 ADMINISTRATIVE POLICY MANUAL	THE CHILDREN'S HOSPITAL OF PHILADELPHIA	No. A-3-1
	Title: CONFLICTS OF INTEREST	Page 1 of 21 Effective Date: 10/11/10

POLICY:

The Hospital is committed to conducting its affairs in accordance with the highest ethical and legal standards. In order to maintain these standards, it is the policy of the Hospital that potential, perceived and actual conflicts of interest are to be avoided.

PURPOSE:

To identify and clarify the standards and responsibilities related to potential, perceived and actual conflicts of interest.

SCOPE:


This policy applies to all Trustees, directors, officers, members of Board committees, employees, members of the Medical Staff, and Scientists engaged in research under the auspices, 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, and 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"), and any other persons whose presence at or affiliation with the Hospital may place them in a position to make or influence Hospital decisions, to disclose or use Hospital information, to have obligations to the Hospital under other Hospital policies, such as the [Patent and Intellectual Property Policy](#), and other persons designated by the President, Senior Management or a Department Chair (all such persons under referenced Scope, "Hospital Personnel").

RELATED POLICIES


- Administrative Policy Manual No. [A-1-4 Organizational Ethics Statement](#)
- Administrative Policy Manual No. [A-1-5 Compliance Standards of Conduct](#)
- Administrative Policy Manual No. [A-3-4 Patent and Intellectual Property](#)
- Administrative Policy Manual No. A-3-5 Confidentiality of Patient and Institutional Information
- Administrative Policy Manual No. [A-3-7 Interactions with Vendors](#)
- Administrative Policy Manual No. A-4-17 Gifts to Employees

DEFINITIONS

A. **"Conflict of Interest"** means any circumstance in which the personal, professional, financial or other interests of Hospital Personnel or a Family Member of Hospital Personnel may potentially or actually conflict with the interests of the Hospital or may be reasonably perceived as potentially or actually conflicting with the interests of the Hospital. In addition, there may be situations where the interests or activities of a person other than a Family Member (e.g., a fiancé or a close friend) may create a conflict of interest for a Hospital Personnel. A Conflict of Interest includes a Significant Financial Interest of an Investigator that could directly and significantly affect the design, conduct or reporting of research or educational activities, including those funded or proposed for funding by the National Science Foundation or the Public Health Service, including the National Institutes of Health.

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- B. **“Family Member”** means as to a Hospital Personnel a spouse or domestic partner, parents, grandparents, great-grandparents, brothers, sisters, children, grandchildren, great-grandchildren and spouses or domestic partners of parents, grandparents, great-grandparents, brothers, sisters, children, grandchildren and great-grandchildren.
- C. **“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.
- D. **“Hospital Information”** means Institutional Information and Patient Information as defined in the Confidentiality of Patient and Institutional Information Policy (A-3-5).
- E. **“Hospital Personnel”** means Trustees, directors, officers, members of Board committees, employees, members of the Medical Staff and Scientists engaged in research under the auspices, of the Hospital, and any other persons whose presence at or affiliation with the Hospital may place them in a position to make or influence Hospital decisions, to disclose or use Hospital information, to have obligations to the Hospital under other Hospital policies, such as the [Patent and Intellectual Property Policy](#), and other persons designated by the President, Senior Management or a Department Chair.
- F. **“Investigator”** means the principal investigator, co-principal investigators, and any other person at the Hospital who participates in the design, conduct or reporting of research or educational activities, including those funded or proposed for funding by the National Science Foundation or the Public Health Service, including the National Institutes of Health. "Investigator" includes the Investigator's spouse and dependent children.
- G. **“Management Role”** means serving as a director, officer, senior manager or equivalent position in a business or entity, or otherwise having a fiduciary duty to a business or entity.
- H. **“Ownership Interest”** means holding a financial or ownership interest in a business or entity; provided, however, that a person is not deemed to hold any Ownership Interest in a publicly-traded corporation if his/her only interest in that corporation is an equity (stock, assuming the exercise of any options and warrants held) ownership and the value of such interest does not either (i) exceed \$10,000 or (ii) represent more than a 5 percent ownership interest of any class of that corporation's securities, provided that, given the person's relationship with the Hospital, such ownership interest would not be reasonably expected to influence or give the appearance of influencing the person's actions. For example, an interest of less than \$10,000 of stock in a publicly-held, start-up biotechnology company might influence or give the appearance of influencing a person involved with licensing valuable Hospital intellectual property to the company.
- I. **“Scientist”** means a person who is, or expects to become, an Investigator with respect to research under the auspices of the Hospital.

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J. **“Significant Financial Interest”** means in the case of an Investigator anything of monetary value, including but not limited to, salary or other payments for services (such as consulting fees or honoraria), equity interests (such as stocks, stock options or other ownership interests), and intellectual property rights (such as patents, copyrights, and royalties from such rights); but does not include (a) salary, royalties or other remuneration from the Hospital, (b) income from seminars, lectures or teaching engagements sponsored by public or nonprofit entities, (c) income from service on advisory committees or review panels for public or nonprofit entities, (d) an equity interest in a business enterprise or entity the value of which, when aggregated for the Investigator and the Investigator's spouse and dependent children, does not exceed \$10,000 or represent more than a 5 percent ownership interest for any one enterprise or entity, or (e) salary, royalties or other payments that when aggregated for the Investigator and the Investigator's spouse and dependent children over a twelve-month period are not expected to exceed \$10,000.

