



TABLE OF CONTENTS

| | |
|-------|---|
| | POLICY |
| | PURPOSE |
| | SCOPE |
| | RELATED POLICIES |
| I. | DEFINITIONS |
| II. | ADMINISTRATION OF THE POLICY |
| III. | GENERAL PRINCIPLES |
| IV. | SPECIAL PRINCIPLES FOR HOSPITAL PERSONNEL REGARDING COMPANIES WITH WHICH THE HOSPITAL HAS A SIGNIFICANT EXTERNAL RELATIONSHIP |
| V. | ANNUAL DISCLOSURES |
| VI. | FINANCIAL CONFLICTS OF INTEREST IN RESEARCH |
| VII. | CONSULTING RELATIONSHIPS |
| VIII. | INSTITUTIONAL CONFLICTS |
| IX. | ENFORCEMENT AND SANCTIONS |

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

The purpose of this Policy is to establish the standards for determining the existence of conflicts of interest, the requirements for disclosing conflicts, and the process for reducing, managing or eliminating conflicts.

SCOPE

This Policy applies Enterprise-wide to all persons affiliated with the Hospital, including without limitation Trustees, officers, employees, members of the Medical Staff, and Scientists engaged in research under the auspices of the Hospital. Hospital Personnel who are members of the faculty of the University of Pennsylvania must also abide by applicable University policies.


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](#)

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|  ADMINISTRATIVE POLICY MANUAL | THE CHILDREN'S HOSPITAL OF PHILADELPHIA | No. A-3-1 |
| | Title: CONFLICTS OF INTEREST | Page 2 of 24 Effective Date: 7/01/2019 |


Administrative Policy Manual No. [A-3-7 Interactions with Vendors](#)
Administrative Policy Manual No. [A-3-9 Retention and Destruction of Records](#)
Administrative Policy Manual No. [A-3-15 Insider Trading](#)
Administrative Policy Manual No. [A-4-17 Gifts to Employees](#)

Job Aid

Administrative Policy Manual No. [Job Aid: Significant External Relationships List](#)

I. DEFINITIONS


- A. Exempt Entity: A Federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education. This exemption does not apply to any foreign (non-U.S.) government agency (which includes local, provincial, or equivalent governments of another country), or foreign institution of higher education, academic teaching hospital, medical center, or research institutes affiliated with an institution of higher education.
- B. Hospital: 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.
- C. Hospital Personnel: 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, and other persons designated by the President and Chief Executive Officer ("CEO") or Senior Management.
- D. Investigator: The project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research, which may include, for example, collaborators or consultants.
- E. Institutional Responsibilities: A Hospital Personnel's professional responsibilities on behalf of the Hospital or the University of Pennsylvania.
- F. Scientist: A person who is, or expects to become, an Investigator with respect to research under the auspices of the Hospital.

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|--|---|---|
|  ADMINISTRATIVE POLICY MANUAL | THE CHILDREN'S HOSPITAL OF PHILADELPHIA | No. A-3-1 |
| | Title: CONFLICTS OF INTEREST | Page 3 of 24 Effective Date: 7/01/2019 |

- G. Senior/Key Personnel: The project director or principal investigator and any other person identified as senior/key personnel by the Hospital in the grant application, progress report, or any other report submitted to the U.S. Public Health Service (“PHS”) by the Hospital.
- H. Senior Management: Hospital Personnel at the level of Vice President and above, Department Chairs, and Division Chiefs.
- I. Significant Financial Interest: A financial interest consisting of one or more of the following interests:
1. With regard to any publicly traded entity, when the value of any remuneration (salary and any payment for services not otherwise identified as salary, for example consulting fees, honoraria, paid authorship) received from the entity in the twelve (12) months preceding disclosure of the interest aggregated with the value of any equity in the entity (for example, stock, stock options, or other ownership interests as determined through reference to public prices or other reasonable measures of fair market value) as of the date of the disclosure exceeds \$5,000;
 2. With regard to any non-publicly traded entity, when the aggregated value of any remuneration received from the entity in the twelve (12) months preceding disclosure of the interest exceeds \$5,000 or any equity in the entity; or
 3. Intellectual property rights and interests (e.g., patents, copyrights) upon receipt of income related to such rights and interests.

The term Significant Financial Interest does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Hospital to a person if the person is currently employed or otherwise appointed by the Hospital, including intellectual property rights assigned to the Hospital and agreements to share in royalties related to such rights; any ownership interest in the Hospital held by the person, if the Hospital is a commercial or for-profit organization; income from investment vehicles, such as mutual funds and retirement accounts, as long as the person does not directly control the investment decisions made in these vehicles; and income from service on advisory committees or review panels for, or from seminars, lectures, or teaching engagements sponsored by, an Exempt Entity.

- J. Significant External Relationship: The Hospital will be deemed to have a Significant External Relationship with any for-profit company on the Significant External Relationships List (Job Aid A).


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|--|---|---|
|  ADMINISTRATIVE POLICY MANUAL | THE CHILDREN'S HOSPITAL OF PHILADELPHIA | No. A-3-1 |
| | Title: CONFLICTS OF INTEREST | Page 4 of 24 Effective Date: 7/01/2019 |

II. ADMINISTRATION OF THE POLICY


The CEO (the Designated Official for purposes of PHS-funded research) is accountable for the administration of this Policy and, where specified, for decision-making, and may delegate such administration and decision making authority (and in the event they are conflicted, shall delegate such authority) to a person or committee. Actions with respect to a conflict of interest may be taken by Senior Management and Department Heads for those reporting up to these individuals and by the Conflict of Interest Committee. The CEO may require that such actions be reported to the CEO or their designee. Such actions are subject to the right of the CEO to review and reconsider any issue. The Conflict of Interest Office in the Office of Compliance and Privacy supports the CEO, the Conflict of Interest Committee, the COI Executive Steering Committee, and all other relevant committees and members of management in the implementation of this policy, and has primary responsibility for the day to day administration of this policy. The Board of Trustees has ultimate oversight of conflict of interest policy and the conflict of interest process. The Board's oversight is principally carried out through the Board Audit, Compliance, and Risk Committee.

