

Governance Policy No. 1

POLICY SUBJECT:

Conflicts of Interest

EFFECTIVE DATE: 09/17/14

*To be reviewed every three years by
the Board of Stewardship Trustees*

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POLICY

It is the policy¹ of Catholic Health Initiatives (CHI or CHI National) its Direct Affiliates² and Subsidiaries³ (collectively referred to as CHI or CHI Entity(ies)) that:

- Each Person (as defined below) acts at all times in a manner that is consistent with CHI's charitable purpose of service to the community and exercises care that he or she does not act in a manner that places the Person's private interests over CHI's community benefit purposes;
- Each Person avoids any perceived, potential or actual conflicts of interest (sometimes COI). If such conflicts of interest cannot be avoided, the conflict will be managed in the best interests of CHI and its community benefit purposes; and
- Each perceived, potential or actual conflict of interest shall be reported, reviewed and managed in accordance with the provisions of this Policy.

PURPOSE STATEMENT

The purpose of this Policy is to protect the interests of CHI in circumstances that may result in a conflict between personal interests of a Person and those of CHI and its patient, resident, and client population.

This Policy describes the procedures for disclosures of conflicts of interest and for subsequent review and management of possible conflicts of interest. These procedures focus on three specific aims:

- Identify actual, potential or perceived conflicts of interest related to Employees, board and committee members, health care providers and researchers who are affiliated with CHI or any CHI Entity, and eliminate, reduce or manage such conflicts.
- Maintain the integrity of all CHI activities.

¹ This Policy replaces, Governance Policy No. 1, *Conflicts of Interest: Stewardship Trustees* and Governance Policy No. 8, *Conflict of Interest: Employees* and their respective disclosure statements. It also replaces any similar conflict of interest policy currently in place at any CHI Entity.

² A Direct Affiliate is any corporation of which CHI is the sole corporate member or sole shareholder.

³ A Subsidiary means either an organization, whether non-profit or for-profit, in which a Direct Affiliate holds the power to appoint a majority of the voting members of the governing body of such organization or any organization in which a Subsidiary holds such power.

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- Ensure compliance with federal and state laws and regulations related to dealings between CHI Employees or affiliated individuals and other entities or individuals.

SCOPE

This Policy applies to the following Persons:

- The CHI Board of Stewardship Trustees (BOST) and members of its committees;
- All board and board committee members of CHI Entities;
- All CHI Employees;
- All CHI physicians (both employed and non-employed) and all physician administrators and leaders;
- Advanced practice clinicians (both employed and non-employed);
- All CHI research personnel (both employed and non-employed).

This Policy is intended to supplement, but not replace, any state laws governing conflicts of interest applicable to non-profit corporations. This Policy also supplements, but does not replace, CHI's *Our Values and Ethics at Work Reference Guide*.

If a Person has a perceived, potential or actual conflict with CHI or any CHI Entity, such Person is deemed to also have such conflict with respect to CHI and all CHI Entities.

Through the powers and rights granted to the CHI BOST via the Governance Matrix, this Policy is considered to be adopted by all CHI affiliate boards once it is adopted by the CHI BOST.

DEFINITIONS

Board and board committee member means any Person who is a member of a CHI National or CHI Entity board having fiduciary duties or responsibilities or a committee of such a board.

Conflicts of interest exist when the personal interests of a Person (as defined above) or a Person's family members or a Person's business may affect the ability of the Person to act in the best interest

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of, and with good faith and loyalty to, CHI, its mission, patients, residents, clients or research participants. A conflict of interest can be considered to exist in any instance where the Person's decisions, actions or activities on behalf of CHI also involve:

- Obtaining a direct or indirect personal gain or advantage, whether in the form of compensation, cash gifts or other items of value, or
- Creating an adverse or potentially adverse effect on CHI's interests.

Conflict of interest transaction is one in which CHI National or a CHI Entity is a party and in which a Person has a direct or indirect financial interest or other fiduciary duty such that it could influence his or her actions on the matter while acting on behalf of CHI.

Corporate opportunity is a business opportunity that: (1) CHI has a reasonable interest in or could be expected to take advantage of; (2) CHI is financially able to undertake; and (3) is in line with CHI's current business and operations.

CHI Conflicts of Interest Review Committee (C-CIRC) is the committee that will review annual COI questionnaires containing disclosures of perceived or possible conflicts of interest for the following Persons: researchers, physicians, advanced practice clinicians, Employees at manager level or above, and Supply Chain Employees.

Employee includes corporate officers, all individuals paid wages or salary by CHI National or a CHI Entity, employed physicians and employed advanced practice clinicians.

Immediate family member includes a Person's relative by blood or marriage, including husband or wife, birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent, or grandchild, and spouse of a grandparent or grandchild.

