

POLICY MANUAL

## THE CHILDREN'S HOSPITAL OF PHILADELPHIA No. A-3-7

Title:

INTERACTIONS WITH VENDORS

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Effective Date: 7/1/2009

## POLICY

It is the policy of the Hospital that interactions with Vendors comply with applicable law, meet ethical standards, avoid or minimize conflicts of interest, protect patient and research subject confidentiality, and promote fair and open dealings.

#### <u>PURPOSE</u>

The purposes of this Policy are to: provide guidance regarding appropriate interactions of Hospital healthcare and research professionals and administrative staff with Vendors; minimize the undue influence or perceived undue influence of Vendors on the business decisions of Hospital professionals and administrative staff and the practice patterns of Hospital professionals; and support safety and privacy of patients and research subjects.

## **SCOPE**

This Policy applies to all Trustees, Officers, employees and members of the Medical and Research Staffs of The Children's Hospital of Philadelphia, including The Children's Hospital of Philadelphia Research Institute, the CHOPPA Practice Plans (currently Children's Anesthesiology Associates, Children's Health Care Associates, Children's Surgical Associates, Radiology Associates of Children's Hospital, and their New Jersey Affiliates) and entities controlling, controlled by or under common control with The Children's Hospital of Philadelphia, including, without limitation, The Children's Hospital of Philadelphia Foundation (together, the "Hospital"), as well as any others who are providing services or conducting research at facilities owned or operated by the Hospital or otherwise on behalf of the Hospital or whose presence at or affiliation with the Hospital may place them in a position to interact with Vendors on behalf of the Hospital (all such persons referenced under Scope, "Hospital Personnel").

All Vendors are expected to abide by this Policy with respect to their interactions with Hospital Personnel or while in Hospital Facilities, including not engaging or attempting to engage in any conduct that could cause Hospital Personnel to violate this Policy.

#### **RELATED POLICIES**

Administrative Policy Manual Administrative Policy Manual Administrative Policy Manual Administrative Policy Manual Administrative Policy Manual

Administrative Policy Manual

Patient Care Manual

No. A-3-1 Conflicts of Interest
No. A-1-4 Organizational Ethics Statement
No. A-1-5 Compliance Standards of Conduct
No. A-4-17 Gifts to Employees
No. A-3-8 Control of On-Site Activity by
Vendors
No. A-4-3 Introduction of New Medical Devices,
Products and Equipment
No. TX-7-05 Medication Samples and Vouchers



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## **DEFINITIONS**

- A. "Hospital" means The Children's Hospital of Philadelphia, including The Children's Hospital of Philadelphia Research Institute, the CHOPPA Practice Plans (currently Children's Anesthesiology Associates, Children's Health Care Associates, Children's Surgical Associates, Radiology Associates of Children's Hospital, and their New Jersey Affiliates) and entities controlling, controlled by or under common control with The Children's Hospital of Philadelphia, including, without limitation, The Children's Hospital of Philadelphia Foundation.
- B. "Hospital Facilities" means any facility owned, leased, licensed or otherwise in the possession of the Hospital.
- C. "**Hospital Personnel**" means Trustees, Officers, employees and members of the Medical and Research Staffs of the Hospital, and others who are providing services or conducting research at facilities owned or operated by the Hospital or otherwise on behalf of the Hospital or whose presence at or affiliation with the Hospital may place them in a position to interact with Vendors on behalf of the Hospital.<sup>1</sup>
- D. **"Vendors"** means entities and persons that have or are seeking to enter into business relationships with the Hospital (e.g., to provide any equipment, product, supply, facility, item or service for which payment may be made, including but not limited to a pharmaceutical product, medical device, or other clinical equipment, product or supply), as well as the representatives and agents of such entities or persons.<sup>2</sup>

## **IMPLEMENTATION**

## I. GENERAL PRINCIPLES

A. The selection of and conduct of business with a Vendor should be solely on the basis of arm's length (i.e., free from improper or inappropriate influence) and appropriate business, medical, clinical and/or research criteria, as applicable, such as cost effectiveness and quality. The selection and conduct of business should not be made on the basis of, or be influenced by, past, present or future gifts to or for the benefit of Hospital Personnel,

<sup>&</sup>lt;sup>1</sup> This Policy is not intended to apply to Hospital Trustees to the extent they are not involved in decision making with respect to the recommendation, use or purchase by the Hospital of particular equipment, products, supplies, facilities, items or services.

<sup>&</sup>lt;sup>2</sup> A Hospital Trustee who owns, works for or has another business relationship with a Vendor is not considered a Vendor for purposes of this Policy when (1) acting only in his/her capacity as a Trustee and (2) there are no discussions of the Vendor's business relationship with the Hospital. For example, a Trustee who is an executive with a company that provides services to the Hospital may host a Hospital executive at an entertainment event to the same extent as any other Trustee, provided the Trustee does not discuss the company's dealings with the Hospital.



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donations to the Hospital, support to the Hospital or Hospital Personnel such as clinical, research or educational support, or factors other than fair and open dealings based on appropriate business, medical, clinical and/or research criteria.

