



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. **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, licensing, or other ownership or equity interests that are reasonably related to the Investigator's Institutional Responsibilities.
 - B. **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 on panels such as Institutional Review Boards (IRB) or Data and Safety Monitoring Boards.
 - C. **Significant Financial Interest:** Interest held individually by the Investigator, his/her/their spouse or domestic partner, and dependent children must be added together and the aggregate value used to determine limits set forth below:
 - 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.
 - 3. Ownership interests (stocks, dividends, equity) 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.



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- D. Financial Conflict of Interest: Significant Financial Interest that could directly and significantly affect the design, conduct or reporting of research.
- 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. Financial Disclosure Form (FDF): Electronic eTRAC document, completed by the Investigator, that lists the Financial Interests of the Investigator (also known as the COI disclosure certification form).
- G. eTRAC: A web-based research tracking system through which an Investigator completes a FDF (also known as a COI disclosure certification form).
- H. Institution: Nationwide Children's Hospital and its affiliated corporations, including the AWRI.
- I. 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.
- J. Senior/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.
- K. Research Conflict of Interest Committee: A designated group, approved by the Corporate Compliance Steering Committee, to assist the Institutional Official in managing or resolving potential Financial Conflicts of Interests.
- L. 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.
- M. Public Health Service ("PHS") Agencies: (1) the Agency for Healthcare Research and Quality (AHRQ), (2) the Agency for Toxic Substances and Disease



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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).

IV. 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).

V. 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. Financial Disclosure Requirements – When and what information must be disclosed

1. Time Requirements for Submission of Financial Disclosure Form (FDF):
 - a. **Research Funds:** Each Investigator and Senior/Key Personnel are required to have an updated FDF, also known as the COI disclosure certification form, in eTRAC no later than the time of application for Research Funds.
 - b. **IRB Submissions:** Before a protocol is submitted to the IRB, FDFs for individuals listed on the IRB protocols must be submitted to the Institutional Official. All identified conflicts must be managed, mitigated or eliminated before the IRB completes its review.
2. The Investigator shall provide the following minimum information on the FDF. Disclosures must include events that **arise in the 12 months preceding** the completion or updating of the FDF.
 - a. **Financial Interests.** For Financial Interests involving remuneration, the Financial Interest must be disclosed if the remuneration was received within the last 12 calendar months from time of completing the FDF.
 - b. **Patents, Patent Applications, Copyrights, Royalties and/or Licensing Payments.**
 - c. **Travel.** Sponsored (Paid by an outside domestic or foreign entity) or reimbursed travel related to an Investigator's Institutional Responsibilities, including teaching, research, clinical, consulting or administrative duties



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must be reported. The Investigator must report the following information about the travel:

- i. Sponsor/Organizer of the travel;
- ii. Purpose of the trip;
- iii. Destination;
- iv. Duration/dates of travel.

Travel does not need to be disclosed if NCH pays for the travel and is NOT reimbursed by an outside domestic or foreign entity.

The disclosure requirement does not apply to travel for or on behalf of 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.**

d. **Affiliations** with outside domestic or foreign entities that provide Research Funds or donations to NCH, or that may be perceived as a competing entity.

3. Investigators are required to update the FDF within thirty (30) days of discovering or acquiring a new Significant Financial Interest.
4. FDFs, unless updated throughout the year in accordance with this Policy, must be updated at least annually by the Investigator.

B. Conflict of Interest Review Process

1. The Institutional Official or his/her/their designee is responsible for reviewing all FDFs with Significant Financial Interests (SFI).
2. For FDFs containing SFIs or large amounts of travel, the Institutional Official will determine if there is a Financial Conflict of Interest (FCOI). The Research Conflict of Interest Committee will review Investigator disclosures as needed to make this determination.



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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.

C. 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.

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, the AWRI 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;



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- 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.
 - 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.

D. Acceptance of Plan

The Investigator's acceptance of the Conflict Management Plan shall occur in eTRAC. Acceptance in eTRAC will serve as the Investigator's acknowledgement and agreement to Plan, equivalent to a signature.

E. 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.

F. 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 a FCOI exists.



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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 a 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;
 - d. If bias is found in a PHS-funded study, NCH shall promptly notify the PHS Awarding Component and submit a mitigation report.

G. Education Requirements

1. Prior to an Investigator engaging in research related to any PHS-funded grant, the AWRI shall inform and educate the Investigator of the AWRI'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 every four (4) years. Education shall be provided through eTRAC 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.

H. 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.



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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;
 - 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).

I. 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.

J. 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



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COI Committee determines that a violation of the policy or procedures may have occurred, he/she/they will refer the matter to the Chief Scientific Officer for further action, in accordance with NCH applicable policies/procedures.

VI. History: This policy was previous known as Research-Compliance-003-04 Research Conflict of Interest.

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APPROVED BY: JOHN BARNARD PRESIDENT ABIGAIL WEXNER RESEARCH INSTITUTE	 John Barnard (Nov 17, 2020 07:47 EST)	Nov 17, 2020