Material financial interest is an equity interest exceeding 1% of the outside organization's market capitalization or 5% of the Employee's or the immediate family member's personal assets. A material financial interest also exists if the total transactions between a Person and CHI or any CHI Entity exceed \$100,000 annually or if all payments related to a single transaction between CHI or any CHI Entity and a Person exceed the greater of \$10,000 or 1% of the CHI Entity's total revenue. Material financial interest shall not include ownership of stock or other type of equity interest of less than 1% in entities

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whose securities are listed on an established public securities exchange and have \$75 million or more in shareholder equity.

Person includes all individuals who are:

- Employees of CHI or a CHI Entity,
- All CHI or CHI Entity board and board committee members,
- All CHI physicians (both employed and non-employed) and all CHI physician administrators and leaders,
- All advanced practice clinicians (both employed and non-employed), and
- All Researchers (as defined below).

Researchers includes all individuals who are engaged in the conduct of research with living human subjects if they are in: direct physical contact with the research participants, responsible for collection or recording of research data, responsible for administration of research centers, submission of Institutional Review Board (IRB) or grant applications, reporting of research results, or regulatory oversight of research. This includes but is not limited to: principal and sub-investigators, research nurses, coordinators, assistants, research managers and directors, and IRB members and chairs.

Physician Payment Sunshine Act (42 CFR § 402-403) requires applicable manufacturers of drugs, medical devices and biologics along with group purchasing organizations (GPOs) to report certain payments and items of value given to physicians. Manufacturers and GPOs are required to furnish this information to the Centers for Medicare and Medicaid Services (CMS). CMS will collect the information and publish it on a public website.

EXAMPLES OF CONFLICTS OF INTEREST

Although it is impossible to list every circumstance giving rise to conflicts of interest, the following situations serve as a guide to the types of activities that might present perceived, potential or actual conflicts of interest. These should be fully and promptly reported as provided below.

Relationships with Vendors, Competitors or Other Outside Interest Holders

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The personal interests of a Person may conflict with the interests of CHI if the Person or an immediate family member is someone:

- Who does business with, seeks to do business with or is in competition with CHI or any CHI Entity;
- Is a party to an arrangement with CHI or any CHI Entity to solicit bids or contracts for the purchase or supply of goods or services (including consulting and professional services), the lease of property or equipment, or the purchase or sale of real property, investment securities or other property;
- Serves as an officer, director, manager, Employee or consultant of, or receives compensation or remuneration from an individual or entity that competes with or is engaged in a transaction with CHI or any CHI Entity; or
- Holds a material financial interest with an individual or entity or a creditor of an individual or entity that competes with or is engaged in a transaction (described above) with CHI or any CHI Entity.

Diversion of Corporate Opportunity

It may be a conflict of interest when a Person fails to inform CHI of a corporate opportunity and instead diverts it to himself or herself (or an immediate family member) to the detriment of CHI.

Disclosure of Confidential or Inside Information

It is a conflict of interest for a Person to disclose non-public, privileged or confidential information relating to the business of CHI or any CHI Entity or to use such information for personal profit or advantage or that of the Person's immediate family members or any other individual or entity of which the Person is an officer, director, manager or Employee or with which the Person has a compensation arrangement.

Acceptance of Gifts, Gratuities and Entertainment

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It may be a conflict of interest for a Person (or an immediate family member) to accept gifts (including cash or cash equivalents), excessive entertainment, unsecured loans or other favors from any outside individual or entity. This is especially so when the outside individual or entity does, or is seeking to do, business with, or is a competitor of, CHI or any CHI Entity and it might be inferred that such action was intended to influence or possibly influence the Person's decisions, actions or activities. Items of nominal or minor value that are clearly tokens of respect or friendship and not related to any particular transaction or activity of CHI or any CHI Entity are permissible. (Please refer to Corporate Responsibility Policy No. 1, *Gifts and Payments from Business Sources; Employee Arrangements with Business Sources.*)

Other Areas of Conflicting Interest

Other circumstances may arise which could result in a conflict between the personal interests of a Person (or immediate family member) and those of CHI. In general, any circumstance that may give rise to reasonable questions of possible favoritism, self-dealing or undue influence may be a perceived, potential or actual conflict of interest. All such conflicts should be avoided, if possible. Persons should also be sensitive to the appearance of conflict, even if no actual conflict exists. If a potential or actual conflict cannot be avoided, it shall be disclosed according to the procedures set forth below. See specific addenda related to this Policy.

DISCLOSURE, REVIEW AND MANAGEMENT OF PERCEIVED, POTENTIAL, OR ACTUAL CONFLICTS OF INTEREST

All Persons (as defined in the Definitions section above) are subject to this Policy and the General Obligation as described below. However, only those Persons listed in the Annual COI Disclosure Requirement section must complete an annual conflicts of interest disclosure.