IMPLEMENTATION:

I. Types of Conflicts of Interest

Without limiting the broad definition of Conflict of Interest, set forth below are examples of Conflicts of Interest.

A. Gifts


To accept a gift (including entertainment) from any person or entity that does or is seeking to do business with the Hospital, the offer or acceptance of which could be reasonably interpreted as intended to influence the Hospital to act favorably toward the person or entity. See the [Interactions with Vendors Policy \(A-3-7\)](#) for specific standards relating to gifts from vendors.

B. Hospital Information

1. To obtain, disclose or use Hospital Information for direct or indirect personal interest, profit or advantage of Hospital Personnel or a Family Member;
2. To obtain, disclose or use Hospital Information for a purpose that may be detrimental to the Hospital; or
3. To obtain, disclose or use Hospital Information without authorization.

C. Outside Interests

1. To hold, directly or indirectly, an Ownership Interest or a Management Role in any business or entity that does, or seeks to do, business with the Hospital, or that is a competitor of the Hospital; or
2. To compete, directly or indirectly, with the Hospital in the purchase or sale of any property, goods or services or in other activities in which the Hospital is or might suitably and appropriately become engaged.


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D. Outside Activities

1. To provide services, whether or not compensated, to any person or entity that provides, or seeks to provide, goods or services to the Hospital or that competes with the goods or services provided to any person or entity by the Hospital;
2. To provide services, whether or not compensated, to any person or entity that requires such time and effort that such services could interfere with fulfillment of his/her Hospital responsibilities (in this regard, acceptance of a full-time appointment at the Hospital entails a commitment to give one's best efforts to the Hospital and to assign first priority to the needs and goals of the Hospital);
3. To accept any other employment or engage in any consulting or other pecuniary activity that would impair or give the appearance of impairing independence of judgment in the exercise of his/her duties on behalf of the Hospital; or
4. To accept a Management Role, whether or not compensated, in another organization whose mission or activities are likely to conflict with the Hospital's mission or activities.
5. If an outside activity was not likely to conflict with the Hospital's mission or activities at the time it was accepted or commenced, but later comes to conflict, Hospital Personnel must promptly either resign from the activity or submit a Conflicts Statement disclosing the matter and seek advice as to how to resolve the conflict.

E. Soliciting Hospital Employees, Medical Staff, Scientists and Others

1. To solicit or assist others in soliciting Hospital employees, members of the Hospital's Medical Staff or Scientists, directly or indirectly, to cease or limit their relationship with the Hospital.
2. To solicit or assist others in soliciting Hospital employees, members of the Hospital's Medical Staff or Scientists, directly or indirectly, to become employed by or contract with a person or entity that competes with, or expects to utilize the solicited employee, Scientist or member to compete with, the Hospital; or
3. To solicit or assist others in soliciting patients, directly or indirectly, to seek services from a person or an entity that competes with or is attempting to compete with the Hospital; provided, however, that nothing herein is intended to prevent a physician from recommending a caregiver to a patient of the physician (or the family of such a patient) when the physician is asked for a recommendation by the patient/family or in the context of the physician-patient relationship, provided that the physician is acting in the best interests of the patient.
4. Soliciting Hospital Personnel for the benefit of competitors of the Hospital is permitted with the advance written permission of the President, or his/her designee; and, in the case of solicitation of housestaff, is permitted when done in the best interests of the

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Hospital residency/fellowship program by the Hospital Graduate Medical Education Committee or persons authorized by the Committee to solicit specific housestaff.

F. Diversion of Corporate Opportunity

To appropriate or divert for personal advantage a business or financial opportunity that the person knows the Hospital is pursuing, is intending to pursue or would have an interest in pursuing if it were aware of the opportunity.

G. Other Circumstances


The nature of Conflicts of Interest is that they may arise in many unique circumstances not encompassed in the preceding categories. This policy applies to any other circumstance that may constitute a Conflict of Interest. For example, Hospital Personnel who provide or accept kickbacks or otherwise violate the law in connection with their Hospital duties or involving their relationship with the Hospital have a Conflict of Interest.

II. Circumstances Under Which Outside Interests or Activities or Soliciting May Be Permitted

A. It is recognized that certain Conflicts of Interest may arise in situations in which a person does not know or have reason to know of the conflict, or are a minor, but an inseparable, part of a larger business relationship, or involve merely passive investments (such as an investment in a mutual fund) or as a practical matter cannot realistically be eliminated but it is highly unlikely to pose a significant Conflict of Interest. These conflicts normally will be considered permissible Conflicts of Interest provided that the Hospital Personnel and Family Members are not in a position to benefit in these external relationships from confidential Hospital information or from the Hospital Personnel's relationship to the Hospital and they do not interfere with the obligation of Hospital Personnel to provide best efforts toward Hospital responsibilities. In such cases, these relationships, if known, should be disclosed on a Conflict of Interest Statement. For example, a Trustee or spouse of a member of Senior Management who is an accountant with a large accounting firm would not be deemed to have an impermissible Conflict of Interest merely because the accounting firm did business with or sought to do business with competitors of the Hospital.