III. GENERAL PRINCIPLES

- A. A conflict of interest is any circumstance where personal, professional, financial or other private interests of a person or institution do, or have the potential to, influence the exercise of professional judgment or obligations related to such person's Institutional Responsibilities, or may be perceived as doing so. Conflicts of interest may arise from interests or activities of the Hospital or Hospital Personnel, or interests or activities of other persons with relationships to Hospital Personnel (such as a relative, partner, or close friend). Conflicts of interest may arise in all aspects of the Hospital's activities, including regarding clinical care, research, education and business matters.
- B. This policy is intended to ensure that the Hospital continues to achieve its aim to be the world leader in the advancement of health care for children through innovation in pediatric research and clinical care without creating inappropriate conflicts of interest that are contrary to the Hospital's mission and core value of integrity and that could be harmful to its reputation. Towards this end:
 - 1. In pursuit of the Hospital's mission, the interests of patients and research subjects, and the institution, must at all times be placed above personal interests of individual Hospital Personnel.
 - 2. In appropriate circumstances, the Hospital's mission may best be advanced through collaboration or other involvement with industry partners who have the necessary resources and expertise to commercialize products or otherwise advance discoveries from the Hospital to accelerate their availability to patients. The Hospital's mission and obligations to its patients, research participants, Hospital Personnel, trainees, students, and larger community must guide any institutional decisions about interactions with industry. This principle applies to the Hospital as an institution and to all Hospital Personnel.

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|--|---|---|
|  ADMINISTRATIVE POLICY MANUAL | THE CHILDREN'S HOSPITAL OF PHILADELPHIA | No. A-3-1 |
| | Title: CONFLICTS OF INTEREST | Page 5 of 24 Effective Date: 7/01/2019 |

3. All Hospital Personnel are required to provide clear and complete disclosure of financial interests both internally as required by this Policy and in publications and presentations of their professional work, including but not limited to disclosures in connection with research. This includes compliance with scientific journal, conference, and other and other external disclosure requirements regarding conflicts of interest/financial interests.
 4. Leaders are held to the highest standards and principles in their conduct and are expected to set an example and abide at all times in their professional and leadership endeavors with both the letter and spirit of this Policy.
- C. Hospital Personnel should be aware of conflicts of interest and address them as they arise, seeking advice from supervisors or the Conflict of Interest Office when faced with circumstances that have the potential to create a conflict of interest.
- D. Although this Policy applies broadly throughout the Hospital, there are specific provisions applicable to those required to submit annual disclosures (see Section V), those who are or may be engaged in research activities (see Section VI), and those who engage in consulting activities (see Section VII).
- E. Subject to special principles related to companies with which the Hospital has a Significant External Relationship (see Section IV below), the following are examples of circumstances that, if related to Institutional Responsibilities, may give rise to individual conflicts of interest and are generally subject to disclosure and management, except as noted.
1. Outside Activities
Providing services, whether or not compensated, to an outside organization that does or seeks to do business with the Hospital, or competes with the Hospital, or engaging in any other activity that may give the appearance of impairing independence of judgment in the exercise of Institutional Responsibilities.
 2. Outside Interests
Seeking to do business with the Hospital or competing with the Hospital, or having an ownership interest in an outside organization that does or seeks to do business with the Hospital or to compete with the Hospital.
 3. Intellectual Property
Having rights as an inventor or author related to inventions, patents, patent applications, licenses, or copyrights, the value of which could be affected by actions taken in the course of carrying out Institutional Responsibilities. This does not apply to authorship or copyrights in peer-reviewed articles and publications.

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|--|---|---|
|  ADMINISTRATIVE POLICY MANUAL | THE CHILDREN'S HOSPITAL OF PHILADELPHIA | No. A-3-1 |
| | Title: CONFLICTS OF INTEREST | Page 6 of 24 Effective Date: 7/01/2019 |

4. Fiduciary Role

Serving as a member of the governing board of an entity, including serving on its board of directors, or holding a position of authority or responsibility to act in the best interest of the entity, including being an officer, manager, partner, or member (this does not include working on a scientific advisory board). However:


- a. Members of Senior Management may be permitted to serve on the Board of a for-profit company in the healthcare industry, or with which the Hospital has a relationship or potential relationship such as a vendor or research sponsor, or whose business otherwise has the potential to create an actual or perceived conflict of interest with regard to CHOP's interests or the individual's duties to CHOP, only with advance review and approval by (i) the Board of Trustees, for the CEO, and (ii) the Board Audit, Compliance, and Risk Committee for all others in Senior Management following review and recommendation by the COI Executive Steering Committee.
- b. Members of the Medical Staff and Scientists are generally discouraged from serving in a fiduciary role for an outside for-profit company, but may be permitted to do so on a case-by-case basis only upon advance review and approval by the Conflict of Interest Committee. Examples of factors that may be considered in determining whether to permit such service are whether the person's role in the company serves an important institutional interest of the Hospital, the duration of the service, the time commitment involved, and the degree of actual conflict with the person's institutional role. If such service is permitted, a written conflict management plan subject to monitoring will be required.
- c. See Section IV.C regarding fiduciary roles in companies on the Significant External Relationships List.

F. The following are examples of circumstances that may give rise to conflicts of interests and are generally prohibited.