- B. Hospital Personnel should conduct business with Vendors in a way that maximizes the ability of the Hospital to carry out its patient care, research and educational missions, and in accordance with legal and ethical standards and Hospital policies aimed at preventing conduct that may inappropriately influence purchasing decisions or be perceived as doing so.
- C. Vendors may not offer or provide, and neither Hospital Personnel nor the Hospital may solicit or accept from a Vendor, any gift, compensation or payment of any kind or in any amount that is:
  - 1. given to influence, or could be perceived as being given to influence, Hospital Personnel or the Hospital with respect to prescribing, recommending, using or purchasing pharmaceutical, medical device, clinical equipment, products or supplies, or any other equipment, products, supplies, facilities, items or services.
  - 2. given based on considerations such as the value or volume of patient referrals, purchases or other business generated; or
  - 3. intended to induce patient referrals.
- D. Vendors have no right of access to Hospital Personnel or the Hospital. Vendors may, in the discretion of the Hospital, have access to Hospital Personnel and the Hospital to promote their products or business if based solely on arm's length and appropriate business, medical, clinical and/or research criteria, as applicable; provided, however, that such access may not be influenced by the receipt, or expectation of receipt, of any gift, compensation or payment of any kind from or on behalf of a Vendor to the Hospital or Hospital Personnel.
- E. The Hospital and Hospital Personnel are held to high standards with respect to appropriate dealings with third parties. Many practices that are common in other industries are illegal or prohibited in the case of a health care organization, physicians, other health care providers, and companies engaged in the manufacture, distribution, marketing or sale of pharmaceuticals, medical devices, and other clinical equipment, products and supplies. Federal and state laws set strict standards for relationships between providers and Vendors. In all interactions with or on behalf of Vendors, Hospital Personnel will endeavor to adhere to all relevant legal standards and the highest standards of ethics and integrity.
- F. The Hospital and Hospital Personnel should avoid conflicts of interest, including the appearance that decisions with respect to the use of pharmaceuticals, medical devices, or other equipment, products, supplies, facilities or services are influenced by benefits expected or received from or on behalf of a Vendor.



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- G. Although this Policy is intended to address a broad spectrum of situations that arise involving the interactions between Vendors and the Hospital or Hospital Personnel, questions may arise about situations that do not appear to be covered by this Policy or the Hospital's <u>Conflicts of Interest Policy (A-3-1)</u>. In those circumstances, Hospital Personnel should seek advice from their Department Chair or applicable Senior Manager, the Office of General Counsel, or the Office of Compliance and Privacy.
- H. Even where interactions with Vendors are not prohibited under this Policy, they may be prohibited or circumscribed by other agreements, guidelines or policies. For example, they may be prohibited under the Hospital's <u>Conflicts of Interest Policy (A-3-1)</u> or require advance approval and/or disclosure under the Hospital's <u>Conflicts of Interest Policy (A-3-1)</u>. In addition, there may be other restrictions. For example, outside activities (e.g., permissible consulting activities) generally are required to be performed on a person's own time (e.g., vacation day, weekend or evening when not providing services for the Hospital) and in the person's personal capacity and not as a representative of the Hospital.

## II. GIFTS, MEALS AND COMPENSATION

## A. Personal Gifts (Gifts to or for the Benefit of Hospital Personnel)

- 1. Hospital Personnel are deemed to have received a "gift" where an item of value is given to them or for their benefit and something of equal value is not provided in exchange. It includes the receipt of free or discounted items that are given to or for the benefit of Hospital Personnel.
  - a. Gifts include cash in any form, cash equivalents such as gift certificates, property or the use of something of value. Gifts can include goods, hospitality, services, travel and travel expenses, use of something of value such as a vacation home, tickets or admissions to events or functions, including but not limited to sporting events, cultural events, and social entertainment, payment of obligations, and any other items of value.
  - b. Gifts also include the payment, subsidy or reimbursement of any travel or lodging expenses for a spouse, family member or guest accompanying Hospital Personnel to any meeting or conference unless such person is participating in a professional capacity.
  - c. Hospital Personnel are deemed to have received a gift where the item of value is given to them personally, or to their designee, or as a result of their actions or expected actions to a member of their family, person with whom they live or another person, where such person's receipt of the gift is valued by the Hospital Personnel.
  - d. Meals are discussed separately in II. C below.