B. Outside interests and outside activities that raise issues concerning a potential Conflict of Interest may be permitted if (i) such activities are fully disclosed in advance by the Hospital Personnel, (ii) they are conducted on an arm's length basis at fair market value; (iii) the Hospital determines that such interests and activities are not inconsistent with the best interests of the Hospital and (iv) the Hospital Personnel does all of the following:


1. Discloses the material facts of the proposed interest or activity, including the specific financial interest(s) and/or role(s) the Hospital Personnel or Family Member proposes to undertake;
2. First offers grants, contracts, opportunities, etc. that reasonably might be undertaken by the Hospital to the Hospital;

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3. Refrains from voting or exercising any personal influence whatsoever in connection with the determination of the matter;
4. Avoids participation in any dealings between the Hospital and the person, entity or company with whom or in which he/she has a financial interest or other role, including with respect to the potential selection of such person, entity or company as a vendor or business partner of the Hospital;
5. Does not permit such outside interests or activities to absorb such amounts of his/her time and effort as to make it impractical for him/her to fulfill his/her assigned responsibilities at the Hospital;
6. Assures that the person, entity or company with whom or in which he/she is involved understands that in dealing with him/her, the person, entity or company is not dealing with the Hospital, but is dealing with him/her in his/her personal capacity.
7. Assures that publications, etc. of the outside person, entity or company do not in any way suggest Hospital involvement or endorsement; and
8. Does not permit such outside interests or activities to compromise or appear to compromise the name or reputation of the Hospital.

III. Institutional Conflicts

- A. In certain instances the Hospital may have an institutional Conflict of Interest based on the financial or other interests of the Hospital itself or of its leadership. Where such conflicts have the potential to be significant, they should be reported to the President or a designee, an appropriate Executive Vice President, the General Counsel or the Chief Compliance Officer, provided such person is not believed to have a personal conflict, or to the Chair or Vice Chair of the Audit & Compliance Board Committee.
- B. In addition to financial interests of the Hospital's leadership, institutional Conflicts of Interest include situations in which the financial investments or holdings of the Hospital, gifts to the Hospital (including restricted or unrestricted monetary gifts), or other financial interests of the Hospital might affect or reasonably appear to affect institutional processes for the design, conduct, reporting, review or oversight of human subjects or other research.
- C. Process for identification of potential institutional Conflicts of Interest with respect to human subjects or other research: In addition to information from the annual conflicts disclosures of the Hospital's leadership, information on the Hospital's financial interests should be reported to the President or a designee, at such frequency and according to such criteria as determined by the President or his designee, by the following offices:
 1. Office of Technology Transfer, for licensing arrangements, patents, invention disclosures; and
 2. Development Office, for gifts to the Hospital from any for-profit organization or philanthropic unit associated with a for-profit organization.

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- D. If the institutional Conflict of Interest is considered to be significant, the matter should be evaluated to determine an appropriate response, which may include eliminating the conflict or instituting a management plan that seeks to have persons without a stake involved in the decision-making.
- E. Examples of institutional Conflicts of Interest management plans might include the following: having the Audit & Compliance Board Committee involved in both the decision-making and on-going oversight of a transaction where the Hospital proposes to make a major purchase from a for-profit company and the President of the Hospital is a director of the company; and having an external expert panel determine whether and under what conditions the Hospital should undertake clinical trials involving intellectual property owned by the Hospital where the potential economic return to the Hospital is significant if such trials show favorable results.

IV. Research-Related Situations

- A. Scientists and others engaged in research under the auspices of the Hospital may be subject to special conflicts of interest rules (such as those imposed by the Public Health Service, including the National Institutes of Health, and the National Science Foundation) that are in addition to the Hospital's rules.
- B. Research matters can pose special Conflicts of Interest situations. Attachment A to this policy, Conflicts of Interest in the Research Setting, provides additional Conflicts of Interest guidance in the context of research matters. The principles set forth in the Attachment also serve to provide guidance in analogous non-research situations.

V. Consulting Relationships

- A. Consulting relationships can result in Conflicts of Interest as described in this policy.
- B. Attachment B to this policy, Consulting Relationships, provides additional Conflicts of Interest guidance in connection with consulting relationships. It also imposes advance review and approval of consulting relationships and other requirements on certain Hospital Personnel, specifically (a) persons who are on the Hospital Medical Staff in the category of Hospital Staff (as defined in the Hospital's Medical Staff Bylaws), (b) Scientists and (c) other persons who are faculty members at the University of Pennsylvania who perform some or all of their duties under the auspices of the Hospital. Advance review for other Hospital Personnel is available on a voluntary basis.
- C. Consulting in the nature of participation on a speaker's bureau also is governed by the [Interactions with Vendors Policy \(A-3-7\)](#).
- D. Certain Hospital Personnel are prohibited by contract from engaging in any outside activities without written approval of the Hospital.

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VI. Administration, Including Disclosure, Review and Actions Regarding Conflicts of Interest

A. General

1. The President of the Hospital, or his/her designee, administers the Conflicts of Interest Policy.
2. Disclosures are required annually, as set forth in VI.B below, and as Conflicts of Interest arise, as set forth in VI.C below.