1. Gifts or Favors

Accepting a gift or favor from the following:

- a. Hospital vendors. See [Interactions with Vendors policy](#).
- b. Companies or other entities with which the Hospital has or may have a sponsored research or licensing relationship in which the person will or may be involved. Exceptions to this prohibition may be granted with advance written approval by the Vice President of Research Administration and Operations or their designee.

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|--|---|---|
|  ADMINISTRATIVE POLICY MANUAL | THE CHILDREN'S HOSPITAL OF PHILADELPHIA | No. A-3-1 |
| | Title: CONFLICTS OF INTEREST | Page 7 of 24 Effective Date: 7/01/2019 |

2. Hospital Information

Obtaining, disclosing, or using Hospital information:

- a. For direct or indirect personal interest, profit, or advantage of Hospital Personnel.
- b. For any purpose that may be detrimental to the Hospital.
- c. Without authorization.

See also [Confidentiality or Patient and Institutional Information policy](#) and [Insider Trading policy](#).


3. Soliciting Hospital Employees, Medical Staff, or Scientists, and Others

- a. Soliciting or assisting others in soliciting Hospital employees, members of the Hospital's Medical Staff, or Scientists, to:
 - i. Cease or limit their relationship with the Hospital.
 - ii. Compete with the Hospital, or to enter into an employment or other contractual relationship with a person or entity that competes with the Hospital.
 - a) Soliciting Hospital Personnel for the benefit of competitors may be permitted only with the advance written permission of the CEO or their designee. Additionally, residents and fellows may be solicited when done in the best interests of the Hospital by the Hospital Graduate Medical Education Committee (or persons authorized by the Committee).
- b. Soliciting or assisting others to solicit patients to seek services from a person or entity that competes or seeks to compete with the Hospital, except that a clinician may recommend a clinician or other provider for his or her patient when asked for a recommendation by the patient, the patient's family, or another clinician caring for the patient and when in the best interest of the patient to do so.

4. Diversion of Corporate Opportunity

Appropriating or diverting for personal advantage a business or financial opportunity with knowledge that the Hospital is pursuing, intending to pursue, or would have an interest in pursuing it if the Hospital were aware of the opportunity.

- G. Conflicts of commitment arise when outside activities and interests interfere with the performance of Hospital duties. Generally, outside activities such as consulting services should be performed on days and at times when Hospital Personnel are not engaged in Hospital activities (e.g., vacation,

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|  ADMINISTRATIVE POLICY MANUAL | THE CHILDREN'S HOSPITAL OF PHILADELPHIA | No. A-3-1 |
| | Title: CONFLICTS OF INTEREST | Page 8 of 24 Effective Date: 7/01/2019 |

nights and weekends when not scheduled to work). Faculty of the University of Pennsylvania may be subject to additional limitations.

- H. Startup and spin-off companies in which the Hospital has a financial interest raise special conflict of interest concerns. As to such companies: the Hospital seeks to conduct its transactions with such companies at arm's length and following appropriate processes designed to address potential conflicts of interest; the roles of CHOP employees who are founders or have other relationships to the companies are subject to scrutiny, conflict management plans, and monitoring as appropriate; and the Hospital takes other steps as appropriate to ensure that the interests of the institution are placed above the interests of any individuals or the company.


IV. SPECIAL PRINCIPLES FOR HOSPITAL PERSONNEL REGARDING COMPANIES WITH WHICH THE HOSPITAL HAS A SIGNIFICANT EXTERNAL RELATIONSHIP

Consistent with the Hospital's mission and in recognition of the fact that collaboration with industry may be important to advance our goals, the Hospital may form significant financial connections through investment or other means with for-profit companies (e.g., acquiring a controlling or very substantial interest in a company).

The intent of this Section IV is to develop a process to identify those situations in which a company's significant relationship with the Hospital makes it prudent to adopt the special principles outlined below in order to avoid actual or perceived conflicts of interest and protect the Hospital, in addition to the conflicts of interest principles that apply generally under this Policy. This section is generally intended to apply to those situations that create particular potential conflicts of interest concerns beyond, for example, routine sponsored research, licensing, or other business arrangements.

A. Designation of Companies on the Significant External Relationships List

1. A Significant External Relationship with a for-profit company may exist if the company is one in or with which the Hospital has a significant (i) investment (not as part of the Foundation's normal investment process), (ii) equity stake, (iii) formal collaboration arrangement, (iv) intellectual property licensing arrangement, or (v) other comparable significant financial relationship. The company may be a startup, spin-off, or any other for-profit company, whether publicly or privately held.
2. The determination of whether a Significant External Relationship exists is to be made on a case-by-case basis and with the approval of the Board or a designated Board Committee after consideration of all facts and circumstances. Some factors that might be considered, by way of example only, include: for investments, the magnitude of the Hospital's investment in relation to the Hospital's total assets or the percentage of equity ownership in the company, whether


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|  ADMINISTRATIVE POLICY MANUAL | THE CHILDREN'S HOSPITAL OF PHILADELPHIA | No. A-3-1 |
| | Title: CONFLICTS OF INTEREST | Page 9 of 24 Effective Date: 7/01/2019 |

the company is publicly traded or privately held, and whether there are other relationships (such as licensing of IP or sponsored research) between the company and the Hospital; and for licensing arrangements, whether the company is a new startup company or a large established publicly-held company with a significant IP portfolio, and the magnitude of expected return on the licensed IP.

3. The list will be maintained and made available to all Hospital Personnel by the Conflict of Interest Office.
4. The Conflict of Interest Office will communicate to Hospital Personnel when a new company is added to the Significant External Relationships List. Individuals covered by this policy should promptly advise the Conflict of Interest Office of any current interests or activities they have that would be inconsistent with the Policy as the result of the company's addition to the list. The Conflict of Interest Office will determine, with the advice of the CEO, the Board Audit, Compliance, and Risk Committee, or the Conflict of Interest Committee, as appropriate, how to address the situation, including the time period in which the particular Hospital Personnel will be required to terminate the interest or activity.

