



Abigail Wexner Research Institute

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Title: Research Conflict of Interest

- I. **Scope:** This policy applies to all individuals who are participating in research at Nationwide Children's Hospital, Inc. and its affiliated corporations, including The Abigail Wexner Research Institute ("AWRI"), collectively referred to in this document as ("NCH").
- II. **Purpose:** The purpose of this policy is to ensure an individual's significant financial interests do not jeopardize the objectivity of research conducted at NCH.
- III. **Definitions:**
 - A. **COI Disclosure Form:** Electronic disclosure form, completed by the Investigator, that lists the Financial Interests of the Investigator (also known as the COI disclosure certification form or COI Profile).
 - B. **Conflict of Commitment:** A conflict between competing demands upon the time and energy of a person as a result of outside activities that interfere with their obligations to NCH.
 - C. **eCOI:** A web-based research tracking system through which an Investigator completes a COI Disclosure Form.
 - D. **Financial Interest:** Anything of monetary value or potential monetary value, including, but not limited to, any payment received for services rendered, consulting fees, honoraria, paid authorship, travel reimbursement, stock, stock options, intellectual property licensing/royalty payments, or other ownership or equity interests.
 - E. **Institutional Official:** The individual designated by NCH to oversee the solicitation and review of Financial Disclosure Forms from any Investigators who will be participating in research. The Chief Compliance Officer, or his/her/their designee, is the Institutional Official for the purposes set forth in this policy.
 - F. **Institutional Responsibilities:** An Investigator's professional responsibilities on behalf of NCH, including but not limited to research, research consultation, teaching, professional practice, institutional committee memberships, and service



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on panels such as Institutional Review Boards (“IRB”) or Data and Safety Monitoring Boards.

- G. Investigator:** Project Director or Principal Investigator (“PI”), or any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research. “Investigator” may include persons who are sub grantees, subcontractors, collaborators, or consultants.
- H. Key Personnel:** Project Director or PI and any other person identified as key personnel by the Institution in the grant application, progress report, or any other report submitted to the Public Health Service (“PHS”) by NCH.
- I. Public Health Service (“PHS”) Agencies:** (1) the Agency for Healthcare Research and Quality (AHRQ); (2) the Agency for Toxic Substances and Disease Registry (ATSDR); (3) the Centers for Disease Control and Prevention (CDC); (4) the Food and Drug Administration (FDA); (5) the Health Resources and Services Administration (HRSA); (6) the Indian Health Service (IHS); (7) the National Institutes of Health (NIH); and (8) the Substance Abuse and Mental Health Services Administration (SAMHSA).
- J. Research Conflict of Interest Committee:** A designated group, approved by the Compliance Steering Committee, to assist the Institutional Official in managing or resolving potential Financial Conflicts of Interests.
- K. Research Funds:** Any monetary funds received by an Investigator to pursue a research project, including, but not limited to funds from a government source (e.g. National Institutes of Health “NIH” or Public Health Service “PHS” funds), a private organization, or an internal source.
- L. Significant Financial Interest (“SFI”):** A Financial Interest consisting of one or more of the following interests related in any way to the Investigator's Institutional Responsibilities:
1. Remuneration or honoraria received from domestic or foreign entities if valued at more than \$5,000.
 2. Income from intellectual property rights and interests, including but not limited to option fees, licensing fees and/or royalties.

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3. Ownership interests (stocks, dividends, equity) in a publicly-traded company valued at more than \$5,000.
4. Ownership or equity interests that are held in non-publicly traded domestic or foreign entities (i.e. start-up company).
5. Any financial remuneration received from a non-publicly traded domestic or foreign entity in the last twelve months, when aggregated, exceeds \$5,000.
6. Holding a management position (e.g. director, officer) in a non-NCH domestic or foreign entity, regardless of compensation.

Financial Interests received from the same entity are added together, along with any interests possessed by the Investigator's spouse or domestic partner and dependent children, and the aggregate value is used to determine the limits set forth above.

IV. Policy Statement: NCH will manage, minimize or eliminate Financial Conflicts of Interest of Investigators to ensure that research will be free from bias that could result from an Investigator's Financial Interest(s).

