property, confidentiality, compliance with federal and state laws, regulations and policies).
Senior Leaders:	Members and officers of the BCH governing boards, including elected and ex-officio members; and 2. members of the senior leadership team (Senior Vice Presidents or above); and 3. certain BCH standing committees; and 4. key employees who have decision making authority or purchasing authority on behalf of BCH. Categories 2-4 are determined by the Compliance Department in consultation with the Office of General Counsel.
Spin Off Company:	A for-profit Business developed by or in close collaboration with BCH, which shall be evidenced by one or more of the following: (i) initial BCH equity ownership of greater than 20%, or (ii) designated fiduciary board position(s) or consent rights over material corporate actions. A Business shall no longer be considered a Spin-Off Company at such time where neither (i) or (ii) exist.

# **Policy Statement**

Boston Children's Hospital (BCH) is committed to conducting its affairs in accordance with the highest ethical and legal standards. Industry relationships are necessary to support BCH's mission. However, such relationships may create Conflicts of Interest (COIs). The purpose of this Policy is to identify, manage and/or mitigate COIs for individuals as well as BCH. This policy aims to promote complex industry collaborations while safeguarding research integrity and patient safety.

### **Procedure**

## **Individual Conflicts of Interest and Commitment**

Individual Conflicts of Interest may arise in operational, clinical and research settings. When Covered

Persons acquire Outside Relationships, the Outside Relationships may conflict with their Primary Interests. Covered Persons are permitted and encouraged to hold Outside Relationships, so long as they receive the approval or their supervisors. Chiefs and Vice Presidents must receive approval from Senior or Executive Vice Presidents, or the Chief Executive Officer, as applicable. Outside Relationships must be reported in accordance with section II below. Outside Relationships that are Conflicts of Interest must be managed, mitigated or eliminated. Additionally, Outside Relationships that are Conflicts of Commitment must be eliminated or managed.

#### I. General Rules Regarding Outside Relationships for Individuals

#### A. Research Funded by PHS Entities

Any researchers who seek or receive funding from Public Health Service (PHS) entities are subject to the policies set forth in the <u>Public Health Service Investigator</u> Conflict of Interest Policy as it is modified from time-to-time.

#### **B.** Harvard Medical School Policy on Conflicts of Interest and Commitment

All Covered Persons who are also HMS faculty members are subject to the <u>Harvard Medical School Policy on Conflicts of Interest and Commitment</u> as it is modified from time-to-time.

#### C. Consulting

As described in the Boston Children's Hospital Intellectual Property Policy, BCH recognizes that Covered Persons may engage in outside consulting activities to further their knowledge and contribution to the community. However, all Covered Persons must receive approval from their Chiefs/Vice Presidents before engaging in a consulting activity. Further, all Consulting Agreements must be sent to the Office of General Counsel for review. The Office of General Counsel's review is meant to protect academic independence, prevent Conflicts of Interest and protect BCH's intellectual property. Covered Persons may wish to retain their own counsel to protect their individual rights. Expert witness agreements do not need to be reviewed or approved by BCH, so long as they do not create a Conflict of Interest. The compensation for services under a Consulting Agreement, including membership on scientific advisory boards, must not exceed fair market value. Compensation exceeding \$50,000 on an annual basis or any equity in a private company will be subject to additional review and may be subject to management.

#### D. Speaking Engagements

Covered Persons are generally permitted to receive honoraria for speaking engagements. It is recommended that individuals who participate in speaking engagements have written agreements in place. Honoraria as referenced in this Policy include reimbursed travel and lodging for the speaker and his or her family members. Participation in Speaker's Bureaus is prohibited. Speaker's Bureaus are generally defined as events where a Business compensates an individual to speak about the Business's product in a scripted manner. Speaker's Bureaus do not include arrangements with an entity other than a pharmaceutical, device, or biomedical

company that acts as an agent or broker to fill national and internationally-based requests for speaking services for prominent figures in certain subject matter areas. These areas include government, foreign service, education, science, medicine, and the like.

