

ADMINISTRATIVE POLICY



NUMBER: XII-17

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Originated: 12/19/11

Reviewed: 10/10/18

Revised: 8/10/15

SUBJECT: INSTITUTIONAL CONFLICT OF INTEREST POLICY

POLICY: NCH, as defined below, shall have a process in order to identify significant institutional financial interests with the intent to appropriately manage the interests so that they do not compromise, or reasonably appear to compromise the integrity of NCH's primary missions, including the safety and integrity of its research.

PURPOSE: The purpose of this policy is to identify situations when an Institutional Conflict of Interest may arise and define a process for managing the Institutional Conflict of Interest.

SPECIAL INSTRUCTIONS:

1. Definitions:

- a. **Institutional Conflict of Interest ("ICOI"):** Whenever the financial interests of NCH or the personal financial interests of a Key Official either affect, or reasonably appear to affect, the design, conduct, reporting, review or oversight of research. The following external relationships or financial interests may trigger a potential ICOI:
 - i. Significant equity interest, greater than 5%, in a publicly traded for profit entity that is sponsoring human subjects research at NCH or whose product or service is being tested in such research;
 - ii. Any equity interest, including stock, stock option, or other ownership interest, in a non-publicly traded entity (i.e. start-up company);
 - iii. Receipt by NCH or a Key Official of royalties, fees or any other one time or periodic payment or the right to receive any such payment in the future under a patent or a copyright license, other license, assignment or other agreement related to a product or service that is being tested in human subjects research at NCH;
 - iv. Receipt or pledge of a gift or gifts to NCH exceeding \$500,000 in aggregate value from a company that is sponsoring human subjects research at the NCH or whose product or service is being tested in such research;
 - v. Appointment of a Key Official to serve as an officer, director or board member of a company sponsoring human subjects research

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at NCH or whose product or services is being tested in such research (not including an appointment as a member of a scientific advisory board of the company);

- vi. Personal receipt by a Key Official of or the right to receive consulting fees, honoraria, gifts, or other compensation exceeding \$25,000 in one year from a company sponsoring human subjects research at NCH or whose product or service is being tested in such research; provided that such payments are received or such rights accrue during the course of the research or within one year of the start or completion of the research; or
 - vii. Such other external relationships and financial interests that could directly and significantly affect human subjects research at NCH.
- b. **Key Official:** As used in this Policy, Key Official includes the Chief Executive Officer, Presidents of any NCH affiliated corporation, all NCH Vice Presidents, Department Chairs, Section/Division Chiefs, Chair of the Institutional Review Board ("IRB"), Executive Director, Research Planning and Business Development, Director, Technology Commercialization and research Center Directors.
- c. **Nationwide Children's Hospital:** As used in this Policy, Nationwide Children's Hospital or "NCH" shall include Nationwide Children's Hospital, Inc. and all of its affiliated corporations, including but not limited to The Research Institute at Nationwide Children's Hospital and the Nationwide Children's Hospital Foundation.
- d. **Institutional Official:** Corporate Compliance Officer, or his/her designee, responsible for the review and oversight of potential ICOI.
- e. **Research Conflict of Interest Committee ("RCOIC"):** A designated group, approved by the Corporate Compliance Steering Committee (CCSC), whose duties include, but are not limited to, assisting the Institutional Official in managing or resolving potential Institutional Conflicts of Interest. The RCOIC serves in an advisory role to the CCSC on conflict of interest matters.

2. Disclosure Process:

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- a. **Disclosure by Key Officials:** Disclosure of external relationships and financial interests held by Key Officials shall be made on an annual basis in accordance with the NCH Conflict of Interest Policy. Copies of these annual disclosures shall be transmitted to the Institutional Official. Key Officials have an ongoing obligation, pursuant to the NCH Conflict of Interest Policy, to update their annual disclosure form.
- b. **Disclosures of Intellectual Property and Equity Interests:** NCH Managers and key departments, including but not limited to, Office of Technology Commercialization and Hospital and Research Finance departments, shall report to the Institutional Official the receipt of any significant equity interest, royalties, fees or any other one time or periodic payment pursuant to a patent, license, assignment or other agreement from an outside company. Reports shall be made within one hundred and twenty (120) days of receipt of the acquisition and on an annual basis.
- c. **Disclosures of Gifts and Grants:** NCH Management and key offices, including but not limited to, NCH Foundation, NCH Education department and Sponsored Projects, will report to the Institutional Official gifts, grants or pledges to NCH from any company when such gifts, grants or pledges exceed \$500,000 in a fiscal year. Reports shall be made within one hundred and twenty (120) days of receipt of such gifts, and on an annual basis.

3. Review Process:

- a. The Institutional Official will review all disclosures referred to him/her and make a preliminary determination as to whether any of the external relationships and financial interests reported constitute potential ICOI. The Institutional Official may engage the RCOIC to review the potential ICOI. Members of the RCOIC with potential conflicts with the subject matter under review will be recused from the RCOIC, if applicable.
- b. The RCOIC will convene at the request of the Institutional Official (at least annually) to review any disclosures of external relationships and financial interests referred to it by the Institutional Official. The RCOIC will determine whether an ICOI exists and how to resolve each Institutional Conflict of Interest on a case-by-case basis taking into consideration several factors, including but not limited to:

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- i. The nature of the affected research;
- ii. The nature of the external relationship or financial interest;
- iii. How closely the external relationship or financial interest is related to the research;
- iv. The degree of risk that the research poses to human subjects;
- v. The degree to which the interest may affect or be affected by the research;
- vi. Whether NCH is well qualified to conduct the research;
- vii. The degree of risk that the research will not be pursued if not conducted by NCH;
- viii. Whether other institutions are well qualified to conduct the research;
- ix. The effectiveness of managing, reducing or eliminating the ICOI through recusal, divestiture or independent oversight of the affected research;
- x. The ability to minimize/eliminate the conflicted Key Official's role in the research.

4. **Resolution Process:** If the RCOIC determines an ICOI exists, the RCOIC shall recommend how the ICOI should be managed, reduced or eliminated.

- a. The following conditions or restrictions may be part of the Institutional Conflict of Interest resolution, but other resolution options may be appropriate depending on the unique facts of the conflict to be managed:
 - i. Public disclosure of the ICOI and how it will be resolved;
 - ii. Monitoring of any affected research by independent reviewers;
 - iii. Modification of the research plan;
 - iv. Disclosure of ICOI to participants in human subject research;
 - v. Disqualification of NCH from participation in all or a portion of the research;
 - vi. Reduction or elimination of the Financial Interest;
 - vii. Modification of role of the conflicted Key Official in relation to the research;
 - viii. Severance of the relationship that creates the ICOI.
- b. All recommendations for ICOI management shall be reviewed by the CCSC.

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- c. The Institutional Official shall prepare the Conflict Management Plan ("Plan"). Each Plan shall specifically state who will be responsible for the Plan's implementation and monitoring.
- d. At least annually, the Institutional Official shall report all existing Institutional Conflict Management Plans to the Corporate Compliance Steering Committee and the Budget, Finance and Audit Committee of the Board of Directors.

Approved by:

Richard J. Miller, Chief Operating Officer

Signature on File