B. Investments and ownership interests of Hospital Personnel

1. Hospital voting Trustees and members of Senior Management are not permitted to invest or otherwise hold an ownership interest in, or have other significant financial relationships with (e.g., a loan), any company on the Significant External Relationships List. Investments and other transactions that an individual Trustee or member of Senior Management are not permitted to make directly cannot be made indirectly, such as through a family member, or through an entity that the Trustee or member of Senior Management controls. Investments through other entities will be evaluated on a case-by-case basis and subject to advance review by the Board Audit, Compliance, and Risk Committee. In exceptional circumstances, exceptions to the provisions of this paragraph may be considered and granted by the Board Audit, Compliance, and Risk Committee.
2. Employees in the Office of General Counsel, Office of Compliance and Privacy, Office of Technology Transfer, Office of Collaborative and Corporate Research Contracts, Office of Entrepreneurship and Innovation, and any other departments as may be designated by the CEO or their designee, are not permitted to invest or otherwise hold an ownership interest in a company on the Significant External Relationships List. This prohibition applies to investments by the employee's spouse, domestic partner, and any other family member whose investments they control.


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|--|---|--|
|  ADMINISTRATIVE POLICY MANUAL | THE CHILDREN'S HOSPITAL OF PHILADELPHIA | No. A-3-1 |
| | Title: CONFLICTS OF INTEREST | Page 10 of 24 Effective Date: 7/01/2019 |

3. All other Hospital Personnel are not permitted to invest or hold an ownership interest in a company on the Significant External Relationships List without prior written approval by the Conflict of Interest Committee, with further review by the Conflict of Interest Executive Steering Committee as deemed appropriate. Advance approval is also required for investments by the employee's spouse, domestic partner, and any other family member whose investments they control.
4. The provisions of this Section IV.B do not apply to investment vehicles, such as mutual funds and retirement accounts, as long as the person does not directly control the investment decisions made in these vehicles.

Note that the provisions above are in addition to requirements in the [Insider Trading Policy](#).


C. Fiduciary roles

1. Hospital voting Trustees and members of Senior Management may be permitted to serve on the Board of a company on the Significant External Relationships List, but only (i) as a Hospital designee, (ii) without any personal compensation, and (iii) with advance review and approval by the Board of Trustees for Trustees and the CEO, and by the CEO and the Board of Trustees or the Board Audit, Compliance, and Risk Committee for others in Senior Management. The determination of whether to permit such service will be made on a case-by-case basis considering whether it is the best interest of the Hospital and including consideration of any limitations on the duration of the service, and if approved, will be subject to an appropriate conflict management plan and monitoring.
2. Members of Senior Management are generally prohibited from serving in an officer or executive role in a company on the Significant External Relationships List. In exceptional circumstances, such service may be permitted, but only (i) as a Hospital designee, (ii) without any personal compensation, and (iii) with advance review and approval by the Board Audit, Compliance, and Risk Committee. Periodic monitoring may be required as appropriate to ensure conflicting loyalties and confidentiality requirements are being appropriately managed.
3. Members of the Medical Staff and Scientists, and all other Hospital Personnel not covered by C.1 and 2 above, are generally only permitted to serve in a fiduciary role for a company on the Significant External Relationships List as a Hospital designee and without personal compensation, unless an exception is permitted with prior approval of an Executive Vice President or Department Chair, and the CEO or the CEO's designee.

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|  ADMINISTRATIVE POLICY MANUAL | THE CHILDREN'S HOSPITAL OF PHILADELPHIA | No. A-3-1 |
| | Title: <p style="text-align: center;">CONFLICTS OF INTEREST</p> | Page 11 of 24 Effective Date: 7/01/2019 |

V. ANNUAL DISCLOSURES

- A. The following persons are required to disclose on an annual basis:
1. All Hospital Personnel whose role is that of manager or above.
 2. All members of the Medical Staff who are Hospital Staff.
 3. All Advanced Practice Providers.
 4. All Hospital employees in the Investment Department, the Office of Technology Transfer, the Office of Collaborative and Corporate Research Contracts, and the Office of Entrepreneurship and Innovation.
 5. All Hospital employees who are known to select or place orders with vendors (other than persons involved with only *de minimis* purchases such as an administrative assistant who orders small quantities of office supplies from the Hospital vendor for office supplies).
 6. Scientists.
 7. Any other person designated by management.
 8. Individual Hospital Personnel may be exempted from the annual disclosure requirement based on a determination that disclosure is not necessary to protect the interests of the Hospital.
- B. The required disclosers must disclose information about outside activities, outside interests, gifts, memberships, management roles in entities other than the Hospital, rights and interests related to intellectual property, and any other information deemed necessary to implement the provisions of this Policy.
- C. The required disclosers may be required to update their disclosures to reflect new rights, interests, activities, and relationships as required by this Policy or otherwise at the discretion of the CEO or their designee.
- D. Disclosures are reviewed by the appropriate Hospital Personnel responsible for implementing this Policy. Necessary actions will be taken to manage, reduce, or eliminate conflicts of interest and to comply with other Hospital policies and procedures, regulations, and any other applicable authority.

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|  ADMINISTRATIVE POLICY MANUAL | THE CHILDREN'S HOSPITAL OF PHILADELPHIA | No. A-3-1 |
| | Title: CONFLICTS OF INTEREST | Page 12 of 24 Effective Date: 7/01/2019 |

- E. Hospital Personnel are strongly encouraged to disclose at any time a matter that may raise a potential conflict of interest and seek guidance or review.
- F. Trustees are required to disclose on an annual basis such information as is required to determine whether they have any actual, potential, or perceived conflicts of interest. The annual disclosures of the Trustees, Officers, and members of Senior Management are reviewed by the Boards of Trustees or their designees. Any substantial personal or business interests of Trustees that conflict with the interests of the Hospital are prohibited (and see Section IV for special principles regarding Trustees and companies on the Significant External Relationships List).