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- e. Honoraria or other payment for the provision of specific permissible substantive services rendered (e.g., speakers fees), including the provision or reimbursement of reasonable travel and food, is not considered a gift provided the compensation is reasonable for the services rendered and treated as compensation (e.g., reported as compensation for tax purposes to the extent required). See also the Conflicts of Interest Policy (A-3-1) regarding outside compensated activities and, with regard to consulting arrangements, additional requirements such as advance review and approval.
- Gifts do not include attendance at an event or function with a Vendor where f. the expense of attending the event or function is borne by Hospital Personnel personally or by the Hospital (where appropriate).
  - i. If a Vendor offers to host Hospital Personnel at an event or function, it does not violate this Policy if Hospital Personnel attends if: (1) Hospital Personnel pays the cost for the Hospital Personnel to attend either personally or the Hospital pays if appropriate (either by directly purchasing a ticket or paying an admission charge, or paying the Vendor for its cost of Hospital Personnel's attendance); and (2) attendance is approved by the Hospital Personnel's supervisor at least at the Department manager or division chief level (or a designee).
  - ii. In special cases, however, where the cost for the Hospital Personnel to attend an event or function hosted by a Vendor varies significantly from the fair market value of the attendance (e.g., a sold out playoff football game), the fair market value of the attendance may be the more appropriate measure of the payment for the attendance, and should be considered by the Hospital's supervisor (or a designee) along with the decision on whether to approve the attendance, in consultation with the Office of General Counsel or Office of Compliance and Privacy if appropriate. See also II. F. for exception process.
- 2. Gifts may not be offered by or on behalf of a Vendor to Hospital Personnel and Hospital Personnel may not accept gifts offered to them by or on behalf of Vendors. Hospital Personnel may not solicit gifts from Vendors.
  - a. A Vendor purchasing sponsorship or tickets to a Hospital fundraising event (e.g., Daisy Day, Carousel Ball, an auxiliary golf outing) may not give tickets to a Hospital Department or program, or to individual Hospital Personnel, to be used by Hospital Personnel and/or their guests to attend the event at the Vendor's expense. If a Vendor has tickets that it does not intend to use and wishes to donate them to the Hospital, the Vendor may return the tickets to



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The Children's Hospital of Philadelphia Foundation, which may distribute the tickets if it chooses to do so, including to Hospital Personnel.

- b. Notwithstanding this prohibition on gifts to individuals, Hospital Personnel are permitted under this Policy to attend, in person or by telephone, webcast or similar means, Vendor-run educational programs that are offered for free to all attendees, not just Hospital Personnel, and to accept books or other written or electronic materials provided to all attendees regarding the subject matter of the program. This exception applies only to Hospital Personnel's attendance at the program and the acceptance of educational materials provided in connection with the program, but not to the receipt of other gifts or meals that may be offered by Vendors at the program, which remain subject to the general restrictions set forth in this II.A and II.C. 2 below.
  - i. See, however, Section V below regarding the consideration to be given to the decision to attend Vendor-run educational programs that are not accredited.
- 3. Hospital Personnel may not accept gifts or compensation for time spent listening to, meeting with or accessing websites of Vendors or their representatives promoting or explaining their products.
- 4. Hospital Personnel may not accept compensation, including payment or reimbursement of expenses, from Vendors simply for attending a CME or other activity or conference unless the person is speaking, teaching or otherwise engaged in a meaningful substantive role and the total compensation, including payment or reimbursement of expenses, is reasonable given the role. See partial exception for Trainees at Section IX.

## B. Gifts to or for the Benefit of the Hospital or Clinical Departments

- 1. The Hospital or a Clinical Department may accept non-cash gifts serving a substantial clinical, research, educational or other mission function, such as anatomical models, medical textbooks, charts, and products or samples for evaluation purposes, provided each of the following requirements is met:
  - a. The gift is not given to, or intended to be for the personal benefit of Hospital Personnel.
  - b. In the case of a single gift with a value in excess of \$500, or more than one gift in a July 1 fiscal year with a total value in excess of \$1,000 from a single Vendor, including affiliated entities, to the Hospital or a Clinical Department, advance approval must be given by a person at the level of Vice President or higher or the applicable Department Chair, or a designee.



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## C. Meals or Other Food

1. On-site

Vendors may not provide or fund and Hospital Personnel may not accept meals or other types of food or drink at Hospital Facilities. This prohibition includes holiday gift baskets, trays of cookies or pretzels and sodas sent to a department or unit.

## 2. Off-site

- a. The position of the Association of American Medical Colleges (AAMC) is that with the exception of food provided in connection with Accreditation Council for Continuing Medical Education (ACCME)-accredited programming and in compliance with ACCME guidelines, food and meals supplied or paid for by industry are personal gifts that academic medical center personnel should not accept when off-site, just as when on-site within academic medical centers. <u>AAMC Report on Industry Funding of</u> <u>Medical Education</u> (June 2008).
- b. The Pharmaceutical Research and Manufacturers of America (PhRMA), in its Code on Interactions with Healthcare Professionals, prohibits: (i) meals in connection with informational presentations made by field sales representatives or their immediate managers at off-site locations, including restaurants; and (ii) meals provided directly by pharmaceutical companies at CME events (meals provided by and at the discretion of the CME provider using financial support provided by a pharmaceutical company are not prohibited). <u>PhRMA Code on Interactions with Healthcare Professionals</u> (effective January 2009).
- c. The following guidelines apply to off-site meals for Hospital Personnel:
  - i. Vendors may not provide or fund and Hospital Personnel may not accept meals outside of Hospital Facilities other than at a Vendor's office premises (see c.ii below). Examples of prohibited off-site meals could include a Vendor-hosted meal at a restaurant, catering facility, or local hotel or conference center for a business meeting or presentation by the Vendor.
  - ii. Vendors may provide or fund and Hospital Personnel may accept meals while at the office premises of Vendors if there is a legitimate business purpose to the meal, the setting and nature of the meal are appropriate to the business purpose and are not excessive or extravagant, the meal does not include the spouse, family member or guest of Hospital Personnel, and the frequency of such meals is not



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excessive. Examples could include a modest lunch or dinner at a Vendor's office during an extended session working on a business transaction, a modest working lunch at a Vendor's office, or a modest lunch during an educational seminar hosted at a Vendor's office for its clients or customers.

