

CHI Conflicts of Interest Review Committee Operations

Addendum D

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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.