General Obligation

Each Person must promptly and fully report to his/her direct manager, supervisor, board or board committee chair any situation or circumstance that may create a conflict of interest. The Person must report the actual or potential conflict as soon as she/he becomes aware of it. In any situation where the

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Person may be in doubt, a full disclosure should be made to permit an impartial and objective determination.

Annual COI Disclosure Requirement

On an annual basis, the following Persons must complete a new conflict of interest disclosure.

- Board and board committee members;
- Employees at the level of manager and above;
- Researchers, as defined in the definition section above;
- All Supply Chain Employees;
- All physicians (both employed and non-employed) and all physician administrators and leaders, and
- All advanced practice clinicians (both employed and non-employed).

Disclosure upon Initial Hiring/Appointment/ Contracting/Credentialing

- **Board and board committee members:** At the time of initial appointment, a copy of this Policy shall be distributed to the board or committee member along with a conflict of interest disclosure. The board or committee member will complete and submit the disclosure. The completed disclosure shall be maintained as provided below.
- **Employees:** At the time of hiring, a copy of this Policy shall be distributed to all Employees. In addition, a conflict of interest disclosure will be provided. The Employee must complete and submit a conflict of interest disclosure. The completed disclosure shall be maintained as provided below.
- **All non-employed, credentialed or contracted physicians, advanced practice clinicians, and physician administrators and leaders:** At the time of contracting or credentialing, a copy of this Policy shall be distributed to such providers. The provider will complete and submit the disclosure. The completed disclosure shall be maintained as provided below.

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Review and Disclosure Process

Disclosure, review and management of perceived, potential or actual conflicts of interest will be accomplished through use of a web-based COI software solution. All disclosures, communications, reviews and conflicts of interest management plans will be stored within the software product in a secure manner in accordance with the CHI Information Technology policies. Access to disclosures and associated documents and data will be restricted to designated officials with specific responsibilities to review or manage conflicts of interest. User names and passwords are required to access any records. A detailed audit trail of access is an integral part of the software product.

Annual COI disclosures that involve no disclosures of financial interests will not be forwarded for review but will remain stored in the software. Disclosures of perceived, potential or actual conflicts of interest on the COI questionnaire involving financial interests will be forwarded to the C-CIRC or Legal Services Group (LSG) for review as defined below.

Review of Disclosures by CHI or CHI Entity Role

Audience	Distribution By	Distribution Time	Disclosure Review	Committee Review of Possible COI
Board Members	CHI Corporate Responsibility Program (CRP)	Upon appointment and annually thereafter	LSG	Executive Committee of the Board
Corporate Officers	CRP	Upon hire and annually as part of the annual performance evaluation (July/August)	LSG	Executive Committee of the Board

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Audience	Distribution By	Distribution Time	Disclosure Review	Committee Review of Possible COI
Employees (management and above plus select groups)	CRP	Upon hire and annually as part of the annual performance evaluation (July/August)	CRP	C-CIRC
All employed or non-employed, credentialed, contracted or appointed - Advanced practice clinicians, - Physicians - Physician leadership	CRP	Upon appointment and annually thereafter	CRP	C-CIRC
Researchers	CRP	Upon consideration of affiliation with a research sponsor and annually thereafter	CRP	C-CIRC

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Considerations

Among the factors that should be considered in determining whether a conflict exists are the nature and magnitude of the opportunity, transaction or arrangement, the degree to which it is related to CHI's business, whether the Person with the conflict is the ultimate decision-maker or holds significant influence over the ultimate decision-maker (*i.e.*, degree of independence of the decision-making process), the unique nature of the opportunity, transaction or arrangement, the existence of other viable alternatives and the quality of those alternatives, and what is customary and reasonable in the health care or research industry.

As appropriate, a conflict of interest management plan will be developed. With respect to those audiences for which the C-CIRC has review responsibility, the C-CIRC will facilitate development of any such conflict of interest management plan in collaboration with local CRP staff. This plan will include documentation of the C-CIRC's determinations and recommendations. The conflict of interest management plan will be stored in the COI software. As necessary, reports to an appropriate governmental agency or sponsor will be made according to the relevant addenda to this Policy. Such reports will provide required information regarding how the conflict of interest will be managed, reduced, or eliminated. Designated CHI Entity staff are responsible for monitoring the conflict of interest management plan and for documenting monitoring activities in the COI software. At its sole discretion, a CHI Entity may reject a Person's request to enter into the relationship in question, or require the relationship be sufficiently altered to avoid a potential conflict of interest.