VI. FINANCIAL CONFLICTS OF INTEREST IN RESEARCH

A. Applicability

This Section applies to all proposed and on-going PHS-funded research, human subjects research, and any other research under the auspices of the Hospital that may be designated as subject to these requirements.

B. Financial Conflict of Interest ("FCOI") Determination Pathway


Below is a summary of the process that will be used to determine if an FCOI is present, as more fully described in the remainder of Section VI below.

1. Is the interest a Reviewable Interest (see Section VI.D.1.)? If yes: ↓
2. Is the Reviewable Interest related to the research (see Section VI.D.2.)? If yes: ↓
3. Could the Reviewable Interest directly and significantly affect the design, conduct, or reporting of the research (see Section VI.E.2.)? If yes: ↓
4. An FCOI is present and must be managed (and, where appropriate, reported).

C. Investigator Disclosure to Hospital

1. Project-Specific Disclosure

In addition to the annual disclosure requirement (see Section V above), Investigators must submit a separate disclosure at the time of application for research funding and/or application to the IRB for approval of research. All Investigators must confirm that their current annual disclosure on file with the Hospital is correct and complete, or provide updated information when warranted, as well as provide any additional information required by the Hospital regarding financial interests related to the Investigator's Institutional Responsibilities.

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|--|---|--|
|  ADMINISTRATIVE POLICY MANUAL | THE CHILDREN'S HOSPITAL OF PHILADELPHIA | No. A-3-1 |
| | Title: CONFLICTS OF INTEREST | Page 13 of 24 Effective Date: 7/01/2019 |

2. Travel

As part of the annual and project-specific disclosures, Investigators must disclose to the Hospital any travel related to their Institutional Responsibilities that is reimbursed or sponsored other than by the Hospital or an Exempt Entity (“Travel”). Such disclosures must include, at a minimum, the following information: (a) the purpose of the trip; (b) the identity of the sponsor/organizer of the trip; (c) the destination of the trip; and (d) the duration of the trip. The Hospital maintains procedures prescribing the details of Travel disclosures, including the timing and when additional information is necessary to determine whether Travel constitutes an FCOI pursuant to Section VI.E below. Investigators must provide in a timely manner any additional information requested by the Hospital that is related to their Travel.

3. Disclosure Update

Investigators are required to update the Hospital within thirty (30) days in the event that they discover or acquire a new interest that would be disclosable to the Hospital if it had been known at the time of the annual or project-specific disclosure.

D. Hospital Review of Disclosures and Relatedness Determination

1. Reviewable Interests


The Hospital is responsible for reviewing any disclosures of (i) Investigator Travel or (ii) Significant Financial Interests belonging to an Investigator, the Investigator’s spouse, or the Investigator’s dependent children, to the extent either reasonably appear to relate to the Investigator’s Institutional Responsibilities ((i) and (ii) collectively, “Reviewable Interests”). The Hospital may, in its discretion, identify through procedures or other guidance documents additional interests that qualify as Reviewable Interests.

2. Relatedness Determination

Each Reviewable Interest will be evaluated to determine whether it relates to the Investigator’s research. A Reviewable Interest will be found to relate to the Investigator’s research when it is reasonably determined that the Reviewable Interest could be affected by the research, or is in an entity whose financial interest could be affected by the research. The Investigator may be asked to provide information to assist in the assessment of whether a Reviewable Interest is related to the Investigator’s research.

3. Timing of Review

a. Initial Reviewable Interests

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|--|---|--|
|  ADMINISTRATIVE POLICY MANUAL | THE CHILDREN'S HOSPITAL OF PHILADELPHIA | No. A-3-1 |
| | Title: CONFLICTS OF INTEREST | Page 14 of 24 Effective Date: 7/01/2019 |

For PHS-funded research, Reviewable Interests disclosed at the time of the funding and/or protocol application will be evaluated prior to the expenditure of funds. For all other research subject to this Policy, Reviewable Interests disclosed at the time of the funding and/or protocol application will be evaluated prior to the initiation of the research activities.

b. Updated Reviewable Interests

To the extent a new Reviewable Interest is disclosed to the Hospital in the course of an on-going research project (i.e., an Investigator who is new to participating in the research discloses a Reviewable Interest or an existing Investigator discloses a new Reviewable Interest), the Hospital will, within a reasonable period of time that for PHS-funded research will not exceed sixty (60) days from the date of the disclosure: (i) determine if the Reviewable Interest relates to the Investigator's research; (ii) if it relates, determine if it qualifies as an FCOI (pursuant to Section VI.E below); and (iii) if it is an FCOI, implement on at least an interim basis a management plan in accordance with Section VI.F below. The Hospital may, depending on the circumstances, conclude that additional interim measures are necessary with regard to the Investigator's participation in the research between the date of disclosure and the completion of the Hospital's review.

E. Hospital Determination of FCOI

1. Evaluation of Related Reviewable Interests

The Hospital will evaluate each Reviewable Interest that is found to relate to an Investigator's research to make a reasonable determination whether an FCOI exists.

2. FCOI Standard

An FCOI will be found to exist when a Reviewable Interest related to the Investigator's research could directly and significantly affect the design, conduct, or reporting of the research.

3. FCOI Process and Criteria


The Hospital maintains a process and criteria for making FCOI determinations. The process and criteria applied will be subject to on-going evaluation and revision as appropriate.

4. Reporting FCOIs in PHS-Funded Research

If the research is PHS-funded, the identified FCOI must be reported to the relevant awarding agency in accordance with Section VI.H of this Policy.


