

Research Financial Conflict of Interest

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Policy: To safeguard the integrity and reputation of our research program, Children's Minnesota (Children's) requires all study investigators, and applicable subcontractors and sub awardees who participate in research activities on behalf of Children's to report financial conflicts of interests relating to research in order to comply with applicable regulations.

Definitions:

Financial Conflict of Interest (FCOI): Significant financial interest that could directly and significantly affect the design, conduct, or reporting of research.

Significant Financial Interest: A financial interest of one or more of the following of, which reasonably appears to be related to the investigator's institutional responsibilities:

- (1) **Publicly traded companies** - any remuneration (consulting fees, honorarium, paid authorship, stock, stock option, ownership interest) exceeding \$5,000 in the previous twelve months;
- (2) **Privately held companies** – any remuneration exceeding \$5,000 in the previous twelve months when the investigator (or spouse or dependents) holds any stock, stock options or ownership interests;
- (3) **Intellectual property rights and interests** - exists upon receipt of any income related to such rights and interests; and
- (4) **Sponsored travel** – any reimbursed or sponsored travel related to their institutional responsibilities.

FCOI Committee: An interdisciplinary group appointed by Compliance to review potential conflict of interest management plans and disciplinary actions due to non-compliance with this policy. Members include the Chief Research Officer and representatives from Compliance, Legal, IRB and HR. The committee will meet quarterly and as determined by Compliance.

Procedure: Investigators must certify, on an annual basis, that they have read Children's Financial Conflict of Interest ("FCOI") policy and will conduct their research in a manner that avoids financial conflicts of interest. Investigators must disclose actual or potential FCOI and cooperate with any FCOI management plans developed for them. This policy does not apply to unfunded chart reviews.

Disclosure: Investigators must disclose an FCOI for each separate protocol in the following situations: (1) Upon initial application for approval by the IRB; (2) during annual continuing review; and (3) any time a new FCOI is discovered or acquired.

Compliance and the IRB are responsible for soliciting and reviewing all FCOI disclosures to determine if a significant financial interest exists in relation to research. All investigators must submit their Financial Conflict

of Interest Disclosure Form (“FCOI Disclosure Form”) to Compliance and the IRB as outlined below.

Prior to Applying for Research Approval

For each study submitted to Children’s IRB for approval, investigators must submit an FCOI disclosure form, which the IRB Administrator will forward to Compliance. For studies submitted to a non-Children’s IRB, the Director of RSP is responsible for ensuring each investigator has filed a current FCOI disclosure form with Children’s IRB and Compliance.

Annual Update

All investigators must submit annual FCOI updates during their annual continuing review.

Discovery or Acquisition of New FCOI

At any time in which an investigator discovers or acquires a new FCOI, or if the value of a previously disclosed financial interest increases in value such that it constitutes a significant financial interest, the investigator must fill out an FCOI disclosure and submit it to Compliance within 30 days of the discovery or acquisition.

Initial Review of FCOI Disclosure

Within 30 days of the submission of an FCOI Disclosure Form, Compliance and the IRB will do an initial review of the disclosure and decide whether the conflict requires a FCOI management plan. Investigators will be notified by Compliance of the result of the initial conflict review and any necessary next steps. All conflicts that require an FCOI management plan will be reported to the FCOI Committee for review and approval.

Management Plan: For all FCOIs requiring a management plan, Compliance will work with the Investigator and the Chief Research Officer to determine how objectivity will be maintained in research. The management plan will outline: (1) the role and duties of the investigator in relation to the conflict; (2) provisions for monitoring compliance to the management plan; (3) reporting responsibilities and (4) sanctions where appropriate. Management plans will be provided to Sponsors based on sponsor requirements.

FCOI Committee: The FCOI Committee will meet, as directed by Compliance and the IRB. Within 30 days of the submission of an FCOI management plan, the FCOI Committee will either approve or disapprove of the disclosed conflict and the FCOI management plan. Compliance will report the results of the FCOI determinations to the Chief Research Officer, the Director of Research and Sponsored Programs, the IRB Administrator, and the Research Council. The Director of RSP will inform the study sponsors that require notification of the conflict, including the remedial action taken.