If an Employee who is required to complete a COI disclosure does not agree with a decision made by either the C-CIRC or LSG, as appropriate, in relation to review of COI disclosures, their interpretation of this Policy, or seeks an exemption or exception, the following steps should be followed. The Employee disputing the review decision, interpretation of the Policy, or seeking exemption or exception must present the matter to the Employee's immediate direct manager or supervisor for review and determination. If the Employee and the manager do not agree with the review decision, interpretation of the Policy, or seek exemption or exception, the manager shall consult with the manager's Vice President (or higher if the manager is a Vice President) to reach a determination. If the matter remains unresolved, it shall be referred to the CHI Vice President of Human Resources and the CHI Corporate Responsibility Officer. If they are unable to reach agreement, the matter shall be referred to the CHI General Counsel, whose decision shall be final. Processes applicable to other categories of Persons subject to this Policy are outlined in the attached addenda.

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Penalties for Violation of the Conflicts of Interest Policy and the Provisions of the Relevant Addenda

A Person who fails to disclose a perceived, potential or actual conflict of interest, or all material facts surrounding an actual or potential conflict, or fails to abide by the final decision regarding the conflict as required by this Policy and relevant addenda, may be subject to disciplinary or corrective actions such as employment termination, removal from a board or committee, possible loss or restriction of clinical privileges, or restriction of research activities in accordance with applicable laws, regulations, rules, contracts, and bylaws, etc.

ADDENDA

- A: Board of Stewardship Trustees (BOST), BOST Subcommittee Members, CHI Entity Board and Board Committee Members**
- B: Physicians, Advanced Practice Clinicians, Physician Administrators and Leaders**
- C: Research**
- D: Conflicts of Interest Review Committee Operations**

***Members of the Board of Stewardship Trustees
(BOST), BOST Committees and Subcommittees,
CHI Entity Boards and CHI Entity Board
Committees and Subcommittees, and Corporate
Officers***

Addendum A

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SCOPE

This Addendum applies to all members of the CHI Board of Stewardship Trustees (BOST), BOST committees and subcommittees, CHI Entity boards, and CHI Entity board committees and subcommittees. It also applies to all CHI and CHI Entity Corporate Officers. These individuals have a duty of loyalty to CHI and CHI Entities and must report any perceived, potential or actual conflict of interest.

DEFINITIONS

In addition to the definitions in CHI Governance Policy No. 1, *Conflicts of Interest* (“COI Policy”), the following definitions apply to research conflicts of interest:

Board Chair – For this Addendum, Board Chair means the Chairperson of the CHI BOST or the CHI Entity board on which the Trustee serves.

Corporate Officers – For this Addendum, Corporate Officers include the Chief Executive Officer, President, Treasurer, and Secretary of CHI or a CHI Entity.

Trustee – For this Addendum, Trustee means a member of the BOST, all BOST committees and subcommittees, any CHI Entity board and CHI Entity board committees and subcommittees.

ADDITIONAL CONSIDERATIONS

General Obligation

Each Trustee and Corporate Officer must promptly and fully report to the Board Chair situations that may create a conflict of interest when he or she becomes aware of such situations. In any situation when a Trustee or Corporate Officer is in doubt, full disclosure should be made to permit an impartial and objective determination. A written record of the disclosure will be made.

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Annual COI Disclosure

In addition to the ongoing disclosure obligation, all Trustees and Corporate Officers shall complete an electronic, web-based COI disclosure form on an annual basis. A copy of Governance Policy No. 1, *Conflicts of Interest* (COI Policy), shall be available through a link on the web-based COI software solution. Definitions of terms used in the disclosure questionnaire/form shall also be included. Each Trustee and Corporate Officer must promptly complete the COI disclosure on-line. The disclosures will be reviewed by the CHI Senior Vice President, Legal Services, and General Counsel (General Counsel) or his or her designee (*e.g.*, the assigned CHI Legal Services Group attorney for the CHI Entity) who will report potential conflicts to the applicable Board Chair.

Review, Evaluation and Initial Determination

The Board Chair or designee shall make such further investigation of any conflict of interest disclosures as he or she may deem appropriate. If the conflict involves the Board Chair, the Vice Chair will assume the Chair's role outlined in the COI Policy and this Addendum. Based on review and evaluation of the relevant facts and circumstances, the Board Chair will make an initial determination as to whether a conflict of interest exists and whether, pursuant to the COI Policy, review and approval or other action by the Board is required. A written record of the Board Chair's determination, including relevant facts and circumstances, will be made. The Board Chair shall then make an appropriate report to the Executive Committee of the Board concerning such review, evaluation and determination. If a difference of opinion exists between the Board Chair and another Trustee as to whether the facts and circumstances of a given situation constitute a conflict of interest or whether Board review and approval or other action is required within the COI Policy, the matter shall be submitted to the Board's Executive Committee, which shall make a final determination as to the matter presented. Such determination, including relevant facts and circumstances, will be reflected in the Executive Committee minutes and will be reported to the Board.

BOARD REVIEW

Transactional Conflict of Interest

The Board shall carefully scrutinize and must in good faith approve or disapprove any transaction in which CHI or a CHI Entity is a party and in which the Trustee or Corporate Officer either:

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- Has a material financial interest; or
- Is a Trustee or Corporate Officer of the other party (other than a CHI-affiliated organization).