F. Management of FCOI

1. Management of FCOI

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|--|---|--|
|  ADMINISTRATIVE POLICY MANUAL | THE CHILDREN'S HOSPITAL OF PHILADELPHIA | No. A-3-1 |
| | Title: CONFLICTS OF INTEREST | Page 15 of 24 Effective Date: 7/01/2019 |

For any identified FCOI, the Hospital will take appropriate action to manage the conflict in order to reduce the potential for it to compromise the safety or validity of the research. Research in which an Investigator is found to have an FCOI will not be permitted to proceed until the Investigator has agreed to implement an acceptable management plan. The appropriate techniques identified by the Hospital to manage an identified FCOI will be outlined in a written management plan. Examples of conditions or restrictions that might be imposed to manage an FCOI include, but are not limited to:

- a. Public disclosure of the FCOI (e.g., when presenting or publishing the research).
 - b. For research involving human subjects, disclosure of the FCOI directly to participants.
 - c. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI.
 - d. Modification of the research plan.
 - e. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research.
 - f. Reduction or elimination of the financial interest (e.g., sale of an equity interest).
 - g. Severance of relationships that create FCOI.
2. Disclosure for PHS-Funded Drug/Device Research
 In any case in which the U.S. Department of Health and Human Services determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with an FCOI that was not managed or reported by the Hospital, the Investigator will be required to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.
3. Management of Other Interests
 When a disclosed interest is not a Reviewable Interest or a Reviewable Interest is determined not to constitute an FCOI, the Hospital may nonetheless determine that some type of management or oversight of the interest is appropriate before certain research activities may proceed. The Hospital may develop additional procedures and/or guidance regarding these types of interests and any associated limitations or requirements.
4. Compliance with Management Plans
 Investigators have an on-going obligation to adhere to an imposed management plan and failure to do so may be grounds for sanctions under this Policy.
- G. Retrospective Reviews; Mitigation Reports
1. Identification of Reviewable Interests Not Timely Disclosed or Reviewed

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|--|---|--|
|  ADMINISTRATIVE POLICY MANUAL | THE CHILDREN'S HOSPITAL OF PHILADELPHIA | No. A-3-1 |
| | Title: CONFLICTS OF INTEREST | Page 16 of 24 Effective Date: 7/01/2019 |

In the event the Hospital identifies a Reviewable Interest that was not disclosed in a timely manner by an Investigator or, for whatever reason, was not previously reviewed by the Hospital in accordance with this Policy during an on-going research project (e.g., was not timely reviewed or reported by a subrecipient), the Hospital will, within a reasonable time period that for PHS-funded research will be within sixty (60) days of identifying such a Reviewable Interest: (i) determine if the Reviewable Interest relates to the Investigator's research; (ii) if it relates, determine if it qualifies as an FCOI; and (iii) if it is an FCOI, implement on at least an interim basis a management plan in accordance with Section VI.F of this Policy to manage the FCOI going forward. Depending on the nature of the FCOI, if a retrospective review for bias is required pursuant to Section VI.G.2 below, the Hospital may determine that additional interim measures are necessary with regard to the Investigator's participation in the research between the date that the FCOI is determined and the completion of the Hospital's retrospective review. For PHS-funded research, the identified FCOI must be reported to the relevant awarding agency in accordance with Section VI.H of this Policy.


2. Retrospective Review for Bias

There may be times when an FCOI is not identified or managed in a timely manner, including: failure by the Investigator to disclose a Reviewable Interest that is determined by the Hospital to constitute an FCOI; failure by the Hospital to review or manage such an FCOI; or failure by the Investigator to comply with an FCOI management plan. In the event such noncompliance is identified, the Hospital will, within a reasonable time period that for PHS-funded research will be within 120 days of the Hospital's determination of noncompliance, complete a retrospective review of the Investigator's activities and the research to determine whether there was any bias in the design, conduct or reporting of the research or any portion thereof during the time period of the noncompliance. The Hospital maintains written procedures regarding the conduct and documentation of the retrospective review, as well as notification of the relevant awarding agency as appropriate, within any applicable required timeframes. Any FCOI report submitted with respect to such research (see Section VI.H.2. below) will be updated as necessary in light of the results of the retrospective review.

3. Documentation of Retrospective Review

For PHS-funded research, the Hospital will document at least the following information regarding any retrospective review:

- a. Project number.
- b. Project title.
- c. Project director (PD)/principal investigator (PI) or contact PD/PI if a multiple PD/PI model is used.
- d. Name of the Investigator with the FCOI.
- e. Name of the entity with which the Investigator has the FCOI.

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|--|---|--|
|  ADMINISTRATIVE POLICY MANUAL | THE CHILDREN'S HOSPITAL OF PHILADELPHIA | No. A-3-1 |
| | Title: CONFLICTS OF INTEREST | Page 17 of 24 Effective Date: 7/01/2019 |

- f. Reason(s) for the retrospective review.
- g. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed).
- h. Findings of the review.
- i. Conclusions of the review.

4. Notification of Awarding Agency; Mitigation Report

If bias is found in the design, conduct or reporting of PHS-funded research during the period of noncompliance, the Hospital will promptly notify the relevant PHS awarding agency and will submit a mitigation report, which will include at least the elements documented in the retrospective review (see Section VI.G.3 above) and a description of the impact of the bias on the research project and the Hospital's plan or action of actions taken to eliminate or mitigate the effect of the bias.

H. Hospital Notification and Reporting to PHS Awarding Agencies

1. PHS Notification

For PHS-funded research, the Hospital will provide all required notifications and reports to the relevant PHS awarding agency, in accordance with applicable regulations and this Policy.