- a. Honoraria are permissible so long as:
  - For speaking engagements coordinated by a third-party, the payment to the Covered Person is made by the program coordinator (e.g., American Medical Association, American Hospital Association, etc.) and not the company;
  - ii. The Covered Person maintains control over the content of the presentation; and
  - iii. The content of the presentation is educational in nature and does not advertise the product or services of the program coordinator or company.
- b. Honoraria greater than \$5,000 must be reviewed by the Compliance Department. The Compliance Department will consider whether the terms of the agreement comply with BCH and HMS policies and any applicable government regulations.
- c. Where Honoraria exceeds \$5,000 and there is no written agreement, or in other circumstances, a conflict of interest management plan shall be required. The management plan must be approved by BCH's Conflict of Interest Committee consistent with BCH and HMS Policies. Other circumstances include those where the compensation exceeds the typical range for honoraria, or where the speaking engagement creates a Conflict of Interest.

#### **E. Fiduciary Roles**

Covered Persons considering a Fiduciary Role for a Business should contact the Compliance Department. Such requests will be considered on a case-by-case basis and may be subject to management and COI Committee approval.

#### F. Gifts and Meals

Gifts from a Company to a Covered Person having a monetary value of less than \$100 in the aggregate in any one calendar year are permissible if such gifts serve a patient care or educational purpose (e.g., stethoscopes, medical textbooks, anatomical models). Such Gifts from a Company having a monetary value of \$100 or greater in the aggregate in any one calendar year are prohibited. All Gifts from a Company that do not serve a patient care or educational purpose, regardless of their value, are prohibited.

Covered Persons who are HMS Faculty should note that all Gifts are prohibited under the HMS policies, regardless of their value.

a. All Meals are subject to this Policy, regardless of their financial value.

Covered Persons are prohibited from soliciting or accepting any Meals from a Company. Exceptions to this prohibition include the following:

- Modest Meals are permitted when incident to an authorized administrative function on behalf of BCH, including for example, user group meetings or advisory councils.
- ii. Other exceptions are available as listed in the HMS Policy on Conflicts of Interest and Commitment:
  - Contractually Required Meeting: Covered Persons are permitted to accept Modest Meals while attending a meeting with a pharmaceutical, medical device, or biotechnology manufacturing or supply company if their attendance at the meeting is included in the terms of their agreement with the company;
  - 2. Education Exception: Covered Persons are permitted to accept Meals offered by a continuing medical education (CME) provider or other professional conference or meeting organizer during the course of a CME event or other professional conference or meeting if the Meals are offered across the board to all participants out of the event's budget at the discretion of the organizer and are not directly provided or earmarked for such purpose by a pharmaceutical, medical device, or biotechnology manufacturing or supply company;
  - 3. Research Collaboration/Funding Request Exception: In general, a Covered Person should pay for the cost of his or her own Meal when meeting with industry representatives. A Covered Person may, however, accept Modest Meals from medical and device manufacturers when discussing potential research collaborations and funding opportunities with nonsales/marketing industry representatives if it is not reasonably feasible for the Covered Person to pay for his or her own Meal. Covered Persons should be aware that under the Physician Payments Sunshine Act and the Massachusetts Pharmaceutical and Medical Device Manufacturer Code of Conduct. manufacturers of drugs, medical devices, and biologics may be required to report the provision of such meals as part of its annual report to Medicare/ Medicaid and the Massachusetts Department of Public Health, respectively.

#### G. Activities Outside the United States

The scope of required disclosures applies without regard to whether the activity originates from or takes place outside the Unites States. All Covered Persons have

an affirmative obligation to disclose outside activities involving any foreign Business or organization, foreign academic institution, or any foreign government department, agency, or program. This includes, but is not limited to:

- a. Any employment, internship, Consulting Agreement, Speaking Engagement, or Fiduciary Role;
- b. Any titled affiliation or appointment;
- c. Any educational, research, or philanthropic grant or support;
- d. Any funding of visiting scientists, students, or other personnel;
- e. Any support or recognition through a talents award or recruitment program;
- f. Any gifts, meals, entertainment, travel, or lodging;
- g. Any equity or other financial interest in a foreign Business; and
- h. Any financial interest relating to foreign licensing, technology transfer, patents, other innovations, or services filed without the involvement of BCH. The financial interest may be any of the following: equity; license payments; milestone payments; royalties; and/or other forms of remuneration and compensation.

The scope of this obligation covers outside activities whether compensated or not.

Upon request, Covered Persons will be required to provide additional supporting documentation related to an outside activity, such as appointment letters, collaboration agreements, contracts, financial records, or other relevant documents.