B. Annual Disclosure

1. A Conflicts of Interest Statement, together with a copy of this policy, is sent annually to: Trustees, directors, officers and members of Board committees of The Children's Hospital of Philadelphia, CHOPPA practice plans and entities controlling, controlled by or under common control with them; the President and other individuals classified as Senior Management of the Hospital; persons who serve as Department Heads, Assistant Department Heads, Administrative Supervisors and Managers of the Hospital; Hospital employees who are known to select or place orders with vendors (other than persons involved with only de minimis purchases such as a secretary who orders small quantities of office supplies from the Hospital vendor for office supplies); Hospital employees in the Hospital Investment Department; Hospital employees in the Hospital's Technology Transfer Department; Department Chairs, Division Chiefs, members of the Hospital Medical Staff with Clinical Privileges (members of the Medical Staff with Clinical Privileges who are not Hospital Staff members of the Hospital Medical Staff may receive the Statement and policy only biennially as part of the recredentialling process); Scientists; employees of CHOPPA practice plans designated by the Department Chairs, President or an Executive Vice President; and other persons designated by the Department Chairs, President, member of Senior Management or the supervisor of a Hospital Personnel. Hospital management may require a person, even if not apparently a person within the scope of the policy, to complete a Statement.
2. Senior Management, Department Chairs, Division Chiefs, and Department Heads ensure that all persons listed above receive the annual Conflicts of Interest Statement and policy and return completed Statements.
3. Each person to whom an annual Conflicts of Interest Statement is sent is required to fully and timely complete the Statement and to return it to the person indicated on the Statement or transmittal memorandum, or to their immediate supervisor if no person is indicated.
4. The Hospital may seek additional information from Hospital Personnel about a disclosed or undisclosed possible Conflict of Interest and the Hospital Personnel is required to cooperate fully with such inquiry.
5. Persons within the scope of the policy are subject to the policy whether it is explicitly communicated annually or not.


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C. Disclosures as Conflicts of Interest Arise


1. A Conflicts of Interest situation can arise at any time in numerous factual circumstances. It is required that such a situation be disclosed by Hospital Personnel as soon as the existence of a possible Conflict of Interest is or should be known. The recommended process for disclosing a possible Conflict of Interest is by Hospital Personnel completing a Conflicts of Interest Statement and submitting that Statement to the applicable member of Senior Management, Department Chair, Division Chief or Department Head. Hospital Personnel may request a Conflicts of Interest Statement from a member of Senior Management, Department Chair, Division Chief, Department Head or the Office of Compliance and Privacy at any time. Hospital Personnel who fail to make timely disclosure remain obligated to rectify the situation by disclosing the possible Conflict of Interest as soon as he/she becomes aware of the deficiency. The Hospital may seek information from Hospital Personnel about a possible disclosed or undisclosed Conflict of Interest at any time and the Hospital Personnel is required to cooperate fully with such inquiry.
2. Investigators are required to make disclosure at the time that a proposal is submitted to the National Science Foundation or the Public Health Service, including the National Institutes of Health, as set forth in Attachment A to this policy, Conflicts of Interest in the Research Setting.
3. If a Hospital Personnel is in doubt about a situation, it should be fully disclosed so that a determination can be made under the processes set forth in this policy. The person can consult with his/her supervisor in the case of an employee, with the Hospital President, Vice President for Research Administration or General Counsel in the case of research issues and with the Hospital President, an Executive Vice President or General Counsel in other cases if there is an issue as to whether disclosure is required or the process for disclosure.

D. Review Process

1. Except as otherwise provided, Completed Conflicts of Interest Statements are reviewed by the person to whom they are returned and forwarded with appropriate recommendations to the applicable member of Senior Management or Department Chair, and then reviewed by the applicable member of Senior Management or Department Chair and forwarded with appropriate recommendations to the President, or his/her designee. Completed Conflicts of Interest Statements submitted by Trustees, officers and members of Board committees of The Children's Hospital of Philadelphia and The Children's Hospital of Philadelphia Foundation are submitted directly to the President who will review them and submit them to the General Counsel for review.
2. If the member of Senior Management or the Department Chair determines that an issue disclosed is not a Conflict of Interest, the determination and Conflicts of Interest Statement (or summary of the issue if a Statement was not completed) should still be forwarded to the President, or his/her designee, with appropriate explanation.

