### Conflict of Interest and Commitment Policy

# Policy Statement and Purpose

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. The purpose of this Policy is to identify, manage and/or mitigate Conflicts of Interest for individuals as well as BCH. This policy aims to promote complex industry collaborations while safeguarding research integrity and patient safety.

# Scope

This Policy applies to all Covered Persons, as defined below. Covered Persons (whether or not they participate in the COI reporting processes described below) have an affirmative obligation to disclose to their supervisors whenever they believe they may have a Conflict of Interest or Commitment.

# 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.

*Company:* Any pharmaceutical or medical device company, or any other person or entity 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 Interest 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 Interests.

*Conflict of*

*Interest:* An Outside Interest 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 [Code of Conduct](http://web2.tch.harvard.edu/compliance/Documents/BCH_Code_of_Conduct.pdf).

*Consulting*

*Agreement:* Any arrangement in which a Company 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 of BCH’s governing boards and members of certain BCH standing committees as determined by the Compliance Department.

*Gift:* Anything from 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 Interest of BCH or BCH’s Senior Leadership 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 [Code of Conduct](http://web2.tch.harvard.edu/compliance/Documents/BCH_Code_of_Conduct.pdf).

*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 Interest*: A financial interest in any entity related to the work or mission of BCH, or an entity with which BCH does business or that provides services which compete with those of BCH. This includes any Company that competes directly or indirectly with BCH in the purchase or sale of any property, goods, or services. This also includes entities that provide direct patient care, conduct biomedical research, produce, provide or market medical services or products, or were vendors of BCH. An Outside Interest includes a financial interest held by a Covered Person’s family member (spouse, partner, and dependent children).

*Primary Interest*: One’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).

*Research*

*Agreement*: Any arrangement in which a Company provides anything of value to a Covered Person, department or Foundation in exchange for testing, analysis, or similar types of services.

*Senior Leadership:* Members of the senior leadership team, as determined by the Compliance Department in consultation with the Office of General Counsel, members of the BCH governing boards, and members of certain BCH standing committees and key employees who have decision-making authority or purchasing authority on behalf of BCH as determined by the Compliance Department.

# Policy

**Individual Conflicts of Interest and Commitment**

Individual Conflicts of Interest may arise in operational, clinical and research settings. When Covered Persons acquire Outside Interests, the Outside Interests may conflict with their Primary Interests. Covered Persons are permitted and encouraged to hold Outside Interests, so long as they receive the approval or their Chief/Vice President. Outside Interests must be reported in accordance with section II below. Outside Interests that are Conflicts of Interest must be managed, mitigated or eliminated. Additionally, Outside Interests that are Conflicts of Commitment must be eliminated or managed.

1. **General Rules Regarding Outside Interests for Individuals**
2. **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 [Public Health Service Investigator Conflict of Interest Policy](http://web2.tch.harvard.edu/compliance/Documents/BCH_Public_Health_Service_Investigator_Conflict_of_Interest_Policy.pdf) as it is modified from time-to-time.

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

All Covered Persons who are also HMS faculty members are subject to the [Harvard Medical School Policy on Conflicts of Interest and Commitment](http://ari.hms.harvard.edu/files/integrity-academic-medicine/files/final_hms_coi_policy_10.25.2016.pdf) as it is modified from time-to-time.

1. **Consulting**

As described in the [Boston Children's Hospital Intellectual Property Policy](http://www.childrenshospital.org/~/media/research-and-innovation/tido/bch_intellectual_property_policy1.ashx?la=en), 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.

1. **Speaking Engagements**

Covered Persons are generally permitted to receive honoraria for speaking engagements. 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 Company compensates an individual to speak about the Company’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.

* 1. Honoraria are permissible so long as:
		1. The payment to the Covered Person is made by the program coordinator (e.g., American Medical Association, American Hospital Association, etc.) and not a Company;
		2. The Covered Person maintains control over the content of the presentation; and
		3. The content of the presentation is educational in nature and does not advertise the product or services of the program coordinator or Company.
	2. Honoraria **greater than $5,000** require written agreements, which 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. In addition, any written agreements must be reviewed by the Office of General Counsel in accordance with section IC above.
	3. 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.
1. **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.

* 1. 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:
		1. Modest Meals are permitted when incident to an authorized administrative function on behalf of BCH, including for example, user group meetings or advisory councils.
		2. Other exceptions are available as listed in the HMS Policy on Conflicts of Interest and Commitment:
			1. *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 non-sales/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.
1. **Individual Conflict of Interest Disclosure Process**
2. **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.

1. **Research Disclosure Process**
	1. 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 [Public Health Service Investigator Conflict of Interest Policy](http://web2.tch.harvard.edu/compliance/Documents/BCH_Public_Health_Service_Investigator_Conflict_of_Interest_Policy.pdf). 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.
	1. 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.
1. **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 Commitment.