Record-Keeping: Compliance will maintain records, identifiable to each research project, of all disclosures and actions taken to manage any actual or potential conflicts of interests for at least three (3) years beyond the termination or completion of the award, or until resolution of any action by any federal agency involving the records—whichever is longer.

The Director of RSP is responsible for ensuring that each Investigator submitting a grant for research, either federal or non-federal, has a current FCOI disclosure form on file at the time of submission, and that the Investigator's FCOI training is documented and current. When submission involves Subrecipients, the Grants Department is responsible for ensuring that a written agreement is established with the subrecipient institution, to include terms set forth in this Policy.

Training: Children's will provide mandatory FCOI training through CITI every four years. In addition, training will be required: (1) if policy changes occur; (2) when an investigator is new to Children's; and (3) when an investigator is found to be non-compliant with the policy or management plan

Non-Compliance: When an FCOI is not disclosed or managed immediately or within 30 days of the new conflict occurring, Children's IRB and Compliance will complete a review of the investigator's activities and the funded research project within in 120 days of learning about the FCOI to determine whether any research conducted during the time period of noncompliance was biased in design, conduct, or reporting.

Children's IRB will document the retrospective review in their electronic system including the following key elements:

1. IRB number;
2. Project title;
3. PD/PI;
4. Name of the investigator with the FCOI;
5. Name of the entity with which the investigator has a FCOI;
6. Reason(s) for the retrospective review;
7. Detailed methodology used for the retrospective review;
8. Findings of the review; and
9. Conclusions of the review.

Failure to comply with this policy may lead to disciplinary action including, but not limited to, removal from a research project.

Internal Reporting: Compliance shall prepare an Annual Summary Report to the Research Council, including number of disclosures received and management plans developed. This information will be included with the Open Payments Data.

External Reporting (PHS): Initial: Prior to using any PHS funds, Compliance will submit a FCOI report for identified FCOI to the PHS. If an identified FCOI is eliminated prior to expenditure of PHS funds, an FCOI report is not required.

Annual: For ongoing PHS-funded research, Compliance will submit annual reports to the PHS for FCOI submitted in the previous year. The report will specify whether the conflict is still being managed or explain why it no longer exists.

New/Updated: If an FCOI is identified subsequent to the initial FCOI report during an ongoing PHS-funded project, Compliance will submit an FCOI report to PHS within 60 days of the determination.

Bias: If the failure of an investigator to comply with the Children's FCOI policy or management plan has biased any PHS-funded research, Children's must promptly notify the HS agency of any correction action.

Subrecipient Monitoring: Children’s Research and Sponsored Programs (RSP) will ensure that all subrecipient agreements define whether Children’s FCOI policy or the subrecipient’s organizational FCOI policy will be applied for purposes of disclosure requirements.

Public Accessibility: Prior to Children’s expenditure of any research funds, Children’s shall ensure public accountability as follows:

1. Keep a current copy of this policy on Children’s public website;
2. Respond in writing within five (5) business days to any request for information concerning identified financial conflicts disclosed by Children’s investigators that meet the following criteria:
 - a. SFI was disclosed and is still held by the investigator;
 - b. Children’s determined that the SFI is related to either federal or non-federal research being conducted at Children’s; and
 - c. Children’s determined that the SFI is an FCOI
 - d. Information released to the requester will include
 - i. Investigator’s name, title and role in research
 - ii. Name of entity in which SFI is held;
 - iii. Nature and dollar value range;
 - iv. Justification of why value cannot easily be determined; and
 - v. General statement about how SFI is being managed.

References: 42 C.F.R. part 50, subpart F (grants and cooperative agreements); and 45 C.F.R. part 94 (contracts).

FDA’s financial disclosure regulations are codified at 21 C.F.R. part 54. (45 CFR part 46, 21 CFR parts 50, 56)

Related Documents: Financial Conflict of Interest FAQs

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Approval Group(s):
Version #

	Group	Date
1	Research Committee	4/16/21
1	Administrative Policy Committee	5/13/21