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3. Actions with respect to a Conflict of Interest may be taken by Senior Management, Department Chairs, Division Chiefs, Department Heads and conflicts committees to the extent within their purview and the actions are then to be reported promptly to the President, or his/her designee. Such actions are subject to the right of the President to review and reconsider any issue. The President has final decision-making authority under this policy, and may delegate such authority (and in the event he/she is conflicted, as set forth in "6" below, will delegate such authority) to a person, committee or the Board or a Board committee; provided, however, that the final decision-making authority with respect to Conflicts of Interest involving Trustees, officers and members of Board committees of The Children's Hospital of Philadelphia Foundation and The Children's Hospital of Philadelphia is the Board, which may delegate such authority, including to a Board committee.
4. The President may, at his/her discretion, refer selected issues or matters for consultation, including but not limited to one or more of the following: a specially constituted Review Committee designated by him/her; the Audit & Compliance Board Committee; the Research Review Committee described in Attachment A to this policy, Conflicts of Interest in the Research Setting; or the Translational Medicine & Science Board Committee. A specially constituted Review Committee might include, for example, the Chief Operating Officer, a member of Senior Management selected by the President, and the General Counsel, or their designees, and when a physician or Scientist is involved might include a leader from the Medical Staff or The Children's Hospital of Philadelphia Research Institute or outside consulting physician, scientist or ethicist in addition to or in lieu of the Chief Operating Officer or member of Senior Management.
5. The Hospital has broad authority in dealing with Conflicts of Interest. Among the actions that the Hospital may take in response to a Conflict of Interest are: management and oversight of the conflict, including the imposition of conditions or restrictions intended to manage, reduce or eliminate such conflict; required disclosure of additional information, discussions with third parties and obtaining background documents; obtaining waivers, consents and/or authorizations; requiring relinquishment of interests and/or restructuring or termination of relationships; and sanctions for violations of this policy.
6. No person should be involved in considering the existence of a Conflict of Interest or the management or oversight of, or the sanctions appropriate for, such a conflict once it becomes apparent that the person is a party or potential party to the conflict or otherwise may lack impartiality. This provision is not intended to preclude reasonably necessary or appropriate participation, subject to the ultimate determination of the President or the Board, or their designees, or to disqualify persons based on their usual Hospital roles (e.g., a Department Chair is not conflicted because a proposed outside activity may compete with the activities of his/her Department).
7. Completed Conflicts of Interest Statements are kept available for review by the Audit & Compliance Committee, and the President, or his/her designee, makes an annual

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report to the Audit & Compliance Board Committee as to the status of compliance. Conflicts of Interest Statements are retained for at least seven years.

VII. Examples

- A. The following are common illustrative situations involving impermissible Conflicts of Interests involving Hospital Personnel:
1. Using a person's influence as a Trustee, member of Senior Management, Medical Staff member, Scientist or other association with the Hospital to seek to have the Hospital contract with a company with which that person or a Family Member has an Ownership Interest, Management Role or may otherwise benefit personally or financially from the transaction. This does not prohibit Hospital Personnel from requesting to have such a company included as a bidder on a project pursuant to a Hospital request for proposal or similar process, provided the person discloses the relationship and does no more than request the company's inclusion in the bidding process and the person is not involved with, and does not attempt to exert any influence on, the selection process or contractual negotiations or, if the company is hired, on the Hospital's management and oversight of the company's work for the Hospital. If the company is hired, the compensation paid to it should not include compensation for services provided by the Hospital Personnel him/herself or a Family Member.
 2. Accepting or agreeing to accept a finder's fee, commission or other remuneration or benefit for assisting a company having or seeking to develop a relationship with the Hospital.
 3. Participating in any activities or transactions that could cause the relationship with a vendor to be less than "arm's length" from the standpoint of the Hospital.
- B. An organization or individual desiring to make a gift to or for the benefit of the Hospital should be asked to contact the Development Department. All gifts to the Hospital should be made through the Development Department. The fact that an organization or individual is a donor to the Hospital should never influence the Hospital to do business with or otherwise take actions that constitute Conflicts of Interest under this policy.

VIII. Enforcement and Sanctions

- A. The Hospital has broad power under this policy to require disclosure of Conflicts of Interest and possible Conflicts of Interest, to determine the existence of Conflicts of Interest, to subject relationships to appropriate management and oversight and to impose appropriate sanctions.
- B. Any Hospital Personnel who violates any provision of this policy may face sanctions up to and including suspension or termination of employment, loss of the privilege of conducting research at or in connection with the Hospital, loss of Medical Staff privileges, loss of administrative appointments, cessation of business with a vendor, liability for damages and other appropriate sanctions.

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RESPONSIBILITY FOR MAINTENANCE OF THIS POLICY:


GENERAL COUNSEL

RESPONSIBILITY FOR OVERSIGHT AND REVIEW:

PRESIDENT
AUDIT & COMPLIANCE COMMITTEE
SENIOR VICE-PRESIDENT, AUDIT, COMPLIANCE & PRIVACY

Attachment A: Conflicts of Interest in the Research Setting
Attachment B: Consulting Relationships

Supersedes 7/1/09	Approved by: Signature: _____ Steven M. Altschuler, MD, – President and Chief Executive Officer
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Attachment A: Conflicts of Interest in the Research Setting

CONFLICTS OF INTEREST IN THE RESEARCH SETTING


This Attachment supplements the Conflicts of Interest Policy with respect to research matters. The principles set forth herein also serve to provide guidance in analogous non-research situations.

I. Conflicts of Interest

- A. The provisions set forth in this Attachment are in addition to the provisions set forth in the Conflicts of Interest Policy.
- B. Scientists and other persons within the scope of this policy may not participate in or seek to influence decisions (including the purchase of a vendor's products or scientific peer review of grants or contracts to a commercial entity) that could affect a third party from which they receive support or in which they have an outside interest.
- C. Scientists and other persons within the scope of this policy may not, without the advance written approval of the Vice President for Research Administration, or his/her designee, accept gifts or favors from a company with which the Hospital has or may have a sponsored-research, licensing or other relationship in which the person is or may be involved. See also the [Interactions with Vendors Policy \(A-3-7\)](#).
- D. Scientists and other persons within the scope of this policy may not, without the advance written approval of the Vice President for Research Administration, or his/her designee, (i) disclose or use for personal interest, profit or advantage Hospital work product, results, materials, records or information that is not made generally available or (ii) obtain, disclose or use without authorization privileged, confidential or proprietary information acquired in connection with their Hospital-based or supported activities.