The Board must approve the transaction by a majority of the Trustees on the Board, without counting the vote of any individual who has an interest in the transaction. In reviewing such transactions between CHI or CHI Entities and vendors or other contractors who are, or are affiliated with, Trustees or Corporate Officers, the Board shall act no more or less favorably than it would in reviewing transactions with unrelated third parties. The transaction will not be approved unless the Board determines that the transaction is fair to CHI or the CHI Entity.

Other Conflicts of Interest

The Board shall carefully review and scrutinize any non-transactional conflict of interest (*e.g.*, disclosure of nonpublic information, competition with CHI or a CHI Entity, failure to disclose a corporate opportunity, excessive gifts or entertainment, etc.). By a majority vote of the disinterested Trustees, the Board shall take whatever action is deemed appropriate with respect to the Trustee or Corporate Officer under the circumstances, including possible disciplinary or corrective action, in order to best protect the interests of CHI or the CHI Entity. The Board should consult with the General Counsel of CHI or his or her designee when considering disciplinary or corrective action.

Disclosure by Interested Trustee or Corporate Officer

When any conflict of interest is considered by the Board, the Trustee or Corporate Officer, as appropriate, must disclose all of the material facts to the Board. The Trustee shall not vote and the Trustee or Corporate Officer shall not use his or her personal influence on the matter. However, if requested, such Trustee or Corporate Officer is not prevented from briefly stating his or her position in the matter, nor from answering pertinent questions from Trustees, as his or her knowledge may be of significant importance. The Trustee or Corporate Officer shall be excused from the meeting during discussion and vote on the conflict of interest.

Record of Proceedings

***Members of the Board of Stewardship Trustees
(BOST), BOST Committees and Subcommittees,
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Minutes of the Board shall reflect the following: the individual making the disclosure, the nature of the disclosure, discussion regarding any proposed transaction, the decision made by the Board, and that the interested Trustee or Corporate Officer was excused during the discussion, and that the interested Trustee abstained from voting.

Implementation and Interpretation

Questions regarding the implementation and interpretation of this Addendum and its application to the COI Policy shall be referred to the General Counsel of CHI or his or her designee.

Policy Violations

If the Board reasonably believes that a Trustee or Corporate Officer has failed to disclose either an actual or potential conflict of interest, or all material facts surrounding an actual or possible conflict as required by the COI Policy or this Addendum, the Trustee or Corporate Officer will be given an opportunity to explain such alleged failure to disclose. After hearing the response of the Trustee or Corporate Officer, the Board will conduct such additional investigation as may be appropriate. If the Board determines that the Trustee or Corporate Officer has in fact failed to disclose as required by the COI Policy or this Addendum, the Board shall take appropriate disciplinary or corrective action.

Maintaining Documentation and Providing Requestors Information

Conflict of Interest disclosures, other documentation used in the review of such statements, and related records shall be maintained in the Conflict of Interest software for a minimum of three (3) years following the date of initial disclosure or until any relevant government, criminal, or civil proceeding has concluded.

*Physicians, Physician Administrators and Leaders,
and Advanced Practice Clinicians*

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SCOPE

This Addendum applies to all physicians, physician administrators and leaders, and advanced practice clinicians (employed and non-employed). These individuals have a duty of loyalty to CHI and CHI Entities and must report any perceived, potential or actual conflict of interest.

DEFINITIONS

In addition to the definitions in CHI Governance Policy No. 1, *Conflicts of Interest* (COI Policy), employed and non-employed physicians and advanced practice clinicians should be aware of the following:

Financial Conflict of Interest means a financial interest that could directly or indirectly affect decisions regarding patient care and treatment choices. These interests include, but are not limited to:

- Employment or contractual relationships with any person or entity doing business with, or seeking to do business with CHI or a CHI Entity;
- Ownership interests in any entity doing business with, or seeking to do business with CHI or a CHI Entity (see definition of Material Financial Interest in the COI Policy);
- Service as an officer, trustee or director of an entity doing business with, or seeking to do business with CHI or a CHI Entity;
- Any personal or business arrangement entered into as a result of access to confidential information gained through a physician's or advanced practice clinician's relationship to CHI or a CHI Entity;
- Acceptance of any gifts, entertainment, loans, favors or other benefits, with a value that will, or has the potential to, influence the physician's or advanced practice clinician's decision-making, from any person or entity doing business with, or seeking to do business with CHI or a CHI Entity (see also CHI Corporate Responsibility Policy No. 1, *Gifts and Payments from Business Sources; Employee Arrangements with Business Sources* (Gifts Policy));
- Certain compensation arrangements with Manufacturers (as defined below); and
- An immediate family member (as defined in the COI Policy) to whom any of the above apply.