A. Disclosure Requirements – When and what information must be disclosed:

Investigators are required to update their COI Financial Disclosure Form within thirty (30) days of discovering or acquiring a new interest identified above.

1. Time Requirements for Submission of COI Disclosure Form:

- a. **Research Funds:** All investigators and Senior/Key personnel are required to have an Updated COI Disclosure Form in eCOI no later than the time of application for Research Funds and within 30 days of Research Funds being awarded.
- b. **IRB Submissions:** Before a research submission is approved by the IRB, COI Disclosure Forms for individuals listed on the IRB protocol must be submitted to and reviewed by the Institutional Official. All identified conflicts must be managed, mitigated or eliminated before the IRB approves the research submission. The IRB may impose any additional interventions they determine to be appropriate and necessary to protect human subjects.

2. Information required to be disclosed: Investigators must disclose their and their immediate family members' (spouse/domestic partner, dependent children) financial and fiduciary relationships with domestic and foreign

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entities, unless otherwise excluded by this section. Investigators shall provide the following minimum information on their COI Disclosure Form:

- a. **Financial Interests.** Any payment or remuneration related to a Financial Interest must be disclosed if the remuneration was received within the last 12 calendar months from time of completing the COI Disclosure Form.
- b. **Intellectual Property.** All intellectual property interests must be disclosed, regardless of whether any payments are received related to the intellectual property. Intellectual property interests must continue to be disclosed regardless of when the interest was obtained or if it is related to NCH.
- c. **Appointments.** Outside positions held regardless of whether compensation is received. Such interest must be disclosed for 12 months after position is resigned.
- d. **Fiduciary Roles.** Executive, C-level, or Board of Director positions with an outside entity, regardless of compensation or whether the entity is for-profit or not-for-profit. Such interest must be disclosed for 12 months after position is resigned.
- e. **Travel.** Any travel funded or reimbursed by any entity, including travel related to the Investigator's Institutional Responsibilities, must be reported. Sponsored travel must be reported for 12 months after the travel occurred or was reimbursed. The Investigator must report the following information about the travel:
 - Sponsor/Organizer of the travel;
 - Purpose of the trip;
 - Destination; and
 - Duration/dates of travel.
- f. **Exceptions to Travel Disclosure Requirement.**
 - i. Travel paid/reimbursed by NCH and NOT reimbursed by an outside entity.
 - ii. Travel funded by the following entities:
 - U.S. government entities (domestic federal, state, or local governmental agency);
 - U.S. institution of higher education;
 - U.S. academic teaching hospital;
 - U.S. academic medical center;
 - U.S. research institute that is affiliated with an Institution of higher education.

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- B. Affiliations:** Investigators must disclose affiliations with outside domestic or foreign entities, including those that provide Research Funds or donations to NCH, or that may be perceived as a competing entity. Such affiliation must continue to be disclosed for 12 months after relationship is ended.
- C. Foreign Talent Recruitment Programs:** Individuals interested in participating in a foreign talent recruitment program (not malign) are required to obtain NCH approval prior to participating in the program. Upon approval, NCH personnel must disclose the foreign talent recruitment program activity on their COI disclosure form in accordance with NCH COI policy. Participation in the program must continue to be disclosed for 12 months after participation has ended.
- D. Malign Foreign Government Talent Recruitment Program:** Participation in a Malign Foreign Government Talent Recruitment Program (as defined in the CHIPS Act, Section 10638) by any NCH personnel, physician, or researcher is strictly prohibited. In general, a Malign Foreign Talent Recruitment Program is a foreign talent program or position having problematic sponsorship and requiring participants to engage in one or more problematic actions or activities.
- E. Conflict of Interest Review Process:**
1. The Institutional Official or his/her/their designee is responsible for reviewing all COI Disclosure Forms for SFI and Conflicts of Commitment.
 2. For COI Disclosure Forms containing SFIs or large amounts of travel, the Institutional Official will determine if there is a Financial Conflict of Interest (FCOI) or Conflict of Commitment. The Research Conflict of Interest Committee will review Investigator disclosures as needed to make this determination.
 3. For SFI disclosures made after the expenditure of Research Funds, the Institutional Official shall, within sixty (60) days of the disclosure, determine if the SFI creates a FCOI.
- F. Conflict Management:**
If there is a determination that the SFI creates a Financial Conflict of Interest for the Investigator, a Conflict Management Plan will be developed.