II. Disclosure of Research Support

- A. The support of research by a commercial entity must be acknowledged in all public forums in which the research is discussed, including conferences, publications, lectures, interviews and testimony before policy makers. The support of research by a nonprofit entity must be acknowledged in all public forums in which the research is discussed, including conferences, publications, lectures, interviews and testimony before policy makers, in accordance with the terms of the grant award.
- B. Grant applications must disclose all relationships between the Scientist or other person and a commercial entity that supports the research of the Scientist or other person.
- C. Prior or current federal support of research must be disclosed to any commercial entity that is considering sponsoring the same research.

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Attachment A: Conflicts of Interest in the Research Setting

III. Financial Disclosure for Sponsored Research

- A. Any Scientist or other person applying for a grant or contract or involved in a project supported by a grant or contract is responsible for assuring his/her compliance with the specific substantive and disclosure requirements involved.
- B. Prior to the submission of a grant or contract proposal, a Scientist or other person involved in the project may seek advice from the Vice President for Research Administration, or his/her designee, as to whether any potential, perceived or actual conflict of interest exists with respect to the proposal.
- C. Any Scientist or other person submitting a proposal to conduct human subjects research must comply with the conflict of interest requirements of the Institutional Review Board ("IRB"). The IRB standards include the requirement that all members of the study team disclose any conflicts with respect to the research being proposed, including with respect to the sponsor, funding or other issues.
- D. Any Scientist or other person submitting a proposal to conduct research funded by the National Science Foundation ("NSF") and/or the Public Health Service ("PHS"), including the National Institutes of Health ("NIH"), must follow the requirements set forth in Section IV below.

IV. National Science Foundation and Public Health Service/National Institutes of Health Requirements

- A. In the case of research funded by the NSF and/or the PHS, including the NIH, regulations provide for the disclosure and consideration of the financial interests of individuals involved in the design, conduct and reporting of such research.
- B. It is the policy of the Hospital to be in compliance with such regulations.
- C. This Conflicts of Interest Policy, including the requirements set forth in this Attachment, is believed to comply with NSF and PHS/NIH requirements. To the extent that it does not wholly comply, this policy is to be interpreted to assure compliance.
- D. The Hospital will inform each Investigator of its policy for identifying and managing, reducing or eliminating Significant Financial Interests by promulgating this policy, through the specific required distribution of this policy and through selected education efforts with respect to this policy by the Vice President for Research Administration, or his/her designee.
- E. Each Investigator must disclose, on the form designated for such purpose by the Vice President for Research Administration, all financial interests, including all Significant Financial Interests, that would reasonably appear to be affected by the research or educational activities funded or proposed for funding by NSF or PHS/NIH, including interests in entities whose financial interests would reasonably appear to be affected by such activities. Such disclosure

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must be made at the time the proposal is submitted to NSF or PHS/NIH and must be updated during the pendency of the award as new financial interests, including new Significant Financial Interests, are obtained. The Hospital seeks disclosure of Conflicts of Interest that go beyond Significant Financial Interests.

- F. Disclosures are reviewed in accordance with the procedures set forth in Section V of this Attachment.
- G. All records of financial disclosures and actions taken to manage, reduce or eliminate actual or potential conflicts of interest will be retained for at least three years after the later of (a) the date of submission of the final expenditures report for the NSF or PHS/NIH award to which they relate or (b) the resolution of any government action involving those records, or longer as required by this policy or other Hospital policies or by research sponsors.
- H. The Vice President for Research Administration, or his/her designee, will make any required notification to NSF or PHS/NIH, as the case may be. Required reports of the existence and management, reduction or elimination of any Significant Financial Interest constituting an actual or potential conflict of interest must be made (i) prior to the Hospital's expenditure of any funds under an award in the case of a conflicting interest identified by the Hospital with respect to the award and (ii) within sixty days of the Hospital identifying an interest as conflicting in the case of a conflicting interest identified by the Hospital after its initial report under the award. If the failure of a person subject to this policy to comply with the policy biases the design, conduct, or reporting of an NSF or PHS/NIH-supported project, the Vice President for Research Administration, or his/her designee, will promptly notify NSF or PHS/NIH, as the case may be, of the corrective action taken. The Vice President for Research Administration, or his/her designee, will make available, upon request, to NSF or PHS/NIH, as the case may be, information regarding any Significant Financial Interest constituting an actual or potential conflict of interest identified by the Hospital to the extent required by law, regulation or condition of NSF or PHS/NIH funding.
- I. In instances where the Hospital carries out NSF or PHS/NIH-funded research through subgrantees, subcontractors or collaborators, the Hospital will either require such external investigators to comply with this Attachment (and such other portions of this Conflicts of Interest Policy as it deems appropriate) or require the entities for which the investigators work to provide assurances that will enable the Hospital to comply with the NSF or PHS/NIH requirements.