Manufacturers means a Group Purchasing Organization (GPO), or pharmaceutical, medical supply or medical device company that does or that seeks to do business with CHI or a CHI Entity, whose products or services are or may be used by the physician or advanced practice clinician in providing

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services to or for CHI or a CHI Entity, or whose payments or items of value when given to a physician is reportable under the Physician Payment Sunshine Act.

Physician Payment Sunshine Act (42 CFR § 402-403) requires applicable manufacturers of drugs, medical devices and biologics along with GPOs to report certain payments and items of value given to physicians. Manufacturers and GPOs are required to furnish this information to the Centers for Medicare and Medicaid Services (CMS). CMS will collect the information and publish it on a public website. CHI may search the CMS public website for payments subject to the Physician Payment Sunshine Act to verify the accuracy of the information disclosed by a physician.

ADDITIONAL CONSIDERATIONS

In addition to the procedures outlined in the COI Policy, examples of conditions, safeguards, or restrictions that may be implemented include, but are not limited to the following:

- Review of the arrangement by the CHI Arrangements Review Group, as defined in the Gifts Policy;
- Divestiture of the relevant financial interest or severance of outside relationships with the entity or individual posing the conflict;
- Modification of the physician's or advanced practice clinician's responsibilities, including suspension of patient care activity; and
- Requirement that the financial conflict of interest be disclosed to patients.

Maintaining Documentation and Providing Requestors Information

Conflict of Interest disclosures, other documentation used in the review of such statements, and related records shall be maintained in the Conflict of Interest software for a minimum of three (3) years following the date of initial disclosure or until any relevant government, criminal, or civil proceeding has concluded.

Penalties for Violation of the Conflicts of Interest Policy and the Provisions of the Relevant Addenda

A Person who fails to disclose a perceived, potential or actual conflict of interest, or all material facts surrounding an actual or potential conflict, or fails to abide by the final decision regarding the conflict as required by this Policy and relevant addenda, may be subject to disciplinary or corrective actions

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such as employment termination, removal from a board or committee, possible loss or restriction of clinical privileges, or restriction of research activities in accordance with applicable laws, regulations, rules, contracts, and bylaws, etc.

Research

Addendum C

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SCOPE

This Addendum applies to all individuals employed by or contracting or affiliated with CHI or a CHI Entity who are responsible for or are in the position to influence the design, conduct, or reporting of human subjects research at CHI or a CHI Entity facility, regardless of research funding source. Such individuals must comply with the provisions of this Research Conflicts of Interest Addendum which is compliant with 42 CFR Part 50, Subpart F, and 45 CFR Part 94.

Individuals include:

- Full- or part-time CHI National or CHI Entity employees;
- Physicians and other healthcare providers, research assistants and nurses engaged in research activities;
- Trainees and students, who are involved in research-related activities, including, but not limited to, nursing, pharmacy, technicians, *et al.*; and
- Independent research contractors and consultants.

Federal regulations require entities engaged in human subjects research to have policies and procedures in place that ensure that investigators disclose any financial interests that may present perceived, potential or actual financial conflicts of interest. CHI aims to foster an environment in which objectivity in the design, conduct, and reporting of research is protected and the public trust in CHI and its mission is not compromised.

DEFINITIONS

In addition to the definitions in CHI Governance Policy No. 1, *Conflicts of Interest* (“COI Policy”), the following definitions apply to research conflicts of interest:

Financial Conflict of Interest means a financial interest that could directly or significantly affect the design, conduct or reporting of research.

Investigator means the principal investigator, co-investigators, project director and any other person, regardless of title, who is responsible for the design, conduct, evaluation, monitoring, expenditure of funds, or reporting of research, which may also include, for example, collaborators and consultants.

Key Research Personnel means the project director or principal investigator and any other individual identified by the institution in a grant application, progress report or other report submitted by CHI or a CHI Entity to any component of the Public Health Service (PHS) by CHI or the CHI

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Entity, or those individuals listed on an IRB submission for a research project; submission to a biohazards committee; or submission to an Institutional Animal Care and Use Committee (IACUC). Additional information and requirements related to animal research is contained in both the CRP Research Addendum and the CRP Teaching Hospital and Academic Medical Center Addendum.

Research for the purposes of this Addendum includes all activities that involve living human beings, conducted in a systematic manner, and designed to develop or contribute to generalizable knowledge relating broadly to public health, including biomedical, behavioral and social sciences research.

Significant Financial Interest means a financial interest involving any of the following:

- Any remuneration received from any publicly traded entity plus any equity interest (e.g., stock, stock option or other ownership interest), as determined on the date of disclosure if the value, in the aggregate exceeds \$5,000;
- Any remuneration received from any non-publicly traded entity if the value, when aggregated, exceeds \$5,000;
- Any equity interest (e.g., stock, stock option, partnership interest, membership interest or other ownership interest) in a non-publicly traded entity on the date of disclosure regardless of value;
- Intellectual property rights and interests (e.g., patents and copyrights), royalties from such rights, or filing of the patent interest or effective date to share in rights to royalties; and
- All reimbursed or sponsored travel (travel paid on an investigator's behalf but not reimbursed by a CHI Entity) related to research responsibilities.