- iii. The principles set forth in II.A.1.f, regarding events or functions hosted by Vendors and paid for by Hospital Personnel or the Hospital, apply equally with respect to meals with Vendors paid for by Hospital Personnel or the Hospital.
- iv. This is not intended to preclude Hospital Personnel from partaking of a meal or social event (e.g., a reception) provided or funded indirectly with Vendor support, if: (1) the meal or social event is provided in connection with an ACCME accredited conference or program attended by Hospital Personnel and in conformity with the ACCME Standards for Commercial Support; (2) the meal or social event is provided in connection with a state Nurses Association accredited continuing education conference or program attended by Hospital Personnel and in conformity with applicable standards for commercial support; or (3) the meal or social event is provided by and in connection with a conference or program conducted by an established third-party scientific, educational or professional organization or other company that offers educational conferences and programs, provided, however, that the organizer may not be affiliated with any Vendor. For example, if a Vendor sponsors a lunch at an annual meeting conducted by a professional society, Hospital Personnel attending the meeting may partake of the meal. If, however, a Vendor invites attendees of a professional society's meeting to a dinner at a restaurant that includes substantive educational presentations, Hospital Personnel may attend the educational presentation but may not accept the dinner unless the Hospital Personnel personally pays for the dinner or, where appropriate, the Hospital pays for the dinner.

## D. Sample Medications and Vouchers

The Medication Samples and Vouchers Policy (Patient Care Manual No. TX-7-05) governs issues relating to obtaining medical samples and vouchers from Vendors.

## E. Other Potentially Improper Attempts to Influence

1. Even where a dealing is at fair market value, a conflict can arise because a Vendor provides a personal opportunity to Hospital Personnel, or a member of their family or person with whom they maintain a living arrangement approximating a family relationship, that might not have been provided but for the Vendor's business relationship or potential business relationship with the Hospital.



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- 2. Examples could include a Vendor offering the spouse or child of Hospital Personnel a job with the Vendor. Even though the spouse or child will be paid fair market value for the services provided, the opportunity for the job may constitute a prohibited attempt to influence.
- 3. In such situations, Hospital Personnel should seek guidance from their Department Chair, applicable Senior Manager, the Office of General Counsel or the Office of Compliance and Privacy,

## F. Exceptions

- 1. Personal Friendships. The Hospital recognizes that there are situations in which Hospital Personnel have personal friendships with employees of Vendors that developed outside of the business relationship. For example, Hospital Personnel may be in a tennis group or book club that includes employees of Vendors. This Policy does not prohibit Hospital Personnel from personal encounters such as going to dinner at the home of an employee of a Vendor or attending a wedding of the child of an employee of a Vendor where Hospital Personnel have such a personal friendship such that, over the long run, there is a mutual reciprocity (e.g., the Hospital Personnel alternatively takes the employee of the Vendor to dinner) and the employee of the Vendor is personally paying for the personal encounter. If the Vendor company is paying for the encounter, this exception does not apply. Where there is any question about the appropriateness of the encounter or where the encounter involves the employee of the Vendor paying for restaurant meals, entertainment or gifts, Hospital Personnel should seek guidance from their supervisor at least at the Department manager or division chief level (or a designee), the Office of General Counsel, or the Office of Compliance and Privacy. In addition, where Hospital Personnel have a personal friendship with an employee of a Vendor and will be in a decision-making role with respect to the use or purchase of equipment, products supplies or services from the Vendor (or a competitor of the Vendor with respect to the product or services under consideration). Hospital Personnel must disclose the existence of the personal friendship to their Department Chair or applicable Senior Manager and a process should be employed to avoid the potential for the personal friendship to influence the decision making in question.
- 2. <u>Hospital Personnel as Guests of Others at Vendor Events</u>. This policy does not prohibit attendance by Hospital Personnel at a meal or other event paid for or provided by a Vendor where: (1) the Hospital Personnel attends as a guest of someone, such as a spouse, who is not Hospital Personnel ("Host"), (2) the Host works for the Vendor or has another business relationship with the Vendor that is unrelated to the relationship the Vendor has or hopes to have with the Hospital Personnel or Hospital, (3) the invitation is extended by the Vendor to the Host because of the Host's business relationship with the Vendor and not the relationship the Vendor has or hopes to have with the Hospital Personnel or the Hospital, and (4) the invitation from the Vendor to the Host and to all other invitees



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includes an invitation to bring a spouse, guest and/or other family members. For example, a Hospital employee whose spouse works for a Vendor may accompany his spouse to an annual holiday party for the Vendor's employees and their spouses.

