# Conflicts of Interest and Commitment in Research

Ann & Robert H. Lurie Children's Hospital of Chicago®

Owner: Jessica Poppenk

Approver: Brenda Paulsen

Site: Organizational

*Last Reviewed: 10/24/2024*

A. The purpose of this policy is to confirm Children's Hospital of Chicago Medical Center's (the "Medical Center's") commitment to fulfill its responsibility to manage, reduce, or eliminate any actual or potential Conflict of Interest that may be presented by a financial interest of an Investigator (as defined in this policy), in accordance with applicable federal regulations.

B. This policy establishes standards and requirements regarding professional activities and interests outside the Medical Center to ensure the Medical Center's personnel and legal obligations are protected.

C. The Medical Center encourages its Medical and Dental Staff, researchers, and, where appropriate, employees to seek and participate in sponsored research or programs that may benefit not only the participants, but also the Medical Center and the public. It is understood that Conflicts of Interest sometimes naturally occur during the course of conducting the Medical Center's daily affairs, because the many persons associated with the Medical Center have multiple interests and affiliations and various positions of responsibility within the community.

D. A potential Conflict of Interest exists when an individual's personal or private interest 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, the Medical Center has a responsibility to manage, reduce, or eliminate any actual or potential Conflict of Interest that may be presented by a financial interest of an Investigator.

**DEFINITIONS:**

A. *Conflict of Commitment* usually involves an issue of time allocation resulting from competing demands on a researcher's time and loyalties that creates a risk of divided loyalty between the Medical Center and an outside entity, or otherwise interferes with their professional obligations and commitments to the Medical Center.

B. *Covered Individual* means any Medical Center personnel who contributes in a substantive, meaningful way to the scientific development or execution of a research and development project that is proposed to be funded by a research and development award, and is designated as a covered individual by applicable Federal research agencies.

C. *Financial Conflict of Interest* means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of research or sponsored program regardless

of sponsoring agency.

D. *Financial Interest* means anything of monetary value, whether or not the value is readily ascertainable.

E. *Institutional Responsibilities* means an Investigator's professional responsibilities on behalf of the Medical Center, which may include for example: research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

F. *Investigator* means the Project Director or Principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research or sponsored program funded by the PHS or other sponsor, or proposed for such funding, which may include, for example, collaborators or consultants.

G. *PHS* means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health ("NIH").

H. *PHS Awarding Component* means the organizational unit of the PHS that funds the research or sponsored program that is subject to this policy.

I. *Research* means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (*e.g.*, a published article, book or book chapter) and product development (*e.g.*, a diagnostic test or drug). The term includes any such activity for which research funding is available from a PHS awarding component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

J. *Sponsored Program* means externally-funded activities in which a formal written agreement, i.e., a grant, contract, or cooperative agreement, is entered into by the Institution and by the sponsor. A sponsored project may be thought of as a transaction in which there is a specified statement of work with a related, reciprocal transfer of something of value.

K. *Senior/Key Personnel* means the Project Director/Principal Investigator and any other person identified as senior/key personnel by the Medical Center in the application, budget, progress report, or any other report submitted to the PHS or other sponsor by the Medical Center. For the purposes of clarity, these individuals are to be considered Investigators within the meaning of this policy.

L. *Significant Financial Interest* means:

1. A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's Institutional Responsibilities:
    a. With regard to any publicly traded entity, a Significant Financial

Interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (*e.g.*, consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

b. With regard to any non-publicly traded entity, a Significant Financial Interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or Investigator's spouse or dependent children) holds any equity interest (*e.g.*, stock, stock option, or other ownership interest); or
c. Intellectual property rights and interests (*e.g.*, patents, copyrights), upon receipt of income related to such rights and interests.

2. Investigators also must disclose the occurrence of any reimbursed or sponsored travel (*i.e.* that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their Institutional Responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, and institution of higher education, and academic teaching hospital, a medical center or a research institute that is affiliated with an institution of higher education. The details of this disclosure shall include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes a Financial Conflict of Interest with the PHS-funded research or sponsored program.