V. Administration, Including Disclosure, Review and Actions Regarding Conflicts of Interest in the Research Setting

- A. The procedures set forth in Section VI of the policy apply, as supplemented herein.


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- B. All financial disclosures will be submitted to the Vice President for Research Administration and reviewed by him/her or a person designated by the Vice President for Research Administration who reports directly to him/her.
- C. In the event any disclosure might be deemed to be a Conflict of Interest or possible Conflict of Interest, the disclosure will be reviewed by a Research Review Committee comprised of the Chief Scientific Officer, Vice President for Research Administration and General Counsel, or their designees, or such other persons as are appointed by the President, or his/her designee. The Research Review Committee will determine whether a Conflict of Interest exists, what conditions or restrictions, if any, should be imposed by the Hospital to manage, reduce or eliminate such Conflict of Interest and what sanctions, if any, should be imposed on those involved in the Conflict of Interest.
- D. The Research Review Committee should forward the financial disclosure with appropriate recommendations to the President, or his/her designee. If the Research Review Committee determines that the situation disclosed is not a Conflict of Interest, the determination and financial disclosure should still be forwarded to the President, or his/her designee, with appropriate explanation. The President, or his/her designee, will make the final determination as to whether a Conflict of Interest exists, as to what conditions or restrictions, if any, should be imposed by the Hospital to manage, reduce or eliminate such Conflict of Interest and as to what sanctions, if any, should be imposed on those involved in the Conflict of Interest.
- E. Any member of the Research Review Committee or the President may refer any matter to the Translational Medicine & Science Board Committee or the Audit & Compliance Board Committee for consultation.
- F. The Vice President for Research Administration, or his/her designee, will keep the President, Chief Scientific Officer, General Counsel and NSF or PHS/NIH, as the case may be, informed if the Hospital finds that it is unable to satisfactorily manage a Conflict of Interest. Each Investigator is responsible for notifying the Vice President for Research Administration if at any time the recommendations of the President cannot be fulfilled.

VI. Enforcement and Sanctions


- A. The Hospital has broad power to require disclosure of Conflicts of Interest and possible Conflicts of Interest involving research situations, to determine the existence of Conflicts of Interest in the research setting, to subject research situations to appropriate management and oversight and to impose appropriate sanctions for Conflicts of Interest involving research situations or for failure to follow this or other applicable Hospital policies.
- B. In the context of research situations, management and oversight include the imposition of conditions or restrictions intended to manage, reduce or eliminate such conflicts, including requiring public disclosure of the relationships, prior scientific evaluation and ongoing monitoring of the research project by independent reviewers, modification of a research

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project, exclusion of the Scientist or others from all or part of a research project or divestiture or severance of a financial relationship that creates a potential, perceived or actual conflict.

- C. In the context of research situations, sanctions for violation of this policy may include suspension or termination of employment, loss of the privilege of conducting research at or in connection with the Hospital, loss of Medical Staff privileges, cessation of funding, loss of administrative, scientific and/or medical responsibilities, liability for damages and other appropriate sanctions.

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Attachment B– Consulting Relationships

CONSULTING RELATIONSHIPS

This Attachment supplements the Conflicts of Interest Policy with respect to outside consulting relationships. It provides additional Conflicts of Interest guidance in connection with consulting relationships. It also imposes advance review and approval of consulting relationships and other requirements on certain Hospital Personnel, specifically (a) persons who are on the Hospital Medical Staff in the category of Hospital Staff (as defined in the Hospital’s Medical Staff Bylaws), (b) Scientists and (c) other persons who are faculty members at the University of Pennsylvania who perform some or all of their duties under the auspices of the Hospital (together, “CHOP Faculty”). Advance review for other Hospital Personnel is available on a voluntary basis.


I. Consulting Relationships

- A. The Hospital recognizes that there can be value to CHOP Faculty and to the Hospital in permitting CHOP Faculty to engage in external consulting relationships. These relationships can have the potential to increase the knowledge and experience of CHOP Faculty in clinical and research areas, to broaden the exposure of CHOP Faculty to external experts in their fields or related fields and to advance the public interest.
- B. Consulting relationships can, however, conflict with the obligations that CHOP Faculty and other Hospital Personnel have to the Hospital, including to Hospital patients and research subjects, and can be at odds with the [Hospital's Organizational Ethics Statement \(A-1-4\)](#), and its [Compliance Standards of Conduct \(A-1-5\)](#).
- C. Some Hospital Personnel are prohibited by contract from engaging outside activities without the advance written approval of the Hospital. All Hospital Personnel should be familiar with restrictions in their employment and other agreements so that they do not inadvertently violate them.
- D. Examples of consulting relationships include engagements to serve: as a member of a scientific advisory board or data safety monitoring board; as a speaker or moderator at a company-sponsored event, on the company’s speakers’ bureau or at a company-sponsored focus group; or as an adviser or consultant to the company in connection with its research or products.
- E. Areas where Conflicts of Interest and other legal and ethical concerns are most common in connection with consulting relationships include:
 - 1. Jeopardizing intellectual property rights that are owned by the Hospital and subject to the [Hospital's Patent and Intellectual Property Policy \(A-3-4\)](#).