3. Employee Discount Programs. This policy does not prohibit employee discounts under an established corporate discount program offered by a Vendor to the Hospital provided: (1) the discounts are made available to all Hospital Personnel, and (2) the discount program is approved in advance by a member of Senior Management.

## 4. Other Exceptions.

- a. Exceptions to these restrictions on gifts, meals and compensation may be granted in limited circumstances with advance approval (see 4.b below). Requests for exceptions should be evaluated on a case-by-case basis, considering factors such as:
  - The value to the Hospital of the associated activity. i.
  - ii. The feasibility or appropriateness of the Hospital and/or Hospital Personnel paying for or reimbursing the Vendor for the gift, meal or compensation.
  - iii. The role of the Hospital Personnel in question and the potential for the receipt of the gift, meal or compensation to influence the Hospital's relationship with the Vendor.
  - iv. The presence or absence of other safeguards to promote fair and arms-length dealings with the Vendor.
  - v. The extent to which external standards (e.g., professional societies, AAMC, PhRMA) provide guidance on the specific situation.

An example of a situation in which it may be appropriate to grant an exception is where a Vendor is honoring Hospital Personnel with an established award funded by the Vendor. In such case, Hospital Personnel and their family may be given permission to attend the dinner at which the award is given and to accept the award.



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- b. The following process applies to the granting of exceptions in accordance with F.4.a:
  - i. In the case of Hospital Personnel (other than a member of Senior Management at the level of Vice President or Department Chair or higher), an exception may be granted with advance approval by both: (1) a member of Senior Management at the level of Vice President or Department Chair or higher; and (2) the General Counsel or Chief Compliance Officer, or their designees.
  - ii. In the case of a member of Senior Management at the level of Vice President or Department Chair or higher, an exception may be granted with advance approval by both: (1) the Chief Executive Officer or a designee; and (2) the General Counsel or Chief Compliance Officer.
  - iii. In the case of the Chief Executive Officer, an exception may be granted with advance approval by the Chair of the Audit & Compliance Committee of the Boards of Trustees or a designee.

## **III. SPEAKERS BUREAUS**

- A. The position of the AAMC is that participation by faculty in industry-sponsored speakers bureaus should be strongly discouraged. The AAMC excepts situations in which academic investigators are presenting results of their industry-sponsored studies to peers and there is opportunity for critical exchange. AAMC Report on Industry Funding of Medical Education (June 2008). The Hospital supports the position of the AAMC with respect to Hospital Personnel participation on speakers bureaus.
- B. While the Hospital discourages the participation of Hospital Personnel in speakers bureaus, it does not prohibit participation in speakers bureaus under all circumstances. Participation in speakers bureaus is prohibited where conflict issues arise under the Hospital's Conflicts of Interest Policy (A-3-1)
- C. Speakers bureaus raise particular concerns in the case of clinicians and researchers who are speaking on professional topics. Clinicians and researchers may not agree to any restrictions by industry regarding the content of their professional presentations or related materials, should not allow industry to censor their presentations or related materials, and should not allow industry to have final approval of their presentations or related materials (except with respect to limiting disclosure of confidential information that does not compromise the presentations or related materials). If any materials are provided by others (such as a graph provided by industry showing study results) and used in the presentations or related materials, the clinician or researcher must acknowledge the source of the materials. It is, however, prohibited for a clinician or researcher to be paid by industry to present materials prepared by the company (even



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though properly acknowledged to have been prepared by the company) where the person has a clinical or research involvement at the Hospital with a product related to the materials. In rare situations, exceptions may be granted on approval of the relevant Chair or the Chief Operating Officer, as applicable (or their designees), and the Research Review Committee.

## **IV. GHOSTWRITING**

- A. Ghostwriting is the provision of written material that is officially credited to someone other than the writer(s) of the material. It includes unacknowledged, undisclosed provision of content. Transparent writing collaboration with attribution between academic and industry investigators, medical writers, and/or technical experts is not ghostwriting.
- B. Hospital Personnel are prohibited from allowing their professional presentations of any kind, oral or written, to be ghostwritten by any party, industry or otherwise.