3. The term Significant Financial Interest does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Medical Center to the Investigator if the Investigator is currently employed or otherwise appointed by the Medical Center, including intellectual property rights assigned to the Medical Center and agreements to share in royalties related to such rights; income from or holdings in investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions made in these vehicles; income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center or a research institute that is affiliated with an institution of higher education; or income from service on advisory committees or review panels for a Federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

**POLICY STATEMENTS:**

A. Individuals should avoid conflicts of commitment, be careful to follow rules and requirements of time allocation, and ensure the appropriate use of Medical Center's personnel and resources.

1. Funded researchers must follow rules for cost accounting and honor time commitments they have made, such as devoting a specified percentage of time to grant or contract; refrain from charging two sources of funding for the same time; and seek advice if they are unsure whether a particular commitment of time is allowed under the Institution's or Federal Government's policies.

2. Medical Center facilities, equipment, and personnel may be used only for Medical Center activities and purposes, except when the Medical Center specifically authorizes other uses.

3. Individuals who intend to engage in any external activity that requires effort outside of the Medical Center that creates a risk of divided loyalty between the Medical Center and an outside entity, or otherwise interferes with their professional obligations and commitments to the Medical Center, must disclose and obtain written approval from their unconflicted people leader.

B. Disclosure Requirements for Investigators Proposing to or Awarded funds from PHS and other funding agencies.

1. Any member of the Medical and Dental Staff, employee, or researcher meeting the definition of Investigator (*see* Section I. above) must complete, at the proposal stage and as may be necessary during the proposal review process, a disclosure statement of all Significant Financial Interests related to or resulting from their Institutional Responsibilities. Additionally, any member of the Medical and Dental Staff, employee, or researcher receiving research or sponsored support or who proposes to or receives awards from any sponsor must complete such a disclosure statement.

2. Investigators also must disclose Significant Financial Interests related to or resulting from their Institutional Responsibilities annually at the time of the non-competing renewal or other funding action, and within 30 days of discovering or acquiring a new Significant Financial Interest.

3. Investigators must also disclose the occurrence of any reimbursed or sponsored travel related to or resulting from their Institutional Responsibilities (including that which is paid on behalf of the Investigator but not reimbursed to the Investigator in such a manner that the exact monetary value if readily available).

C. Determination of Financial Conflicts of Interest

1. Related to any award that may result from a proposal, disclosures must be reviewed to determine if further action is required before the Medical Center expends any awarded funds or issues a purchase order or subcontracts for the acquisition of goods and services.

2. If the Research Compliance Officer of the Stanley Manne Children's Research

Institute (the "Research Institute") or their designee determines, after reviewing the disclosure form and other available information, that a Significant Financial Interest could affect the design, conduct, or reporting of research or sponsored program activities, the Research Compliance Officer or their designee will then review the matter to determine which of the following actions to take, which may include as applicable to:

a. Accept the proposed sponsored project;

b. Accept the proposed sponsored project provided certain conditions or restrictions are imposed so that the Financial Conflict of Interest will be managed, reduced or eliminated. In addition, the results of the evaluation and management plan will be disclosed to the chair of the appropriate compliance committee reviewing the research (i.e., IRB, IACUC, etc.) which has the final authority to decide whether or not to approve the protocol given the circumstances of the conflict of interest and its management. For research involving human subjects, the management plan will be reviewed and amended if necessary by the IRB. The following are examples of possible conditions or restrictions:

i. Public disclosure of Significant Financial Interests;
ii. For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
iii. Monitoring of research by independent reviewers;
iv. Modification of the research plan;
v. Disqualification from participation in the portion of the sponsored funded research project that would be affected by the Significant Financial Interest;
vi. Divestiture of Significant Financial Interests;
vii. Severance of relationships that create actual or potential conflicts;
viii. Disclosure of the FCOI in each public presentation of the results of research;
ix. Request an addendum to previously published presentations
x. Refuse the proposed sponsored project

3. If the Investigator is dissatisfied with the determination of the Research Compliance Officer or their designee, the Investigator may, within ten (10) calendar days of such determination, submit a written appeal to the Chief Operating Officer.

i. In reviewing the matter and determining whether a Financial Conflict of Interest exists and/or what actions should be taken to manage, reduce or eliminate a potential conflict, the Chief Operating Officer or their designee may consult with other Medical Center officials and staff as appropriate. After such review, the Chief Operating Officer, in consultation with the Chief Research Officer and President and Chief Executive Officer of the Medical Center and, if required under 2. b. above, the approval of the IRB, will make the final decision.

ii. The Chief Operating Officer's decision will be final, and any failure by the individual to adhere to the decision will be cause for disciplinary action, up to and including termination.