#### II. Individual Conflict of Interest Disclosure Process

#### A. Annual Disclosure Process

Certain Covered Persons must complete an electronic disclosure form in BCH's Electronic Research Portal (CHeRP) on an annual basis. These Covered Persons include:

- medical and associate medical staff;
- · researchers; and
- Senior Leaders

The Compliance Department shall initiate the annual disclosure process and will determine to which individuals it applies; the Compliance Department will notify the individuals and their Chiefs/Vice Presidents accordingly.

#### B. Research Disclosure Process

a. Grants- All researchers submitting proposals for funding through the
Office of Sponsored Programs must submit an electronic Conflict of
Interest statement through CHeRP. Researchers must submit the
statement regardless of whether the funding sought is from a PHS entity.

Individuals seeking grant funding from a PHS entity must follow the additional requirements set forth in the <u>Public Health Service Investigator Conflict of Interest Policy</u>. Specifically, investigators who plan to participate in PHS-funded research must:

- submit disclosures no later than at the time of application for PHS-funded research;
- update disclosures annually during the entire period of the federal award; and
- update disclosures within thirty (30) days of discovering or acquiring a new outside activity or interest.
- b. Clinical Research Institutional Review Board (IRB) Protocols- All researchers who are submitting protocols for IRB review must complete the financial disclosure section of the CHeRP submission form at the time of submission.

#### C. Situational Disclosure Process

All Covered Persons (whether or not they receive an annual disclosure) have an affirmative obligation to disclose to their supervisors whenever they believe they may have a Conflict of Interest or Conflict of Commitment.

#### D. Harvard Medical School Disclosure Process

All Petitions for exceptions to HMS COI Rules must be submitted to the Compliance Department. The Compliance Department will communicate with HMS to ensure the appropriate dual institution review process described in the <u>Harvard Medical School Policy on Conflicts of Interest and Commitment</u>.

#### E. Disclosure Outside of BCH

It is the responsibility of all Covered Persons to disclose outside Relationships in presentations and academic publications as required by the journal or event organizer.

#### III. Review for Individual Conflicts

The Compliance Department shall review individual disclosures. They may be shared with the following in order to facilitate the identification of Conflicts of Interest and Conflicts of Commitment: The Office of General Counsel, the Tax Department, Chiefs/Vice Presidents, and HMS.

Working in consultation with the Office of General Counsel and/or the Chief Executive Officer, the Compliance Department shall draft a management plan for any Outside Relationships that are or may be Conflicts of Interest. The Compliance Department shall send management plans that pertain to research to the Conflict of Interest Committee for approval. Additionally, for management plans that pertain to human subject research, Covered Persons shall be responsible for notifying the IRB of the nature of the conflict and approved management strategies. The IRB will make the final determination regarding whether the Conflict of Interest may be managed. The IRB may suggest additional or alternative management strategies.

Finally, the Compliance Department shall maintain a copy of all management plans.

### **Institutional Conflicts of Interest**

BCH relies upon institutional collaborations with industry in advancing its mission and improving patient care and research. BCH is also committed to ensuring that its relationships with industry do not result in inappropriate influence, or the perception of inappropriate influence.

#### i. General Rules Regarding Outside Institutional Interests

#### A. Philosophy Statement

Boston Children's Hospital is committed to prioritizing the highest quality patient care and academic integrity. Outside relationships and activities can support BCH's contributions to the business and broader community through exchange of ideas and collaboration. As a non-profit charitable organization, our mission is to promote these scientific discoveries and medical advancements to improve the health and welfare of children across the globe. These relationships and activities also provide valuable experiences for Senior Leaders. Non-profit or community board roles, for example, can advance BCH's mission, including our commitment to equity, diversity and inclusion. However, all outside relationships and activities must be arranged as to not present a conflict of commitment that would compete with or undermine a Senior Leader's core obligations to BCH.

Partnerships with companies that work to commercialize innovations and bring therapies to patients have great potential for scientific and clinical advances and are consistent with the mission of the Hospital. However, outside for-profit Fiduciary Roles have the potential to create a potential or actual conflict of interest. As a result, additional attention is necessary related to members of the senior leadership team (Senior Vice Presidents or above) and for-profit Fiduciary Roles in order to mitigate risks to the institution. Accordingly, BCH has a rebuttable presumption that members of the senior leadership team will not participate in outside for-profit Fiduciary Roles. The presumption can be overcome when there are compelling reasons that the for-profit Fiduciary Role will advance the mission of Boston Children's Hospital.