1. **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 [Harvard Medical School Policy on Conflicts of Interest and Commitment](http://ari.hms.harvard.edu/files/integrity-academic-medicine/files/final_hms_coi_policy_10.25.2016.pdf).

1. **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 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 Executive Office, the Compliance Department shall draft a management plan for any Outside Interests 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.

1. **General Rules Regarding Outside Institutional Interests**
2. **Senior Leadership**

A Conflict of Interest may arise when a Senior Leader has an Outside Interest that relates to a particular financial 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 discussion and decisions regarding the arrangement. However, the Compliance Department may implement a management plan where a Senior Leader’s knowledge from an Outside Interest 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.

1. **Boston Children’s Hospital’s Financial Interest in an Entity**

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 entities in order to further BCH’s charitable mission.

* 1. Non-Research Conflicts. A Conflict of Interest may arise where BCH holds equity or a financial interest in a Company 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.
	2. Research Conflicts
		1. Equity**-** a Conflict of Interest may arise if BCH equity in a Company 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 Company that will sponsor clinical research at BCH or whose technology is proposed to be studied or tested in clinical research. As provided in the [Institutional Review Board (IRB) Conflict of Interest Policy](http://www.childrenshospital.org/~/media/research-and-innovation/office-of-clinical-investigation/irbm_101_001_coi_investigator_irb-42816.ashx?la=en), there is a presumption that BCH will not participate in clinical trials sponsored by a Company in which it holds equity except in extraordinary situations. 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.
		2. Financial Interest other than Equity **-** BCH may have a financial interest in a Company 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 success-based milestone payments and/or royalties from the sale of products incorporating 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.
			2. Royalties for Sales to BCH - Royalties based on BCH’s purchase of products incorporating BCH licensed technology are 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.
1. **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](http://chbshare.chboston.org/elibrary/cht/insider/manuals/chtm/chtm/Guidelines%20for%20Fundraising%20and%20Philanthropic%20Activity.doc) 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.

1. **Institutional Conflict of Interest Disclosure Process**
	1. **Board of Directors and Senior Leaders**

The Compliance Department shall circulate an annual disclosure statement to Senior Leadership, including BCH’s Board of Directors; Senior Leadership shall identify any Outside Interests and Outside Activities. These will include interests in entities in which BCH has equity. 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 Office, Chief Operating 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.

* 1. **TIDO**

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

* 1. **Investment Office**

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

* 1. **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.

1. **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 Executive Office, the Compliance Department shall draft a management plan for any Outside Interests 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. 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.

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.

# Related Policies

For the Policy on Meals with foreign officials and Gifts to Companies, please see the [Foreign Corrupt Practices Act Policy](http://web2.tch.harvard.edu/compliance/Documents/160803_FCPA_Compliance_Policy.pptx) .

For soliciting or accepting gifts to the Institution, or for information about sponsorship of and donations for educational events, please see the [Children’s Hospital Trust Guidelines for Fundraising and Philanthropic Activity](http://chbshare.chboston.org/elibrary/cht/insider/manuals/chtm/chtm/Guidelines%20for%20Fundraising%20and%20Philanthropic%20Activity.doc) and the [Continuing Medical Education Department Policies](http://web2.tch.harvard.edu/cme/mainpageS3049P23.html).

For Policies regarding Conflicts of Interest in Research, please see the [Code of Conduct](http://web2.tch.harvard.edu/compliance/Documents/BCH_Code_of_Conduct.pdf) , the [Institutional Review Board (IRB) Conflict of Interest Policy](http://www.childrenshospital.org/~/media/research-and-innovation/office-of-clinical-investigation/irbm_101_001_coi_investigator_irb-42816.ashx?la=en), and the[Public Health Service Investigator Conflict of Interest Policy](http://web2.tch.harvard.edu/compliance/Documents/BCH_Public_Health_Service_Investigator_Conflict_of_Interest_Policy.pdf).

For Policies that apply to Harvard Faculty Members please see the [Harvard Medical School Policy on Conflicts of Interest and Commitment](http://ari.hms.harvard.edu/files/integrity-academic-medicine/files/final_hms_coi_policy_10.25.2016.pdf).

For Policies regarding forming companies, consulting arrangements, and inventorship interests, please see the [Boston Children's Hospital Intellectual Property Policy](http://www.childrenshospital.org/~/media/research-and-innovation/tido/bch_intellectual_property_policy1.ashx?la=en).

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](http://chbshare.chboston.org/elibrary/hr/manuals/hrpp/hrpp/fin_pp_gift.aspx).

# Document Attributes

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