The following are excluded from the requirement to disclose:

- Remuneration from the CHI or a CHI Entity, if the investigator is employed by CHI or the CHI Entity;
- Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, or institutions 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 or any service on advisory or review panels for such agencies or institutions;
- Income from investment vehicles, such as mutual funds and retirement accounts, provided that the investigator does not directly control the investment decisions made about these vehicles; and
- Travel that is reimbursed or sponsored by a federal, state, or local government agency, or institutions of higher education (as defined at 20 U.S.C. 1001(a)), an academic teaching

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hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

ADDITIONAL CONSIDERATIONS

PHS-Funded Research

Additional requirements for the institution and investigators who participate in PHS-funded research include additional procedures when a financial conflict of interest is not identified or managed in a timely manner and procedures specified in 45 CFR Part 50. Additionally, investigators and institutions involved in PHS-funded research must comply with 42 CFR Part 50 Subpart F.

Requirement for Researcher Training in Financial Conflicts of Interest

As of August 2012, all investigators are required to receive training in financial conflicts of interest in research at least every four (4) years. CHI policy requires that all researchers receive this training. This includes research coordinators, research nurses, research assistants, etc. Refer to the COI Policy for the definition of researcher. There are multiple resources available for this training.

Maintaining Documentation and Providing Information to Requestors

Conflicts of Interest disclosures, other documentation used in the review of such disclosures, and relevant records shall be maintained in the COI software for a minimum of three (3) years following the completion of the research project that generated the disclosure statements, or until any relevant government, criminal, or civil proceeding has concluded. For PHS-funded research, such records shall be maintained as specified in 45 CFR 74.53(b) and 92.42(b).

CHI or the CHI Entity, as appropriate, will provide to any requestor (within five business days) a written response containing information on financial conflicts of interest the CHI Entity determines are related to the research as required by 45 CFR Part 94.

Applicable Regulations

Investigators must comply with all applicable state and federal laws and regulations, including those specifically related to financial conflicts of interest and objectivity in research. These provisions include, but are not limited to, Public Health Service Regulations (42 C.F.R. Part 50, Subpart F and 45 C.F.R. Part 94) and guidance material located in the National Institutes of Health (NIH) Grants Policy Statement (12/03).

Penalties for Violation of the Conflicts of Interest Policy and the Provisions of the Relevant Addenda

A Person who fails to disclose a perceived, potential or actual conflict of interest, or all material facts surrounding an actual or potential conflict, or fails to abide by the final decision regarding the conflict as required by this Policy and relevant addenda, may be subject to disciplinary or corrective actions such as employment termination, removal from a board or committee, possible loss or restriction of clinical privileges, or restriction of research activities in accordance with applicable laws, regulations, rules, contracts, and bylaws, etc.

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SCOPE

Introduction

This Addendum has been created to provide Catholic Health Initiatives (CHI) and CHI Entities an overview of the CHI Conflicts of Interest Review Committee (C-CIRC) processes related to disclosed or otherwise identified financial interests and relationships of Persons who are required by CHI Governance Policy No. 1, *Conflicts of Interest* (COI Policy) to complete annual conflicts of interest (COI) disclosures. The C-CIRC is responsible for:

- Reviewing certain categories of disclosures, as designated in the COI Policy;
- Making certain COI determinations; and
- Determining the need for elimination or management of the disclosed or identified conflicts.

Purpose of the C-CIRC

In support of CHI's core values, the C-CIRC is responsible for protecting the integrity and interests of CHI in circumstances that may involve a conflict between personal interests of a Person (as Person is defined in the COI Policy) and those of CHI, a CHI Entity, or the populations CHI or the CHI Entity serves. Specifically, the C-CIRC will review disclosures and make COI determinations with respect to the following groups of individuals:

- Employees at a level of manager or above (excluding corporate officers, whose disclosures are subject to board or board committee review with guidance from the CHI Legal Services Group (LSG), as noted below);
- Supply chain employees;
- Researchers; and
- Physicians, physician administrators and leaders, and advanced practice clinicians (both employed and non-employed).

The C-CIRC will determine whether a conflict of interest exists based on disclosures pursuant to the COI Policy. The C-CIRC is also responsible for assuring the development of COI management plans (as appropriate) to implement controls to manage, reduce, or eliminate conflicts of interest. Reviews and determinations involving board and board committee members and corporate officers will be the responsibility of the board, board executive committee, or board chair, with guidance from the Legal Services Group (LSG).