2. FCOI Reports

The Hospital will report any identified FCOI that is related to PHS-funded research to the relevant PHS awarding agency, whether identified in advance of commencing a PHS-funded research project (an "Initial FCOI Report") or in the course of an on-going PHS-funded research project as a result of new FCOI information ("Updated FCOI Report"). For any identified FCOI related to on-going PHS-funded research that was previously reported in an Initial FCOI Report, the Hospital will provide an annual FCOI report that addresses the status of the FCOI (including any changes in the value of the previously reported interest) and any changes to the management plan ("Annual FCOI Report"). Such Annual FCOI Reports will be provided for the duration of the PHS-funded research.

3. Timing of FCOI Reports

The Hospital will provide required FCOI reports in accordance with the following timeframes:

- a. Initial FCOI Reports: prior to the expenditure of funds.
- b. Updated FCOI Reports: within sixty (60) days of identification of a new FCOI pursuant to Section VI.D.3.b of this Policy (whether due to a new Investigator or a new FCOI disclosed by an existing Investigator) or identification of an FCOI that was not timely disclosed or managed pursuant to Section VI.G.2.

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|--|---|--|
|  ADMINISTRATIVE POLICY MANUAL | THE CHILDREN'S HOSPITAL OF PHILADELPHIA | No. A-3-1 |
| | Title: CONFLICTS OF INTEREST | Page 18 of 24 Effective Date: 7/01/2019 |

- c. Annual FCOI Reports: at least annually, in accordance with the awarding agency's specifications. For NIH-funded research, the Annual FCOI Report is due at the same time as the Hospital is required to submit the annual progress report for a grant, including a multi-year funded progress report if applicable, or at the time of the extension.

4. Content of FCOI Reports


Any FCOI Report shall provide sufficient information to enable the PHS awarding agency to understand the nature and extent of the FCOI and to assess the appropriateness of the Hospital's management plan. Any FCOI Report will include at least the following information:

- a. Project number.
- b. PD/PI or contact PD/PI if a multiple PD/PI model is used.
- c. Name of the Investigator with the FCOI.
- d. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium).
- e. Value of the financial interest, provided in dollar ranges, or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.
- f. A description of how the financial interest relates to the PHS-funded research and the basis for the Hospital's determination that the financial interest conflicts with such research.
- g. A description of the key elements of the Hospital's management plan, including:
 - i. The role and principal duties of the conflicted Investigator in the research.
 - ii. The conditions of the management plan.
 - iii. How the management plan is designed to safeguard objectivity in the research.
 - iv. Confirmation of the Investigator's agreement to the management plan.
 - v. How the management plan will be monitored to ensure Investigator compliance.
 - vi. Any other information the Hospital deems necessary to meet its obligations under applicable regulations and this Policy.

5. Additional Notifications

In addition to the required FCOI reports, the Hospital will promptly notify the relevant PHS awarding agency in the event that it finds that an Investigator's failure to comply with this Policy or an imposed management plan has biased the design, conduct, or reporting of PHS-funded research (such notification will include the corrective action taken or to be taken in response to the identified Investigator non-compliance).

I. Requirements for Subrecipients of PHS-Funded research

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|--|---|--|
|  ADMINISTRATIVE POLICY MANUAL | THE CHILDREN'S HOSPITAL OF PHILADELPHIA | No. A-3-1 |
| | Title: CONFLICTS OF INTEREST | Page 19 of 24 Effective Date: 7/01/2019 |

The Hospital may from time to time carry out aspects of PHS-funded research through a subrecipient with which the Hospital contracts through a subaward agreement or other similar contract to provide research funding. The Hospital will grant such subawards where the subrecipient has its own policy on FCOIs and certifies, through the subaward agreement or other contract, that the policy complies with applicable PHS regulations. In rare circumstances, the Hospital will make an exception and allow the subrecipient to apply the Hospital's policy as its own for the purposes of the subaward. The subaward agreement or other contract will specify the time period(s) for the subrecipient to report all identified FCOIs to the Hospital, which will be sufficient to allow the Hospital to provide timely reports to the PHS funding agency as applicable and in accordance with this Policy.

J. Public Access

For any PHS-funded study, any person may request certain information regarding the FCOIs of Senior/Key Personnel following the process established by the Hospital and published on its web site. The Hospital will provide, within five (5) business days of the receipt of a request (as defined by the Hospital), the following information about a Senior/Key Personnel who continues to hold an identified FCOI:


1. The Investigator's name.
2. The Investigator's title and role with respect to the research project out of which the FCOI arises.
3. The name of the entity in which there is a Significant Financial Interest that forms the basis of the FCOI.
4. The nature of the Significant Financial Interest (or Travel, if applicable).
5. The approximate value of the Significant Financial interest provided in dollar ranges, or a statement that the interest is one whose value cannot readily be determined through reference to public prices or other reasonable measures of fair market value.

K. Training

1. Content of Training

All Scientists and Investigators must complete training on:

- a. The PHS regulations applicable to FCOIs, as may be amended from time to time.
- b. The portions of this Policy governing conflicts of interest in research.

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|  ADMINISTRATIVE POLICY MANUAL | THE CHILDREN'S HOSPITAL OF PHILADELPHIA | No. A-3-1 |
| | Title: CONFLICTS OF INTEREST | Page 20 of 24 Effective Date: 7/01/2019 |

- c. Their obligations regarding disclosure to the Hospital of interests related to their Institutional Responsibilities.

2. Timing of Training


Scientists and Investigators must complete this training prior to engaging in research under the auspices of the Hospital, or as otherwise required by a relevant awarding agency, and at least every four years following the initial training. Additionally, Scientists and Investigators will be required to receive training immediately in any of the following circumstances:

- a. The Hospital revises the portion of its policy governing conflicts of interest in research or procedures in any manner that affects the requirements applicable to Scientists or Investigators.
- b. A Scientist or Investigator is new to the Hospital.
- c. The Hospital finds that a Scientist or Investigator is not in compliance with the portion of the Hospital's policy governing conflicts of interest in research or an imposed management plan.