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2. Allowing the Hospital's name to be used in a manner that suggests Hospital endorsement of the person or entity for which the Hospital Personnel is consulting ("Consulting Company"), its products or the consulting relationship.
 3. Entering into financial terms that give rise to a conflict of interest (such as a payment from a Hospital vendor that is in substance a gift or a kickback) and/or that may be inconsistent with legal and ethical dictates (such as a referral fee for prescribing a specific drug). Compensation for consulting services in excess of fair market value for the work performed, compensation based on economic benefits provided other than in connection with the consulting services and compensation based or paid in a manner that violates the law or Hospital policy are expressly prohibited.
 4. Agreeing to withhold or inappropriately delay disclosures or to other confidentiality terms that interfere with disclosures that should be made to the Hospital, its patients and/or research subjects, a governmental authority or regulatory body, and/or others in a timely fashion; or that interfere with the CHOP Faculty member's academic activities, Hospital research, ability to publish research conducted under the auspices of the Hospital, scholarly duties or performance of other Hospital duties.
 5. Allowing an exclusivity or non-compete provision to restrict the CHOP Faculty member's academic activities, Hospital research, ability to publish research conducted under the auspices of the Hospital, scholarly duties or performance of other Hospital duties.
 6. Failing to make it clear to the Consulting Company that the Hospital has no role in connection with what is a private consulting relationship of the Hospital Personnel.
 7. Utilizing Hospital Facilities, Hospital Funds, or other Hospital Resources, including other Hospital Personnel, in connection with the consulting relationship (beyond incidental use of computers, email and phones that does not interfere with Hospital obligations or activities).
 8. Undertaking a level of consulting activities that, together with other external activities, creates a conflict of commitment or interferes with performing Hospital duties. Generally, consulting services should be performed on days and at times when Hospital Personnel are not engaged in Hospital activities (e.g., vacation, nights and weekends when not scheduled to work).
- F. Consulting relationships that assign intellectual property rights to the Consulting Company are discouraged and require special review. Such assignments must be limited to intellectual property rights as to which the Hospital has no ownership claim under the Hospital Patent and [Intellectual Property Policy \(A-3-4\)](#). For example, the Hospital Personnel must be able to prove by clear and persuasive evidence that the intellectual property was conceived and developed entirely outside the scope of the Hospital Personnel's relationship with the

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Hospital, on the Hospital Personnel's own time, and without the use of any using Hospital Facilities, Hospital Funds, or other Hospital Resources; and no other Hospital Personnel participated in the conception or development of the Intellectual Property within the scope of such person's relationship with the Hospital, on Hospital time, or using Hospital Facilities, Hospital Funds, or other Hospital Resources, including other Hospital Personnel. See the [Patent and Intellectual Property Policy \(A-3-4\)](#).

- G. Consulting relationships in the nature of participation on speakers' bureaus for commercial ventures or for-profit companies are discouraged and require special review. See also the [Interactions with Vendors Policy \(A-3-7\)](#).

II. Review of Consulting Relationships

- A. Except as set forth in C below, all consulting relationships involving CHOP Faculty must be in writing, set forth all understandings of what the prospective consultant is to do and must be ethical, legal and consistent with Hospital and, where applicable, University of Pennsylvania policies.
- B. Except as set forth in C below, all proposed consulting relationships involving CHOP Faculty must be reviewed and approved in advance by the Hospital in accordance with the procedures established by the Hospital's Office of General Counsel and Technology Transfer Department. Such review is intended to avoid Conflicts of Interest and protect the Hospital, but is not intended to provide Hospital Personnel with the personal protections that may be warranted. See E below.
- C. The requirements in A and B above with respect to consulting relationships being in writing and being reviewed and approved in advance by the Hospital do not apply to professional presentations made by CHOP Faculty to governmental or nonprofit organizations (such as schools and hospitals) that are independent of for-profit companies so long as the CHOP Faculty are not subject to any restrictions regarding the content of their professional presentations or related materials, do not allow a for-profit organization, or a nonprofit organization related to a for-profit organization, to censor their presentations or related materials, do not allow a for-profit organization, or a nonprofit organization related to a for-profit organization, to have final approval of their presentations or related materials and the materials are not written by a for-profit organization, or a nonprofit organization related to a for-profit organization, or are ghostwritten. All other Conflicts of Interest and other policy considerations apply to such professional presentations.
- D. Advance review and approval for proposed consulting relationships is available on a voluntary basis in those situations where advance review and approval is not required.
- E. Hospital Personnel engaged in consulting relationships should be aware that they are undertaking a personal relationship outside of the Hospital that may engender personal

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liability and other personal risks and Hospital Personnel are not protected by the Hospital in connection with such personal endeavors. The Hospital's insurance and other resources are not available to Hospital Personnel in connection with such personal liabilities and risks. The Hospital's Office of General Counsel and Technology Transfer Department review proposed consulting agreements and make suggestions about consulting relationships focused on the Hospital's interests, not on the interests of the Hospital Personnel. Accordingly, Hospital Personnel may wish to seek the advice of personal counsel, at their own expense, to review proposed consulting agreements with respect to issues that impact the personal interests of the Hospital Personnel.