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In discharging its responsibilities to review and manage potential COI, the C-CIRC will have as its primary objectives:

- Care and well-being of the populations CHI or the CHI Entity serves;
- Minimization of risks to CHI or CHI Entity patients and research participants;
- Safeguarding of the integrity of the CHI or CHI Entity research enterprise and
- Preservation of the professional integrity of CHI or the CHI Entity in all its endeavors and responsibilities

DEFINITIONS

In addition to the definitions in CHI Governance Policy No. 1, *Conflicts of Interest* (“COI Policy”), the following definitions apply to research conflicts of interest:

Conflict of Interest Management Plan means a formal document created to acknowledge the existence of a conflict of interest for a Person with interests that may or may be perceived to be conflicting with the Person’s duties and responsibilities to CHI or the CHI Entity. Further, the COI management plan specifies any restrictions or conditions for continued participation of the disclosing Person in the activity determined to be a conflict of interest.

PROCESS

The C-CIRC Review and Determination Process

- **Selection and Composition of the C-CIRC:** The C-CIRC will consist of between 12 and 15 members and a Chair appointed by the CHI Senior Vice President and CHI Corporate Responsibility Officer (SVP-CRO). The C-CIRC will be composed of individuals with sufficient independence, expertise and authority to assure the integrity of the COI review and determination process.
- The C-CIRC will include the following, all of whom have the right to vote.
 - **Standing Members**
 - At least one CRP Vice President
 - An LSG representative
 - A Human Resources representative

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- A Mission representative
- The Director of Research Compliance
- The Chair of the C-CIRC
- **Ad Hoc Members (to be included as appropriate):**
 - The Director of the Human Research Protections Program
 - CRP Director of Physician Enterprise
 - A Supply Chain Vice President
 - A Clinical Service Line representative
 - A Regional Corporate Responsibility Officer
 - Subject matter experts (as appropriate)
- **Division representatives (as pertinent to the disclosures under review):**
 - Clinical representative
 - Regional Corporate Responsibility Officer
 - An LSG representative
 - Local member of senior leadership (as appropriate)

C-CIRC Meetings

A quorum (50% + 1) of voting members must be in attendance at a C-CIRC meeting for determinations to be made. The following individuals must be included in the quorum such that, if any of these individuals are not present, determinations may not be made.

- LSG representative
- C-CIRC Chair
- Divisional clinical representative
- Regional CRO

C-CIRC Membership Duty of Confidentiality

Information revealed as part of the C-CIRC process may not be used for any employment or performance review purposes except as specified as part of a COI management plan. By agreement of the C-CIRC Chair and LSG representative, such information may be shared with other Corporate Responsibility and LSG representatives as necessary for creation of a COI management plan or notification of C-CIRC recommendations regarding disclosures.

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C-CIRC Determinations and Recommendations for COI Management Plan Provisions

The C-CIRC will determine whether a disclosed or otherwise identified interest is a conflict of interest using the standard operating procedure (SOP) designed for that purpose and approved by both CRP and LSG, including any updates to such SOP. If the C-CIRC determines that there is a potential or actual conflict of interest that does not currently have appropriate controls to address the conflict of interest, it may recommend that the disclosing Person be allowed to participate in the activity or transaction subject to restrictions as outlined in a written COI management plan using the standard template for this purpose contained in the C-CIRC SOP. All determinations of conflicts of interest will be reported as required by law, regulations, and CHI policy.

C-CIRC Record Retention

The C-CIRC shall retain records in accordance with the CHI Legal Policy No. 1, *Records Management and Retention* (National Offices) but for no less than a period of three years.

Monitoring of Implementation and Enforcement of COI Management Plans

Within 30 days of the date of a COI management plan created by the C-CIRC, the Regional Corporate Responsibility Officer (or designated CRO) must provide the C-CIRC with a signed copy of the management plan, or notification that the Person with the COI as determined by the C-CIRC intends to appeal the determination. The C-CIRC will conduct periodic monitoring to verify that the COI management plan has been implemented and is being enforced.

Appeals Process

If a Person, other than a board or board committee member or corporate officer, required to complete a COI disclosure does not agree with a determination made by the C-CIRC, its interpretation of this Policy or Addenda, or seeks an exemption or exception, the following steps should be followed. The Person must present the matter to the Person's immediate direct manager or supervisor for review and determination. If the Person and the manager do not agree, the manager shall consult with the manager's Vice President (or higher if the manager is a Vice President) to reach a determination. If the matter remains unresolved, it shall be referred to the CHI Vice President of Human Resources and the CHI SVP-CRO. If they are unable to reach agreement, the matter shall be referred to the CHI General Counsel, whose decision shall be final. Management of actual or potential conflicts of interest of board or board committee members and corporate officers will be determined by the appropriate board, as reflected in the COI Policy and related Addendum A.