VII. CONSULTING RELATIONSHIPS

A. General Principles

1. Examples of consulting relationships and other outside activities (referred to collectively as "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 a company in connection with its research or products.
2. Consulting relationships have the potential to increase the knowledge and experience of Hospital Personnel in clinical and research areas, to broaden their exposure to external experts in their fields or related fields, and to advance the public interest. Nevertheless, consulting relationships also have the potential to conflict with the obligations that 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).
3. Consulting relationships may raise other legal and ethical concerns such as:
 - a. Jeopardizing Hospital intellectual property rights.


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|  ADMINISTRATIVE POLICY MANUAL | THE CHILDREN'S HOSPITAL OF PHILADELPHIA | No. A-3-1 |
| | Title: CONFLICTS OF INTEREST | Page 21 of 24 Effective Date: 7/01/2019 |

- b. Misuse of the Hospital's name in a manner that suggests Hospital endorsement of a product or entity.
- c. Excessive compensation that may be considered an illegal kickback or referral fee.
- d. Interference with confidentiality obligations to the Hospital, patients, and research subjects.
- e. Restrictions or obligations that interfere with the consultant's Hospital and academic duties.
- f. Inappropriate use of Hospital resources.
- g. Acting as a member of a speaker's bureau not in accordance with Hospital policy. See [Interactions with Vendors policy](#) (A-3-7) and guidance from the University of Pennsylvania School of Medicine for faculty.

B. Advance review and approval

1. Any Hospital Personnel may seek review of a consulting relationship on a voluntary basis and those in a clinical role are strongly encouraged to do so. The following persons must have their consulting relationships reviewed and approved in advance:
 - a. Hospital Staff (as defined in the Hospital's Medical Staff Bylaws)
 - b. Scientists
 - c. Advanced Practice Providers
 - d. 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. (Faculty members at the University of Pennsylvania who hold privileges at the Hospital but do not perform any duties under the auspices of the Hospital do not have to submit consulting relationship to the Hospital for review.)

2. Consulting relationships subject to advance review and approval are any arrangements to provide services to an outside person or entity when such services are related to the consultant's Institutional Responsibilities, except:
 - a. Advising or consulting for non-governmental public health organizations such as the World Health Organization.
 - b. Service on or for federal, state, and local government agencies, boards, commissions, committees, review panels, or granting agency review panels unless administered by a for-profit government contractor.
 - c. Seminars, lectures, teaching engagements, and service on advisory committees and review panels for Exempt Entities.
 - d. IRB memberships at outside institutions of higher learning and academic medical centers.
 - e. Editorial boards for peer-reviewed journals.

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|--|---|--|
|  ADMINISTRATIVE POLICY MANUAL | THE CHILDREN'S HOSPITAL OF PHILADELPHIA | No. A-3-1 |
| | Title: CONFLICTS OF INTEREST | Page 22 of 24 Effective Date: 7/01/2019 |


- f. Service as an expert witness in any litigation in which neither the Hospital nor its affiliates is a party.
- g. Any other arrangements as may be determined by the Hospital to not require advance review and approval.

Note that consulting relationships with foreign (non-U.S.) government agencies (which include local, provincial, or equivalent governments of another country), and foreign (non-U.S) institutions of higher education, academic teaching hospitals, medical centers, boards, commissions, committees, review panels, granting agencies, or research institutes affiliated with an institution of higher education are not excepted from the requirement for advance review and approval.

- 3. All consulting relationships requiring advance review and approval must be set forth in a written agreement.
- 4. All proposed consulting agreements are reviewed and approved in advance in accordance with the procedures established by the Hospital's Office of General Counsel, Office of Collaborative and Corporate Research Contracts, and Conflict of Interest Office. Such review is intended to avoid conflicts of interest and protect the Hospital.

VIII. 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 CEO or their 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 Board Audit, Compliance, and Risk 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 CEO or their designee, at such frequency and according to such criteria as determined by the CEO or their designee, by the following offices:

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|--|---|--|
|  ADMINISTRATIVE POLICY MANUAL | THE CHILDREN'S HOSPITAL OF PHILADELPHIA | No. A-3-1 |
| | Title: CONFLICTS OF INTEREST | Page 23 of 24 Effective Date: 7/01/2019 |

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.
- 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 Board Audit, Compliance, and Risk 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 CEO 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.

IX. ENFORCEMENT AND SANCTIONS

- A. The Hospital has the authority to require appropriate management and oversight of matters disclosed or reviewed in accordance with this Policy. Management may include the reduction or elimination of any interest or participation in an activity.
- B. The Hospital will monitor compliance with management and oversight requirements in such manner as deemed appropriate. The Hospital will investigate and take corrective action as necessary.
- C. Any Hospital Personnel who violates any provision of this Policy, or any conditions imposed pursuant to 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 actions at the Hospital's discretion.

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|  ADMINISTRATIVE POLICY MANUAL | THE CHILDREN'S HOSPITAL OF PHILADELPHIA | No. A-3-1 |
| | Title: CONFLICTS OF INTEREST | Page 24 of 24 Effective Date: 7/01/2019 |

RESPONSIBILITY FOR MAINTENANCE OF THIS POLICY:

GENERAL COUNSEL

RESPONSIBILITY FOR OVERSIGHT AND REVIEW:

CHIEF EXECUTIVE OFFICER
BOARD AUDIT, COMPLIANCE, AND RISK COMMITTEE
CHIEF COMPLIANCE OFFICER

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| Supersedes 6/24/2013 | Approved by: Signature: _____ Madeline Bell, President and Chief Executive Officer |
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