

**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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**REVIEW BY: 06/21/20**

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## **POLICY**

It is the policy of Catholic Health Initiatives (CHI or CHI National) its Direct Affiliates<sup>1</sup> and Subsidiaries<sup>2</sup> (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 discloses any perceived, potential or actual conflicts of interest (sometimes, COI); and
- CHI has an opportunity to review and manage each perceived, potential or actual conflict of interest in the best interests of CHI and its community benefit purposes and 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.
- Ensure compliance with federal and state laws and regulations related to dealings between CHI Employees or affiliated individuals and other entities or individuals.

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<sup>1</sup> A Direct Affiliate is any corporation of which CHI is the sole corporate member or sole shareholder.

<sup>2</sup> 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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## **SCOPE**

This Policy applies to the following Persons:

- The CHI Board of Stewardship Trustees (BOST) and members of its committees;
- All CHI or CHI Entity board and board committee members;
- All CHI Employees; and
- 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 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.

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**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 COI questionnaires containing disclosures of perceived or possible conflicts of interest for Persons requiring additional review (excluding board and board committee members).

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

**Person** includes:

- All Employees of CHI or a CHI Entity,
- All CHI or CHI Entity board and board committee members, and
- All Researchers (as defined below).

**Researchers** include 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; or 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.

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**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.

## **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.

### **General Obligation**

Each Person must promptly and fully disclose to his/her direct manager, supervisor, medical staff office, board or board committee chair any situation or circumstance that may create a conflict of interest. The Person must disclose the actual or potential conflict as soon as she/he becomes aware of it. In any situation where the Person may be in doubt, a full disclosure should be made to permit an impartial and objective determination.

### **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 in confidence and access shall be limited to persons who have a reasonable need to know the contents.
- **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 in confidence and access shall be limited to persons who have a reasonable need to know the contents.

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### **Annual COI Disclosure Requirement for Certain Individuals**

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 vice president and above;
- Researchers, as defined in the definition section above;
- Supply Chain Employees at the level of vice president and above and those employees involved in contracting regardless of employment level;
- Other Employees as deemed applicable by CHI Leadership.

### **Review Process**

Review and management of perceived, potential or actual conflicts of interest will be accomplished through a defined COI disclosure review process. Access to disclosures and associated documents and data will be restricted to designated officials with specific responsibilities to review or manage conflicts of interest.

COI disclosures that involve no disclosures of conflicts of interest will not require review. Disclosures of perceived, potential or actual conflicts of interest on the COI questionnaire involving financial interests will be reviewed as set forth in Appendix B.

### **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. When a Person has, or is considering initiating, a business interest or relationship outside of CHI but is uncertain whether the interest constitutes a conflict of interest requiring disclosure under this Policy, the Person should consult with local Corporate Responsibility Program (CRP) staff or CHI Legal Services Group (LSG) staff, as appropriate.

### **COI Management Plans**

As appropriate, a COI 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 COI

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management plan in collaboration with local CRP staff or CHI LSG staff, as appropriate. This plan will include documentation of the C-CIRC's determinations and recommendations. As necessary, reports to an appropriate governmental agency or sponsor will be made according to the relevant appendices to this Policy to provide required information regarding how the conflict of interest will be managed, reduced, or eliminated. Designated CHI Entity staff are responsible for monitoring the COI management plan and for documenting monitoring activities. 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.

### **Appeals Process**

Processes for appealing or seeking an exemption or exception to COI decisions with respect to the various categories of Persons subject to this Policy are outlined in the attached appendices.

### **Penalties for Violation of the Conflicts of Interest Policy and the Provisions of the Relevant Appendices**

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 appendices, 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.

### **APPENDICES**

- A: Examples of Conflicts of Interest
- B: Conflicts of Interest Disclosure and Review Process
- C: Members of the Board of Stewardship Trustees (BOST), BOST Committees, CHI Entity Boards and CHI Entity Board Committees, and Corporate Officers
- D: Employed Physicians, Physician Administrators and Leaders, and Employed Advanced Practice Clinicians
- E: Research
- F: CHI Conflicts of Interest Review Committee Operations

## ***Governance Policy No. 1***

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### **APPROVED AND AMENDED BY BOARD**

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### **SCOPE**

This Appendix applies to Researchers as defined by CHI Governance Policy No. 1: *Conflicts of Interest* (COI Policy), conducting any funded Research, and to Researchers who have an intellectual property or ownership interest in the research (excluding publicly traded stock ownership). This includes 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. Researchers must comply with the provisions of this Research Conflicts of Interest Appendix, which is compliant with 42 CFR Part 50, Subpart F, and 45 CFR Part 94.

