

## Policy on Conflict of Interest for Sponsored Programs

### INTRODUCTION

These guidelines define the general Children's Memorial Hospital and Children's Memorial Research Center (hereafter jointly referred to as "Hospital") policy and procedures regarding conflicts of interest in relationship to sponsored projects involving research, education and other sponsored activities. Their purpose is to protect the integrity and credibility of the Hospital and its faculty and staff and to ensure compliance with federal regulations.

A potential conflict of interest exists when an individual's personal or private interests might lead an independent observer reasonably to question whether the individual's professional actions or decisions are determined by considerations of significant personal interest, financial or otherwise. In accordance with federal regulations, ( 42 CFR Part 50), the Hospital has a responsibility to manage, reduce, or eliminate any actual or potential conflicts of interest that may be presented by a financial interest of an investigator (as defined in this policy). Thus, the Hospital requires that *all investigators* disclose any *significant financial interest* (as defined in this policy) that could reasonably appear to affect or be affected by a sponsored project. The term *sponsored project* is defined as a grant, contract, agreement or subcontract for research or other scholarly activity between the Hospital and any outside entity or agency. This policy applies to all *investigators*.

### I. DEFINITIONS

#### A. Investigator

The term *investigator* as used in this policy means the principal investigator/project director, co principal investigators and any other persons who are responsible for the design, conduct, or reporting of research, educational or service activities funded - or proposed for funding - by an external sponsor. This may include students, postdoctoral fellows, and other staff. For purposes of financial interests, 'investigator' includes the investigator's spouse, domestic partner, brothers or sisters (by blood, adoption or marriage), children, grandchildren and spouses of brothers, sisters, children and grandchildren, and all other persons living in the same household as the investigator.

#### B. Conflict of Interest

For purposes of federal regulations and this policy, a *conflict of interest* exists when a *significant financial interest* could directly and significantly affect the design, conduct or reporting of a sponsored project.

#### C. Significant Financial Interest

*Significant financial interest* means anything of monetary value including, but not limited to, the following:

1. Salary or other payments for services (e.g., consulting fees or honoraria) that, when aggregated for the *investigator* and the *investigator's* spouse and dependent children over the next twelve months, are expected to exceed \$10,000
2. Equity interests (e.g., stocks, stock options or other ownership interests) that, when aggregated for the *investigator* and the *investigator's* spouse and dependent children, **either** a) exceed \$10,000 in value (as determined through reference to public prices or other reasonable measures of fair market value) or b) represent more than a five-percent ownership interest in any single entity.

4. Intellectual property rights (e.g., patents, copyrights and royalties from such rights) that, when aggregated for the *investigator* and the *investigator's* spouse and dependent children over the next twelve months, are expected to exceed \$10,000

The term does not include the following:

- a. Salary, royalties, or other remuneration from the Hospital
- b. Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities
- c. Income from service on advisory committees or review panels for public or nonprofit entities

## II. GUIDELINES

*Investigators* engaged in externally sponsored activity must, in accordance with federal and Hospital policy, disclose to the Senior Vice President & Chief Operating Officer, CMRC, on the form provided by the Senior Vice President & Chief Operating Officer, CMRC, whether or not they have any *significant financial interests*, including those of their spouse, domestic partner, brothers or sisters (by blood, adoption or marriage), children, grandchildren and spouses of brothers, sisters, children and grandchildren, and all other persons living in the same household as the investigator, that would reasonably appear to affect or be affected by the sponsored activity. *Investigators* may choose to disclose any other financial or related interest that could present an actual or perceived conflict of interest, or the reasonable appearance of a conflict of interest. Any disclosure of a significant financial interest or any other financial or related interest should provide sufficient detail to permit an accurate and objective evaluation.

The principal investigator/project director is responsible, for each proposed activity, for determining who meets the definition of *investigator* as set forth in this policy and for ensuring and certifying that each investigator has submitted a completed Proposal and Protocol Authorization form along with the proposal submitted to the Office of Sponsored Programs (OSP). Such disclosure forms must be completed and submitted to OSP before a proposal is endorsed by the Hospital and forwarded to an external sponsor.

The disclosure must be reviewed to determine if further action is required before the Hospital expends any awarded funds or issues a purchase order or subcontracts for the acquisition of goods and services related to any award that may result from the proposal.

If the Senior Vice President & Chief Operating Officer, CMRC determines, after reviewing the disclosure form and other available information, that a *significant financial interest* could affect the design, conduct, or reporting of research activities, the Senior Vice President & Chief Operating Officer, CMRC shall refer the matter to the President and Scientific Director of the Children's Memorial Research Center (hereafter Scientific Director) or his/her designee. The Scientific Director or his/her designee will then review the matter and will determine which of the following actions to take:

- A. Accept the proposed sponsored project.
- B. Accept the proposed sponsored project **provided** certain conditions or restrictions are imposed so that the conflict will be managed, reduced or eliminated. Following are examples of possible conditions or restrictions:
  1. Public disclosure of *significant financial interests*

2. Monitoring of research by independent reviewers
  3. Modification of the research plan
  4. Disqualification from participation in the portion of the sponsored funded research project that would be affected by the *significant financial interests*
  5. Divestiture of significant financial interests
  6. Severance of relationships that create actual or potential conflicts
- C. Refuse the proposed sponsored project.

If the *investigator* is dissatisfied with determination of the Scientific Director, the *investigator* may, within ten (10) calendar days of such recommendation, submit a written appeal to the President of the Children's Memorial Hospital (hereafter President). In reviewing the matter and determining whether a *conflict of interest* exists and/or what actions should be taken to manage, reduce or eliminate a potential conflict, the President or his/her designee may consult with other Hospital officials and staff as appropriate. After such review, the President will make the final decision.

The required forms must be updated at least annually or more frequently if new reportable information is obtained during the period of an award. Records of *investigator* financial disclosures and of actions taken to manage actual or potential conflicts of interest shall be retained by **ASP** until three years after the later of the termination or completion of the award to which they relate, or the resolution of any government action involving those records.

Collaborators/sub-recipients/subcontractors from other institutions involved in externally sponsored projects of the Hospital must either comply with this policy or provide a certification from their institutions that they are in compliance with federal requirements regarding disclosure of *conflicts of interest* and that their portion of the project is in compliance with their institutional policies.

#### IV. COMPLIANCE

All persons subject to this policy are expected to comply with it fully and promptly. Whenever an *investigator* has violated this policy, the Scientific Director shall report such violation to the appropriate Hospital official and, where appropriate, sanctions will be imposed in accordance with the applicable Hospital policies.

In addition, the Hospital shall follow federal regulations regarding the notification of the sponsoring agency in the event an *investigator* has failed to comply with this policy. The sponsor may take its own action as it deems appropriate, including the suspension of funding for the *investigator* until the matter is resolved.

<sup>1</sup> Various federal agencies (e.g., Public Health Service, National Science Foundation, Food and Drug Administration) have slightly different policies. This policy is intended to be compliant with all of these varying policies by adopting the strictest definitions set forth by the various agencies. Copies of these federal policies are available upon request from the Director of the Office of Sponsored Programs.

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