

Child Mind Institute

Policy on Financial Conflicts of Interest For PHS-funded Projects

Table of Contents

I.	Introduction	3
II.	Relevant Regulations	3
III.	Applicability.....	3
IV.	Definitions	3
V.	Responsibilities	6
VI.	Public Accessibility	7
VII.	Training Requirement	7
VIII.	Subrecipients	7
IX.	Institutional Official	8
X.	Disclosures Required of Investigators	8
XI.	Guidelines for Analyzing Financial Interests.....	9
XII.	Management of Financial Conflicts of Interest	10
XIII.	Handling Noncompliance.....	12
XIV.	Reporting FCOI's to the Public	13
XV.	Reporting FCOI's to the PHS	14
XVI.	Maintenance of Records.....	15
XVII.	Enforcement mechanisms and sanctions	16
XVIII.	Policy Changes	16
	Form A – Part 1	17
	Form A – Part 2	19
	Form B21	
	Form C23	
	Form D25	

I. Introduction

The Child Mind Institute (CMI) recognizes the importance of promoting objectivity in research for which Public Health Service funding is sought or accepted. In the design, conduct, and reporting of such research, the organization intends to avoid bias caused by financial conflicts of interest on the part of the investigator. This document elaborates CMI's policy on Financial Conflicts of Interest.

II. Relevant Regulations

CMI's policy is designed to comply with all regulations of the National Institutes of Health (NIH) and the Public Health Service (PHS). Specifically, CMI acknowledges the following portions of the Code of Federal Regulations as the source of such regulations and the guide for setting Organization policy:

- 42 CFR Part 50 Subpart F (grants and cooperative agreements)
- 45 CFR Part 94 (contracts)
 - Initial Regulation effective 10-1-95
 - http://grants.nih.gov/grants/compliance/42_CFR_50_Subpart_F.htm
 - Revised Final Rule published on 8-25-11
 - <http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>

III. Applicability

This policy applies to any CMI investigator who participates in the design, conduct or reporting of research supported by NIH or PHS as a result of a proposal submitted on or after July 1, 2012. The policy also applies to subawardees, as described in section VIII.

IV. Definitions

A. Research

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 NIH or any other PHS component. The funding may be a cooperative agreement, a research grant, a career development award, a center grant, an individual fellowship award, an infrastructure award, an institutional training grant, a program project, or a research resources award.

B. Investigator

An investigator is the project director or principal investigator or any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by NIH or PHS or proposed for such funding. Collaborators or consultants may be investigators.

C. Senior/key personnel

Senior/key personnel means the PD/PI and any other person identified as senior/key personnel in the grant application, progress report, or any other report submitted to the PHS by CMI as part of compliance with FCOI regulations. (This definition differs from the one found in the NIH Grants Policy Statement.)

D. PD/PI

PD/PI means a project director or principal investigator of a PHS-funded research project; the PD/PI is included in the definitions of senior/key personnel and Investigator.

E. Institutional Responsibilities

Institutional responsibilities are an investigator's professional responsibilities on behalf of Child Mind Institute. Examples of institutional responsibilities include—but are not limited to—research, research consultation, professional practice, and service on committees.

F. Financial Interest

A financial interest is anything of monetary value, whether or not the value is readily ascertainable.

A financial interest can be created by any of three routes:

1. Equity or remuneration from an entity

An investigator has a financial interest in an entity if, within the twelve months preceding the reporting date, the investigator receives remuneration from or owns equity in an entity. (A financial interest by the investigator's spouse or dependent child is considered to be a financial interest of the investigator.)

2. Revenue from intellectual property

An investigator has a financial interest in intellectual property (e.g. patents and copyrights) if he or she receives revenue from such property within the twelve months preceding the reporting date.

3. Travel

An investigator has a financial interest in travel if, within the twelve months preceding the reporting date, the investigator has received reimbursement or sponsorship for travel that is related to institutional responsibilities. (Sponsorship means that the travel is paid on behalf of the investigator, and the exact monetary value may not be readily available.)