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1. The Institutional Official or his/her/their designee shall develop a Conflict Management Plan for all Investigators with FCOIs.
2. **FCOI Report for PHS-funded research projects:**
 - a. For research projects funded by PHS, NCH shall not expend any funds until a FCOI report is submitted to the PHS Awarding Component, unless the conflict arises or is discovered after the initial expenditure of funds. The Institutional Official or the Vice President of Research Planning and Finance, or their designee, shall be responsible for submitting the FCOI report. Such report will contain all minimum information required by 42 CFR 50.605, including:
 - i. Project Number;
 - ii. PI or Contact PI if multiple PI model is used;
 - iii. Name of the Investigator with the FCOI;
 - iv. Name of the domestic or foreign entity with which the Investigator has a FCOI;
 - v. Nature of the financial interest;
 - vi. Value of the financial interest, or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measure of fair market value;
 - vii. A description of how the financial interest relates to the PHS-funded research and the basis for NCH's determination that the financial interest conflicts with such research; and
 - viii. A description of the key elements of NCH's conflict management plan, including:
 - a) Role and principal duties of the conflicted investigator in the research project;
 - b) Conditions of the management plan;
 - c) How the management plan is designed to safeguard objectivity in the research project;
 - d) Confirmation of the investigator's agreement to the management plan;
 - e) How the management plan will be monitored to ensure investigator compliance;
 - f) Other information as needed or requested by the funding agency.
 - b. For FCOIs that arise or are discovered after expenditure of Research Funds, NCH shall submit a FCOI report within sixty (60) days after identification of the FCOI.

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- c. **Annual reports:** For FCOIs previously reported by the Institution to the PHS agency, the Institution shall provide an annual FCOI report that addresses the status of the financial conflict of interest and any changes to the management plan for the duration of the PHS-funded research project.

G. Acceptance of Plan:

Investigator's acceptance of the Conflict Management Plan shall be documented by the Investigator's electric signature on the conflict management plan. After the conflict managed plan has been signed, it shall be accepted by the Investigator in eCOI.

H. Communication of Plan:

Conflict Management Plans for clinical trial studies will be shared with the IRB. Plans may be shared with others involved with the research study in question, if deemed necessary by the Institutional Official to ensure the objectivity of the research.

I. Untimely Disclosures:

1. When NCH discovers a SFI that was not disclosed timely by an Investigator, or, for whatever reason, was not previously reviewed by NCH during an ongoing research project, the Institutional Official, with the assistance of the Research Conflict of Interest Committee, shall, within sixty (60) days, perform the following:
 - a. Review the SFI;
 - b. Determine whether it is related to PHS-funded research;
 - c. Determine whether an FCOI exists.
2. If a FCOI exists:
 - a. The Institutional Official shall implement a Conflict Management Plan with specific actions that have been or will be taken;
 - b. If PHS funding is involved, NCH shall submit the FCOI report to the PHS funding agency;
 - c. If failure to timely disclose/identify the FCOI is due to noncompliance with policy, NCH shall, within 120 days of the determination of non-compliance, complete a retrospective review of the Investigator's activities and the research to determine if, during the non-compliance, there is bias in the design, conduct or reporting of such research;



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- d. If bias is found in a PHS-funded study, NCH shall promptly notify the PHS Awarding Component and submit a mitigation report. Additional administrative or corrective actions may be considered, as appropriate.