#### **B. Senior Leaders**

Senior Leaders have heighted responsibility to identify and manage potential conflicts due to their roles at BCH. Conflicts may be created by the nature of Senior Leaders' Outside Relationships as well as the time commitments and efforts that may be required to engage in the activities.

#### a. Senior Leaders' Interests in Companies

A Conflict of Interest may arise when a Senior Leader has an Outside Relationship that relates to a particular arrangement into which the Senior Leader knows BCH is considering entering. When this conflict arises, a Senior Leader must inform his or her direct supervisor of the conflict. Members of the governing Board of Directors must report such conflicts to the Compliance Department. Generally, a conflicted Senior Leader must recuse him or herself from any and all discussions and decisions

regarding the arrangement. However, the Compliance Department may implement a management plan where a Senior Leader's knowledge from an Outside Relationship would benefit BCH during any discussions of the arrangement but will not pose a Conflict of Interest. Such a management plan may require that the Senior Leader inform others involved in the discussion and refrain from decision-making.

b. Senior Leaders' Interests and Roles in Spin Off Companies

It is presumed that Senior Leaders and members of the BCH Board of Directors and the BCH Trust Trustees may not directly or indirectly invest in, serve in an Executive Position or in a Fiduciary Role of a BCH Spin Off Company. In all cases, compensation for serving in an Executive Position or Fiduciary Role for a BCH Spin Off Company is prohibited. Compensation for consulting services for a BCH Spin Off Company is subject to review and approval by the Compliance Department and the Executive Committee of the BCH Board of Directors.

c. Senior Leaders' Fiduciary Roles for Businesses in the Health Care Field and For-Profit Businesses

Conflicts of Interest may arise when Senior Leaders or members of BCH's Board of Directors or the BCH Trust Board of Trustees hold a Fiduciary Role for a Business in the healthcare field or in any for-profit Business regardless of field.

Senior Leaders, members of the Board of Directors, members of the BCH Trust Trustees must report any Fiduciary Role for a Business pursuant to Section II(a) of this Policy. The Compliance Department will review any reported Fiduciary Role and may implement a management plan in those cases where a potential conflict of interest may arise.

There is a presumption that members of the senior leadership team (Senior Vice Presidents or above) will not participate in outside for-profit Fiduciary Roles.

The presumption may be overcome when individuals holding presumptively prohibited for-profit Fiduciary Roles present demonstrable, compelling justifications that the Fiduciary Role will advance the mission of BCH.

Members of the senior leadership team will request approval for outside for-profit Fiduciary Roles from the Senior Vice President, Chief Compliance Officer. The Compliance Department will review any reported Fiduciary Roles and will recommend a management plan if necessary. Any proposed Fiduciary Roles will be reviewed by the Executive Committee of the BCH Board of Directors and two additional at large members of the BCH Board of Directors. They will determine if a demonstrable, compelling justification exists and whether any potential conflicts may be effectively

managed.

One of the at large members will be a member of the Audit and Compliance Committee and will also be the designated Board representative to the BCH Conflict of Interest Committee as described in Section III.

The Compliance Department shall maintain all related documentation, including management plans.

#### C. Advisory Committees

BCH relies on a number of advisory committees, composed, in part, of non-fiduciary members with specific expertise in the relevant field. Because non-BCH members will have Outside Relationships by virtue of their position on an advisory committee, there is a heightened risk for Conflicts of Interests. Recognizing that the organization, purpose, and voting rights across the committees are varied, the Chair of each advisory committee will consult with the Compliance Department to ensure transparency and appropriate management of any Conflicts of Interest.

#### D. Boston Children's Hospital's Financial Interest in a Business

BCH will from time to time obtain a financial interest relating to licensing, technology transfer, patents, other innovations, and services. The financial interest may be any of the following:

- equity;
- license payments;
- · milestone payments;
- royalties; and/or
- other forms of remuneration and compensation

Additionally, BCH's Investment Office routinely makes investments in Businesses in order to further BCH's charitable mission.

a. Non-Research Conflicts. A Conflict of Interest may arise where BCH holds equity or a financial interest in a Business whose products or devices are used at BCH. Generally, such an interest is permissible when the equity was not acquired in connection with BCH's decision to use the product and there is independent decision-making in acquiring the product. For products or devices used at BCH from a BCH Spin Off Company, a management plan must be established and subject to the review process for Institutional Conflicts of Interest.