## V. VENDOR- RUN EDUCATIONAL PROGRAMS

- A. The position of the AAMC is that academic medical center faculty and trainees should not attend industry events billed as continuing medical education that are not accredited by the ACCME. AAMC Report on Industry Funding of Medical Education (June 2008). Examples of Vendor events billed as continuing medical education include Vendor-sponsored seminars at off-site locations and Vendor-sponsored journal clubs.
- B. While the Hospital does not prohibit attendance at Vendor-run educational programs that are not accredited, all Hospital Personnel should carefully consider the propriety of attending.
  - 1. See II.A.2.b regarding the exception to the prohibition on gifts to individuals for attendance at Vendor-run educational programs offered for free to all attendees and the acceptance of educational materials provided in connection with the program.
  - 2. The provision by Vendors and receipt by Hospital Personnel of other gifts or meals that may be offered by Vendors at Vendor-run educational programs remain subject to the general restrictions set forth in II.A and II.C.2. For example, with respect to meals, Hospital Personnel attending a Vendor-run educational program at a Vendor's office may partake of a modest lunch offered during the program. However, Hospital Personnel attending a Vendor-run educational program at an offsite location other than a Vendor's office (e.g., a restaurant) may not accept a lunch offered during the program unless the Hospital Personnel personally pays for the lunch or, where appropriate, the Hospital pays for the lunch.



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## VI. VENDOR FUNDING FOR EDUCATIONAL PROGRAMS AT OR SPONSORED BY THE HOSPITAL

## A. ACCME Programs

Vendor funding for any educational program sponsored or organized by the Hospital or conducted in a Hospital Facility and accredited by the ACCME for continuing medical education credit is: (i) handled exclusively by the Continuing Medical Education Department of the Office of Medical Staff Affairs; and (ii) subject to the ACCME Standards for Commercial Support. The ACCME Standards for Commercial Support may be found at www.accme.org.

## **B. Nursing Continuing Education Programs**

Vendor funding for any educational program sponsored or organized by the Hospital or conducted in a Hospital Facility and gualifying for continuing nursing education credit (contact hours) awarded by a state Nurses Association, an accredited approver by the American Nurses Credentialing Center's Commission on Accreditation or equivalent accrediting entity is: (i) handled exclusively by the Office of Nursing Education; and (ii) subject to the standards for commercial support required by the state Nurses Association.

## C. Standards for Vendor Funding for Educational Programs

While certain programs such as those that qualify for ACCME or state Nurses Association credit may be subject to additional or more stringent requirements, Vendor funding for all educational programs sponsored or organized by the Hospital or conducted in a Hospital facility is, at a minimum, subject to the following requirements:

- 1. The funding from the Vendor may not be in consideration of or related to any business relationship, whether past, present or future, existing or desired.
- 2. The funding from the Vendor must be provided in the form of a grant to The Children's Hospital of Philadelphia or The Children's Hospital of Philadelphia Foundation, and may not be made to an individual.
- 3. The funding must be documented in a written agreement between the Vendor and The Children's Hospital of Philadelphia or The Children's Hospital of Philadelphia Foundation, in a form approved by the Office of General Counsel.
- 4. For educational programs involving clinicians or involving researchers engaged in clinical trials, except for funding for state Nurses Association continuing nursing education programs as described in VI.B above, the Continuing Medical Education Department of the Office of Medical Staff Affairs approves all funding and, in consultation with the Office of General Counsel, approves the written agreement memorializing the support.



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- 5. For other educational programs not described in VI.C.4 above, funding should be approved by a member of Senior Management at the level of Vice President or Department Chair or higher.
- 6. The Vendor may not have any role with respect to the educational content of the program, including with respect to the program topics, objectives, content, methods, speakers or evaluations.
- 7. The fact that the Vendor has provided funding for the program must be disclosed to all participants in the written materials, if any, and, if none, verbally at the outset of the program or lecture; provided, however, that the acknowledgement must be limited to the Vendor's name as a sponsor of the program.
- 8. If there is any financial or in-kind relationship in any amount within the past 12 months between the Vendor, including affiliated entities, and any presenter, author whose materials are being presented, researcher whose results are being presented or a person with control over the content of or speakers at the program, such relationship must be disclosed to all participants in the written materials, if any, and, if none, verbally at the outset of the program or lecture. The disclosure must include the following information: (a) the name of the individual; (b) the name of the Vendor; and (c) the nature of the relationship the person has with the Vendor. If there is no financial or in-kind relationship between an individual presenter, author or researcher and the Vendor, the fact that no such relationship exists must be disclosed to all participants in the written materials, if any, and, if none, verbally at the outset of the program or lecture.
- 9. The content or format of the program and its related materials must be educational and not for the purpose of promoting a specific proprietary business interest of a commercial interest. If the educational materials or content includes trade names, where available trade names from several companies should be used, not just trade names from a single company. If presentations speak to a therapeutic option, the presentation must give a balanced view of appropriate therapeutic options.
- 10. Product promotion material or product-specific advertisement of any type is prohibited in or during the educational activity. Live (staffed exhibits, presentations) or enduring (printed or electronic advertisements) promotional activities must be kept separate from the educational activity. Educational materials that are part of the educational activity (such as slides, abstracts and handouts) may not contain any advertising, trade name or product-group message or promotion.
- 11. The funding from the Vendor will be used to pay expenses in connection with the program (such as payment of honoraria and expenses for outside lecturers, and provision of modest meals for participants in conjunction with the educational



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program, but the funding may not be used to pay, including payment or reimbursement of expenses, any person simply for attending the program) in accordance with Hospital policy in effect from time to time; provided, however, that if all of the funds are not needed to support the program, then any remaining monies will be available for other medical education purposes in accordance with Hospital policy in effect from time to time unless such use was prohibited by the Vendor when it provided the funding.