Researchers include:

- Full- or part-time CHI National or CHI Entity employees engaged in Research at a CHI Entity;
- Physicians and other healthcare providers, Research assistants and nurses engaged in Research activities at a CHI Entity (whether or not they are employed by CHI);
- Trainees and students, who are involved in federally funded Research-related activities at a CHI Entity, including, but not limited to, nursing, pharmacy, technicians, *et al.* (whether or not they are employed by CHI); and
- Independent Research contractors and consultants engaged in Research at a CHI Entity.

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. In addition, patients at CHI Entities who participate in Research have an expectation that the Research and any Research-related services are not impacted by a Conflict 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.

This Appendix does not apply to Researchers conducting unfunded Research, unless they have an intellectual property interest in the Research.

### **DEFINITIONS**

In addition to the definitions in the COI Policy, the following definitions apply to Research Conflicts of Interest:



**Financial Conflict of Interest** means a significant 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.

**Research** for the purposes of this Appendix means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

**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;

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

### **REQUIREMENT TO DISCLOSE**

With the exception of Researchers conducting unfunded Research and Students/Trainees conducting non-federally sponsored research, all Researchers, including Investigators and other members of the Research team (as described under Scope and in the Researcher definition under the COI Policy) are required to disclose to CHI the presence of a Significant Financial Interest. Disclosures to CHI are required at least annually, and within 30 days of any change in the Significant Financial Interest. All Significant Financial Interests as defined by this Appendix E must be disclosed using the format prescribed by CHI, whether or not the Significant Financial Interest is directly related to any proposed or current Research.

### **Researchers Covered by Agreements with Academic Centers, Research Institutes, and other Third Parties**

In situations where a Researcher is employed by a Research institute, academic center, or any third party for which CHI or a CHI Entity is required to confirm disclosures of Financial Interest (“home institution”) and conducts Research at a CHI facility, and where a formal agreement exists between CHI and the home institution, the Researcher may be permitted to disclose directly to his or her home institution using the home institution’s disclosure mechanism instead of using the format prescribed by CHI. In such instances, the following conditions **must** be met:

- The Research institute, academic center, or other third party maintains a Public Health Service (PHS)-compliant COI policy in place which is acceptable to CHI, and has sufficient processes to comply with such policy.
- A formal agreement between the home institution and CHI exists. This agreement must state that individuals who conduct Research at a CHI facility will follow the home institution’s PHS policy with respect to submission of disclosures and COI training requirements.

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- If Researchers have a Significant Financial Interest related to the proposed project, then CHI or a CHI Entity may request an attestation from the Researcher in a format acceptable to CHI stating that all Significant Financial Interests have been disclosed to the home institution as required by the home institution's PHS-compliant COI policy. Information about management of a determined Financial Conflict of Interest related to a CHI research study by the home institution must be shared with the CHI Research Corporate Responsibility Officer (CRO). CHI and associated IRBs have the authority to make the home institution's COI management plan covering CHI research more stringent.
- With respect to Research that will be conducted at a CHI facility, the CHI Research CRO has the latitude to determine whether the home institution's determination of the existence of a COI and any management of such COI is sufficient, or whether additional management is necessary before the Research can begin at the CHI facility. For example, consistent with CHI's commitment to its Mission, Vision, and Core Values, CHI may require that the consent form be modified to disclose to CHI patients the existence of a financial interest held by the Researcher.

## **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**

Researchers conducting PHS-sponsored Research are required to receive training in Financial Conflicts of Interest in Research prior to engaging in Research at a CHI Entity, and at least every four (4) years. In addition, PHS-regulations require retraining if the COI Policy is revised in a manner that affects the individual's duties. This training requirement 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. Contact the Research CRP staff for a list of acceptable COI training resources. The Researcher is required to maintain documentation of training completion, which must be made available to CHI upon request for auditing and monitoring purposes.

### **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 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 42 CFR 50.604(i), 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, PHS 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 Appendices**

A Person who fails to disclose a perceived, potential or actual COI or all material facts surrounding an actual or potential conflict, or fails to abide by the final decision regarding the conflict as required by the COI Policy and relevant appendices, 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.