D. Retrospective Review and Reporting

1. Whenever, in the course of an ongoing sponsored project, an Investigator who is new to participating in the project discloses a Significant Financial Interest, or an existing Investigator discloses a new Significant Financial Interest, or the Medical Center identifies a Significant Financial Interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by the Medical Center, the Chief Operating Officer of the Research Institute and the Research Compliance Officer of the Medical Center shall, within sixty (60) days:

    a. Review the Significant Financial Interest;

    b. Determine whether the Significant Financial Interest relates to the sponsored project; and

    c. If so, implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such Financial Conflict of Interest as applicable.

2. Whenever a Financial Conflict of Interest is not identified or managed in a timely manner, including: failure by the Investigator to disclose a Significant Financial Interest that is determined by the Medical Center to constitute a Financial Conflict of Interest; failure by the Medical Center to review or manage such a Financial Conflict of Interest; or failure by the Investigator to comply with a Financial Conflict of Interest management plan, the Medical Center shall, within 120 days of the Medical Center's determination of noncompliance, complete a retrospective review of the Investigator's activities and the sponsored project to determine whether the project, or any portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.

    a. The Medical Center shall document the retrospective review, including, at a minimum:

        i. Project number;
        ii. Project title;
        iii. Principal Investigator;
        iv. Name of the Investigator with the Financial Conflict of Interest
        v. Name of the entity with which the Investigator has a Financial Conflicts of Interest;
        vi. Reason(s) for the retrospective review;
        vii. Detailed methodology used for the retrospective review (*e.g.*, methodology of the review process, composition of the review panel, documents reviewed;
        viii. Findings of the review; and
        ix. Conclusions of the review.

    b. Based on the results of the retrospective review, if appropriate, the Medical Center shall update the previously submitted Financial Conflict of Interest report, specifying the actions that will be taken to manage the Financial Conflict of Interest going forward.

c. If bias is found, the Medical Center is required to notify the PHS Awarding Component or other sponsor promptly and submit a mitigation report to the PHS Awarding Component or other sponsor as applicable. The mitigation report must include, at a minimum:

i. The key elements documented in the retrospective review (*see* above);
ii. A description of the impact of the bias on the research project; and
iii. The Medical Center's plan of action or actions taken to eliminate or mitigate the effect of the bias.

E. Reporting of Financial Conflicts of Interest to PHS and to the Public

1. The PHS and other sponsors regulations require the Medical Center to provide initial and ongoing reports on Investigators' Financial Conflicts of Interest to the funding agency.

2. For Financial Conflicts of Interest with other sponsors adopting the PHS (or similar) regulations, the Medical Center will provide the sponsor with Financial Conflict of Interest information as reflected by individual sponsor policy.

3. The information that the Medical Center must provide to PHS includes:

a. Grant number;
b. Principal Investigator;
c. Name of Investigator with the Financial Conflict of Interest;
d. Name of the entity with which the Investigator has a Financial Conflict of Interest;
e. Nature of the Financial Conflict of Interest (*e.g.*, equity, consulting fees, travel reimbursement, honoraria);
f. Value of the Significant Financial Interest ($0-4,9999; $5K-9,999; $10K-19,999; amounts between $20K-100K by increments of $20K; amounts above $100K by increments of $50K) or statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;
g. A description of how the Financial Interest relates to PHS-funded research and the basis for the Medical Center's determination that the Financial Interest conflicts with such research; and
h. Key elements of the Medical Centers management plan.

4. In addition to reporting Financial Conflicts of Interest to the PHS funding agency, PHS regulations require that the Medical Center make available to the public, within 5 calendar days, upon written request, the following information regarding Financial Conflicts of Interest for Senior/Key Personnel:

a. Investigator's name;
b. Investigator's title and role with respect to the research project;
c. Name of the entity in which the Significant Financial Interest is held;
d. Nature of the Significant Financial Interest; and
e. Value of the Significant Financial Interest ($0-4,9999; $5K-9,999; $10K-19,999; amounts between $20K-100K by increments of $20K; amounts above $100K by increments of $50K) or statement that the interest is one whose

value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

F. Training Requirements

1. The Medical Center will inform each Investigator of this policy, the Investigator's responsibilities regarding disclosure of Significant Financial Interests, and the applicable regulations, and require each Investigator to complete training regarding the same prior to engaging in research or sponsored programs related to any funded grant to which this policy applies and at least every four (4) years and immediately when any of the following circumstances exist:

2. The Medical Center revises its Financial Conflict of Interest Policies or procedures in any manner that affects the requirements of Investigators;

3. An Investigator is new to the Medical Center; or

4. The Medical Center finds that an Investigator is not in compliance with the Medical Center's Financial Conflict of Interest policy or management plan.