12. The intent of this Section VI.C. is to apply key principles of the ACCME Standards for Commercial Support to Vendor funding of non-ACCME /state Nurses Association accredited educational programs sponsored or organized by the Hospital or conducted in a Hospital Facility. For additional guidance in the interpretation of the standards set forth herein, see the ACCME Standards for Commercial Support (available at www.accme.org).

## **VII. PURCHASING DECISION MAKING**

- A. Hospital Personnel who are involved in decision making with respect to the use or purchase of equipment, products, supplies or services should avoid the appearance of a conflict of interest with respect to Vendors.
  - 1. Certain Hospital Personnel, such as employees involved in the Hospital's Supply Chain, have such significant Vendor interactions that they are held to a higher standard in terms of avoiding the appearance of a conflict of interest with respect to Vendors.
  - 2. Involvement in Decision Making
    - a. Hospital Personnel serving on the Therapeutic Standards Committee or Medical Device Committee must disclose any relationship they have with respect to a Vendor (or competitor of the Vendor with respect to the product under consideration) whose product is being considered that constitutes an actual, potential or perceived conflict of interest under the Conflicts of Interest Policy (A-3-1) and, after any presentation by the conflicted person with respect to information it is important for such person to present (e.g., the person uniquely understands certain scientific or clinical information about the product that is important for the Committee to know), the conflicted person should leave the Committee meeting while the matter is being discussed and/or voted upon and the minutes should reflect the fact that the conflicted person was not present for the discussion or vote.
    - b. Any Hospital Personnel serving as a member of a Hospital Institutional Review Board ("IRB") that has under its review a study in which the product of a Vendor is being considered for use in human subjects research, must disclose any relationship they have with respect to the Vendor (or competitor of the Vendor with respect to the product under consideration) that constitutes an



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actual, potential or perceived conflict of interest under the Conflicts of Interest Policy (A-3-1), and abide by the procedures set forth in the "Policy on Avoiding Conflicts of Interest in IRB Actions" (Committees for the Protection of Human Subjects SOP 904).

- c. A process similar to that described in "a" should be employed in other situations where the decision maker has a relationship with respect to the Vendor (or competitor of the Vendor with respect to the equipment, product, supply or services under consideration) that constitutes an actual, potential or perceived conflict of interest under the Conflicts of Interest Policy (A-3-1).
- d. Hospital Personnel who provide input, but are not involved in decision making with respect to the use or purchase of equipment, products, supplies or services, must, prior to providing input, disclose any relationship they have with respect to the Vendor (or competitor of the Vendor with respect to the equipment, product, supply or services under consideration) whose equipment, product, supply or service is being considered that constitutes an actual, potential or perceived conflict of interest under the Conflicts of Interest Policy (A-3-1), to their Department Chair or applicable Senior Manager, and to the person(s) or committee(s) to whom the conflicted person expects to provide input. Disclosure to the Department Chair or applicable Senior Manager should be made at least annually if the provision of input is ongoing and the disclosure to the person(s) or committee(s) to whom the conflicted person expects to provide input should be made at each instance prior to the conflicted person providing such input.

#### VIII. **VENDOR SUPPORT FOR RESEARCH**

- A. All external research support from a Vendor, whether in the form of funding or in-kind donations such as equipment, must be paid or gifted to The Children's Hospital of Philadelphia or The Children's Hospital of Philadelphia Foundation, and Hospital Personnel, Departments, divisions and programs may not receive research support directly from Vendors.
- B. All external research support must be documented in a written agreement between the Vendor and The Children's Hospital of Philadelphia or The Children's Hospital of Philadelphia Foundation.
- C. The Office of Technology Transfer approves all Vendor support of research activities at the Hospital and, in consultation with the Office of General Counsel, approves the written agreement memorializing the support.
- D. All external research funding is accessed through accounts at the Hospital, usually the The Children's Hospital of Philadelphia Research Institute, and expended in accordance with policies of the Hospital and, where applicable, the Foundation, in effect from time to time.

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E. The Hospital accepts funding for research from external sources, including Vendors, in accordance with policies and practices that are consistent with all legal requirements, the Hospital's mission, its status as a nonprofit tax-exempt organization (the funding may not generate unrelated trade or business income without the consent of the President & CEO of the Hospital, please see the Office of General Counsel if there are any issues), and prevailing standards for academic medical centers. Vendors may not prohibit Hospital Personnel or the Hospital from publishing the results of the Hospital's research.