J. Education Requirements:

1. Prior to an Investigator engaging in research related to any PHS-funded grant, NCH shall inform and educate the Investigator of the NCH's policy on Financial Conflicts of Interest, the Investigator's responsibilities regarding disclosure of Significant Financial Interests, and of the federal regulations governing conflict of interest disclosure. Education shall be required at least every four (4) years). Education shall be provided through eCOI or another educational medium approved by The Research Conflict of Interest Committee.
2. In addition to the requirements set forth in the previous paragraph, education shall be required immediately under the following circumstances:
 - a. The Institution revises its conflict of interest policies or procedures that affects the requirements of Investigators;
 - b. An Investigator is new to an Institution and will be engaging in PHS-funded research; or
 - c. An Institution finds that an Investigator is not in compliance with the Institution's Conflict of Interest Policy or his/her Conflict Management Plan.

K. Public Disclosure Requests:

1. The Public Disclosure requirements may apply to those interests that are determined to be a FCOI. Public requests must be made in writing and must include a named recipient and return address with a physical street address. All public inquiries about an Investigator's FCOI (if any) must be submitted to the following address:

Vice President and Chief Compliance Officer
Nationwide Children's Hospital, Inc.
431 South 18th Street
Columbus OH 43205

2. All written requests will receive a written response within five (5) days of the request, with the following information:
 - a. Project number;

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- b. Name of the Investigator with a conflicted interest;
- c. Investigator's title and role with respect to the research project;
- d. Nature of the Financial Interest(s);
- e. Value of the Financial Interest(s) (in ranges).

L. Applicability to Sub Recipients:

1. When NCH, as the awardee Institution, subcontracts with a sub recipient on a PHS-funded study, the written agreement between the parties shall state which party's conflict of interest policy applies to the sub recipient's investigators.
2. If the written agreement states the sub recipient's policy applies, the agreement shall state the following:
 - a. Certification that the sub recipient policy complies with the current PHS regulation on conflict of interest;
 - b. Specifications on time period for the sub recipient to report all identified FCOIs to NCH. The specified time period must provide enough time for NCH to provide timely FCOI reports, as necessary, to the PHS awarding entity.

If the written agreement states NCH's policy applies, the sub recipient shall provide all FCOI reports to NCH prior to the expenditure of funds and within sixty (60) days of subsequently identified FCOIs.

M. Investigator Compliance and Remedy:

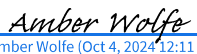
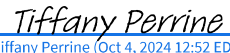
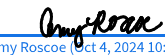
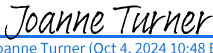
An Investigator's failure to comply with the Conflict of Interest Policy or procedures or with a Conflict Management Plan will be subject to review by the NCH Chief Scientific Officer. If the Institutional Official and/or the Research COI Committee determines that a violation of the policy or procedures may have occurred, they will refer the matter to the Chief Scientific Officer for further action, in accordance with NCH applicable policies/procedures.

V. History: Updated for content and signature lines.

VI. References: 42 CFR Part 50, 45 CFR Part 94, Conflict of Interest or Commitment Policy (ADMIN –XII-10), PAA External Consulting Policy, and Research Policy: Faculty Members and Employees Engaged in Research and Paid External Consulting or Other Activities (Research –Administration-011-00).

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REVIEWED/REVISED BY: MICHELE NGUYEN CONFLICTS OF INTEREST ADMINISTRATOR NATIONWIDE CHILDREN'S HOSPITAL	 Michelle Nguyen (Oct 8, 2024 09:12 EDT)	Oct 8, 2024
REVIEWED/REVISED BY: AMBER WOLFE CONFLICTS OF INTEREST SUPERVISOR NATIONWIDE CHILDREN'S HOSPITAL	 Amber Wolfe (Oct 4, 2024 12:11 EDT)	Oct 4, 2024
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REVIEWED BY: AMY ROSCOE VP RESEARCH STRATEGIC PLANNING & FINANCE ABIGAIL WEXNER RESEARCH INSTITUTE	 Amy Roscoe (Oct 4, 2024 10:56 EDT)	Oct 4, 2024
REVIEWED BY: JOANNE TURNER CHIEF SCIENTIFIC OFFICER ABIGAIL WEXNER RESEARCH INSTITUTE	 Joanne Turner (Oct 4, 2024 10:48 EDT)	Oct 4, 2024
APPROVED BY: DENNIS DURBIN, MD PRESIDENT ABIGAIL WEXNER RESEARCH INSTITUTE		Oct 6, 2024