#### b. Research Conflicts

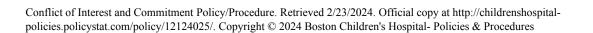
i. Equity - a Conflict of Interest may arise if BCH equity in a Business would result in inappropriate influence, or the perception of such influence over BCH research. Additionally, a Conflict of Interest may arise where BCH holds equity in a Business that will sponsor clinical or basic research at BCH or whose technology is proposed to be studied or tested in clinical research. As provided in the <u>Institutional Review Board (IRB)</u> Conflict of Interest Policy, there is a presumption that BCH will not participate in clinical trials sponsored by a Business in which it holds equity except in extraordinary situations, as defined in the Policy. The Conflict of Interest Committee shall determine whether the presence of extraordinary situations exists. Further the Conflict of Interest Committee shall determine whether the conflict may be effectively managed. The IRB will make the final determination regarding whether the equity interest may be managed. The IRB may suggest additional or alternative management strategies.

- ii. Financial Interest other than Equity BCH may have a financial interest in a Business as a result of a licensing agreement. The agreement may include upfront milestones or license related payments or royalties.
  - 1. License-Related or Milestone Payments- If BCH earns more than \$500,000 in gross income over the course of two years in pre-market payments, including for example, success-based milestone payments relating to BCH licensed technology that is the subject of clinical research, the arrangement must be reviewed and approved by the COI Committee. The COI Committee shall assess whether a Conflict of Interest exists and whether it must be managed, mitigated, or eliminated. The IRB will make the final determination regarding whether the financial interest may be managed. The IRB may suggest additional or alternative management strategies.
  - Royalties for Sales to BCH Royalties based on BCH's purchase of products incorporating BCH licensed technology are presumptively prohibited. In certain circumstances, the COI Committee may permit such an arrangement. For example, where the royalty amount is donated to a non-institutional charitable organization.

#### E. Charitable Donations

Charitable donations or Gifts from entities may result in Conflicts of Interest. The *Children's Hospital Trust Guidelines for Fundraising and Philanthropic Activity* set forth the Boston Children's Hospital Trust (the Trust) process for managing donations and gifts. The Policy aims to ensure a clear separation between BCH acceptance of Gifts and operational, clinical or research activity. The Trust maintains sole responsibility for accepting and managing the following forms of support:

- Gifts:
- · grants;



- educational grants (including seminars, conferences or training sessions);
- · fundraising events;
- · philanthropic activities; and
- · any other contacts, programs or actions related to philanthropic support

This includes Gifts from individuals, foundations, corporations, and organizations. Gifts from a Company to a department or Foundation must be made to the Trust and must be reviewed and approved by the Office of General Counsel. Covered Persons may not accept any donations by a Company to support or sponsor education activities unless they are made to the Trust and comply with the Trust's policies.

#### ii. Institutional Conflict of Interest Disclosure Process

#### a. Board of Directors and Senior Leaders

All members of BCH's Board of Directors, the BCH Trusts Board of Trustees and Senior Leaders shall complete conflict of interest disclosure statements prior to assuming their roles. Additionally, the Compliance Department shall circulate an annual disclosure statement to Senior Leaders, including BCH's Board of Directors and the BCH Trust Trustees who have not otherwise completed a conflict of interest disclosure in CHeRP pursuant to Section IIA; Senior Leaders shall identify any Outside Relationships. These will include relationships with entities in which BCH has equity as well as BCH Spin Off Companies. Any person who does not receive a disclosure statement nevertheless has an affirmative obligation to disclose potential Conflicts of Interest. Conflicts of Interests should be disclosed to the Chief Executive Officer, or his/her supervisor. Similarly, each person completing a disclosure statement has an affirmative obligation to update the statement any time circumstances change or a potential Conflict of Interest arises. The Compliance Department shall review the disclosures. The Compliance Department may refer any potential Conflicts of Interest to the Office of General Counsel or the Executive Committee of the BCH Board of Directors.