G. Ongoing management and reporting of Financial Conflicts of Interest to the PHS, other sponsors, and the public, in accordance with the established sponsor requirements, will be the responsibility of the Director of the Office of Sponsored Programs of the Research Institute.

H. Records of Investigator financial disclosures and of actions taken to manage actual or potential Financial Conflicts of Interest shall be retained by the Office of Research Integrity & Compliance until three (3) years after the latter of the termination or completion of the award to which they relate, or the resolution of any government action involving those records.

I. Collaborators/sub-recipients/subcontractors from other institutions involved in externally-sponsored projects of the Medical Center must either comply with this policy or provide a certification from their institutions that they are in compliance with the sponsor's requirements regarding disclosure of Financial Conflicts of Interest and that their portion of the project is in compliance with their institutional policies.

J. Please note that various federal agencies (e.g., PHS, National Science Foundation, Food and Drug Administration) and other non-federal agencies 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, Research Compliance.

K. Compliance

1. All persons subject to this policy are expected to comply with it fully and promptly. Whenever an Investigator has violated this policy, the Research Compliance Officer or their designee shall report such violation to the Chief Operating Officer and appropriate Medical Center officials as applicable and, where appropriate, sanctions will be imposed in accordance with the applicable Medical Center policies.

2. In addition, the Medical Center 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.

3. Covered Individuals who participate as a principal investigator, co-investigator, or senior or other key personnel in applicable federally-funded Medical Center Research may not participate in a Malign Foreign Talent Recruitment Program as that term is defined by the Federal Government.

L. Institutional Conflicts

1. In certain instances, the Medical Center may have an institutional conflict of interest in research based on the financial or other interests of the Medical Center itself or of its leadership. Where such conflicts have the potential to be significant, the Research Compliance Officer or their designee should report the interest and proposed management plan as applicable to the Chief Operating Officer, the Chief Research Officer, and the General Counsel or the Chief Compliance and Integrity Officer, provided such person is not believed to have a personal conflict, for further review and action.

2. In addition to financial interests of the Medical Center's leadership, institutional conflicts of interest include situations in which the financial investments or holdings of the Medical Center, gifts to the Medical Center (including restricted or unrestricted monetary gifts), or other financial interests of the Medical Center might affect or reasonably appear to affect institutional processes for the design, conduct, reporting, review or oversight of human subjects or other research.

3. Process for identification of potential institutional conflicts of interest with respect to human subjects or other research: In addition to information from the annual conflicts disclosures of the Medical Center's leadership, information on the Medical Center's financial interests should be reported to the Chief Operating Officer or their designee, at such frequency and according to such criteria as determined by the Chief Operating Officer:

    a. Stanley Manne Children's Research Institute, for licensing arrangements, patents, invention disclosures; and

    b. Lurie Children's Foundation, for gifts to the Medical Center from any for-profit organization or philanthropic unit associated with a for-profit organization.

4. If the institutional conflict of interest is considered to be significant, the matter should be evaluated to determine an appropriate response, which may include eliminating the conflict or instituting a management plan that seeks to have persons without a stake involved in the decision-making.

**REFERENCES:**

- Institutional Review Board Policies and Procedure Manual, Section 4.1: "Conflict of Interest (COI) for Sponsored Programs"
- 42 CFR 50 Subpart F "Responsibility of Applicants and Institutions for Promoting Objectivity in Research"

- Lurie Children s Hospital of Chicago Medical Center Policies Procedures - Workforce Conflict of Interest Policy.pdf - All Documents (sharepoint.com)
- Lurie Children s Hospital of Chicago Medical Center Policies Procedures - Vendor Relations.pdf - All Documents (sharepoint.com)