#### IX. VENDOR FUNDS FOR RESIDENT AND FELLOW TRAINING

- A. All external funding from a Vendor for resident and fellow training (including Ruth L. Kirschstein National Research Service Award (NRSA) and other trainees) must be paid to The Children's Hospital of Philadelphia or The Children's Hospital of Philadelphia Foundation, and Hospital Personnel, Departments, divisions and programs may not receive such funding for training directly from Vendors.
- B. All external funding for training must be documented in a written agreement between the Vendor and The Children's Hospital of Philadelphia or The Children's Hospital of Philadelphia Foundation.
- C. The Graduate Medical Education Committee, through the Graduate Medical Education Department of the Office of Medical Staff Affairs, approves all Vendor funding for resident and fellow training and, in consultation with the Office of General Counsel, approves the written agreement memorializing the support. The Office of Sponsored Projects approves all Vendor funding for research fellows and, in consultation with the Office of General Counsel, approves the written agreement memorializing the support.
- D. All external funding for training is expended in accordance with policies of the Hospital and, where applicable, the Foundation, in effect from time to time.
- E. Vendor support of trainees, in the form of financial assistance or scholarships, may be provided but should be free of any actual or perceived conflict of interest, must be specifically for the purpose of education, and each of the following additional requirements must be met:
  - 1. The Hospital Department, division or program selects the trainee who will receive the support based on institutional criteria and the Vendor may not recommend or suggest a candidate.
  - 2. The support is provided to The Children's Hospital of Philadelphia or The Children's Hospital of Philadelphia Foundation, which provides the support directly to the trainee in accordance with Hospital policies, and not directly by the Vendor to the student or trainee.



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- 3. The Department, program or division has determined that the proposed use of the support (e.g., covering expenses to allow a trainee to attend an educational, scientific or health care policy conference of a national, regional or specialty medical association) has educational merit.
- 4. The proposed use of the support does not benefit the Vendor and there is no implicit or explicit expectation that the recipient will do something to benefit the Vendor in return for support.

## X. VENDOR GIFTS OR GRANTS FOR OTHER PURPOSES

- A. For other situations in which a Vendor seeks to provide support for Hospital programs (such as funding a position in a clinical division), the matter must be reviewed by the Office of General Counsel for a determination of the terms under which such support may, if at all, be accepted.
- B. All grants or financial support from Vendors for other purposes must be documented in a written agreement, approved by the Office of General Counsel, between the Vendor and The Children's Hospital of Philadelphia or The Children's Hospital of Philadelphia Foundation.
- C. All external funding for such other purposes is expended in accordance with policies of The Children's Hospital of Philadelphia and, where applicable, the Children's Hospital of Philadelphia Foundation, in effect from time to time.

## XI. TRAINING AND SITE VISITS BY HOSPITAL PERSONNEL

- A. On occasion, it may be appropriate for Hospital Personnel to travel to other locations to evaluate new systems, to review installations or designs of facilities, to receive training, to benefit from the experiences of other users or for other legitimate purposes that require site visits to another location. In such situations, a Vendor may reimburse the Hospital for the travel expenses for Hospital Personnel to make the site visit provided each of the following requirements is met:
  - 1. The arrangement has been reviewed and approved in advance by a member of Senior Management at the level of Vice President or Department Chair or higher.
  - 2. The Senior Manager determines there is a valid business reason for the site visit and for the participation of the particular Hospital Personnel selected to attend.
  - 3. The expenses paid by the Vendor are paid to The Children's Hospital of Philadelphia or The Children's Hospital of Philadelphia Foundation, which in turn reimburses the expenses of the Hospital Personnel involved in accordance with the Hospital's Travel Policy (A-2-2).



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- 4. The Vendor may directly provide meals so long as the setting and nature of the meals are appropriate to the business purpose and are not excessive or extravagant. and meals are not provided for the spouse, family member or quest of Hospital Personnel.
- 5. The Vendor may directly provide lodging only with the advance approval of a member of Senior Management at the level of Vice President or Department Chair or higher and the lodging must not be excessive or extravagant.
- 6. Hospital Personnel are prohibited from attending entertainment events at Vendor's expense during site visits. Hospital Personnel who choose to attend entertainment events offered at Vendor's expense during site visits must personally pay or reimburse the Vendor for the cost of attending, and may not seek reimbursement from the Hospital for the expense.

#### XII. **OTHER VENDOR ACTIVITY**

Supply Chain Management maintains a policy, Control of On-Site Activity by Vendors (A-3-8), which includes additional provisions pertaining to Vendor activity, such as requiring Vendors to have appointments and wear identification badges, restricting areas of Vendor access at Hospital facilities, and placing limits on Vendors' use of Hospital Facilities and resources.

#### XIII. ENFORCEMENT

- A. Vendors who fail to comply with this Policy are subject to appropriate action, up to and including having their access to Hospital Facilities restricted and losing their business privileges at the Hospital.
- B. Any Hospital Personnel who violate any provision of this Policy may face sanctions up to and including discharge and/or removal from the Medical and Research Staffs, as appropriate, depending on the seriousness of the violation.



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### **RESPONSIBILITY FOR MAINTENANCE OF THIS POLICY**

GENERAL COUNSEL SENIOR VICE-PRESIDENT, AUDIT, COMPLIANCE AND PRIVACY

Supersedes 1/1/2009	Approved by: Signature:	Madeline Bell, Executive Vice President and Chief Operating Officer		
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