# b. The Technology and Innovation Development Office (TIDO) and the Innovation & Digital Health Accelerator (IDHA)

TIDO and IDHA shall provide a list of all Businesses in which BCH has equity or financial interests above \$250,000 to the Compliance Department on an annual basis.

#### c. Investment Office

The Investment Office shall provide a list of all Businesses in which BCH has investments to the Compliance Department on an annual basis.

#### d. Trust

The Trust shall maintain a list of all significant gifts and donations. The Trust shall send this list annually to the Compliance Department. The Compliance Department shall determine the threshold amount of significant Gifts and donations. This amount may be changed from time-to-time based on prevailing standards.

#### iii. Review for Institutional Conflicts

The Compliance Department shall review individual disclosures. They may be shared with the following in order to facilitate the identification of Conflicts of Interest and Commitment: The Office of General Counsel, the Tax Department, Chiefs/Vice Presidents, and HMS.

Working in consultation with the Office of General Counsel and/or the Chief Executive Officer, the Compliance Department shall draft a management plan for any Outside Relationships that are or may be Conflicts of Interest. The Compliance Department shall send management plans pertaining to research to the Conflict of Interest Committee for approval. For any Conflict of Interest Committee meetings involving the review of an institutional conflict of interest or a conflict for a member of the senior leadership team, a representative from the BCH Board of Directors will attend the Conflict of Interest Committee meeting. Additionally, for management plans that pertain to human subject research, the Compliance Department shall be responsible for notifying the IRB of the nature of the conflict and approved management strategies. The IRB will make the final determination regarding whether the Conflict of Interest may be managed. The IRB may suggest additional or alternative management strategies.

All institutional management plans shall be subject to final review by the Executive Committee of the BCH Board of Directors as referenced in Section I.(B)(c).

Finally, the Compliance Department shall maintain a copy of all management plans.

# **Non-Compliance and Sanctions**

Violation of this Policy may result in disciplinary or other remedial action. Other remedial action may include termination of employment or removal from office Covered Persons who become aware of an actual, apparent, or potential violation of this Policy are expected to report it to:

- · their supervisors;
- · the Compliance Department; or
- the Anonymous Compliance Hotline at (888) 801-2805.

Retaliation against any Covered Persons who make such reports in good faith, or who cooperates in the investigation of such reports, is unlawful, violates BCH policy, and is prohibited.

## **Note on Policy Interpretation**

Nothing in this policy is intended to interfere with an employee's rights to discuss his or her wages, hours and working conditions, or otherwise exercise his or her rights to engage in protected concerted activity under Section 7 of the National Labor Relations Act, including the right to self-organization, to form, join or assist a labor organization or to refrain from any of such activities.

### **Related Policies**

- For the Policy on Meals with foreign officials and Gifts to Companies, please see the <u>Foreign</u> Corrupt Practices Act Policy.
- For soliciting or accepting gifts to the Institution, or for information about sponsorship of and

donations for educational events, please see the <u>Children's Hospital Trust Guidelines for Fundraising and Philanthropic Activity</u> and the <u>Continuing Medical Education Department Policies</u>.

- For Policies regarding Conflicts of Interest in Research, please see the <u>Code of Conduct</u>, the <u>Institutional Review Board (IRB) Conflict of Interest Policy</u>, and the <u>Public Health Service</u> <u>Investigator Conflict of Interest Policy</u>.
- For Policies that apply to Harvard Faculty Members please see the <u>Harvard Medical School Policy on Conflicts of Interest and Commitment</u>.
- For Policies regarding forming companies, consulting arrangements, and inventorship interests, please see the Boston Children's Hospital Intellectual Property Policy.
- For the requirements and restrictions for gifts, gift cards and gift certificates funded by the Hospital, please see the *Hospital Gifts to Children's Personnel Policy*.

### **Approval Signatures**

Step Description Approver Date

### **Applicability**

Boston Children's Hospital-Policies & Procedures

### Chapter / Tags

Activities outside US, Annual Disclosure, Consulting, Consulting Agreement, Fiduciary Role, Gifts, HMS COI, HMS Conflict of Interest, Harvard Medical School COI, Honoraria, Industry Relationship, Institutional COI, Institutional Conflict of Interest, Lodging, Meals, Outside Relationship, Research Collaboration, Research Disclosure, Speaking Engagement, Spin Off Company