G. Significant Financial Interest (SFI)

A financial interest rises to the level of a SFI only if three criteria are met:

1. The financial interest reasonably appears to be related to the investigator's institutional responsibilities.
2. The value of the financial interest exceeds specific threshold values.
 - a. Interest in a publicly traded entity:
The sum of remuneration from and equity in the entity exceeds \$5,000.
(Remuneration includes salary and any other payment for services, e.g. consulting fees, honoraria, and paid authorship. Equity includes stock, stock options, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.)
 - b. Interest in a non-publicly traded entity:
Total remuneration from the entity exceeds \$5,000 or the investigator (or spouse or dependent child) holds any equity interest.
 - c. Interest in intellectual property rights (e.g. patents and copyrights):
Total income related to such rights exceeds \$5,000.
 - d. Interest in travel:
Any reimbursed or sponsored travel is a significant financial interest unless the reimbursement has been made by or routed through CMI.
3. The financial interest does not arise from any of the following sources, all of which are excluded from the PHS definition of a significant financial interest:
 - a. Salary, royalties or other remuneration paid by CMI to the investigator.
 - b. Intellectual property rights that have been assigned to CMI and agreements to share in royalties produced by such rights.
 - c. Income from investment vehicles such as mutual funds and retirement accounts, provided the investigator does not control the investment decisions made in these vehicles.
 - d. 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.

- e. Income from service on advisory committees or review panels for a federal, state, or local government agency, institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

The foregoing five exclusions are the only ones that CMI recognizes as valid.

CMI, rather than the investigator, makes the determination of whether a financial interest should be considered a SFI.

H. Financial Conflict of Interest (FCOI)

An SFI that could directly and significantly affect the design, conduct, or reporting of research funded by NIH (or PHS) is a Financial Conflict of Interest (FCOI). CMI, rather than the investigator, makes the determination of whether an SFI should be considered an FCOI.

I. FCOI Report

An FCOI report is CMI's report of a FCOI which is submitted to NIH or some other component of PHS.

V. Responsibilities

1. Responsibilities of the Investigator
 - a. Disclose all Significant Financial Interests.
 - b. Comply with CMI policies and procedures.
2. Responsibilities of Child Mind Institute
 - a. Develop and implement policies and procedures that promote compliance with NIH regulations.
 - b. Provide information to each Investigator. Information will include:
 - i. the existence of the relevant federal regulations mentioned in part II
 - ii. CMI's FCOI policy
 - iii. the Investigator's responsibility to disclose SFI's
 - iv. the Investigator's responsibility to complete training as described in part VII.

The process used to communicate this information will consist of the following action: The Vice President of Research will send an email message to each new investigator. (A new investigator is an investigator who has not yet completed two steps: (1) submitting a disclosure of financial interests using Form A, and (2) completing FCOI training as described in part VII.)

3. Evaluate Significant Financial Interests and identify any that qualify as a Financial Conflict of Interest.
4. Report to the PHS as described in section XIII and XV.

5. Make this FCOI policy publicly available by posting it on the organization website.

VI. Public Accessibility

This FCOI policy will remain accessible on CMI's website. Public disclosure of FCOI information about individual investigators will also be publicly available as described in section XIV.

VII. Training Requirement

Prior to engaging in PHS-funded research, each investigator must complete the online training program found at <https://www.citiprogram.org/Default.asp>

After initial training, the investigator will complete training at least every four years. In addition to the forgoing two conditions, immediate training is required when any of the following circumstances apply: (1) CMI revises its financial conflict of interest policies or procedures in any manner that affects the requirements of Investigators; (2) An Investigator is new to CMI; or (3) CMI finds that an Investigator is not in compliance with the organization's financial conflict of interest policy or management plan.

VIII. Subrecipients

If CMI carries out research through a subrecipient (e.g. a subcontractor or a consortium member), CMI is responsible for ensuring that each subrecipient Investigator complies with PHS FCOI regulations. In consultation with the subrecipient, CMI will craft a written agreement that ensures such compliance by either of the following two options:

(1) Depend on the Subrecipient's FCOI policy

If the parties agree that the subrecipient's Investigators must comply with the subrecipient's FCOI policy, the subrecipient shall certify as part of a written agreement with CMI that the subrecipient's policy complies with the Code of Federal Regulations sections mentioned in part II of CMI's FCOI policy. Additionally, the written agreement shall specify time period(s) for the subrecipient to report all identified financial conflicts of interest to Child Mind Institute. Such time period(s) shall be sufficient to enable CMI to provide the PHS FCOI reports prior to the expenditure of any funds by the subrecipient and within 60 days of any subsequently identified FCOI.

By the time of the initial application for funding from the PHS, the potential subawardee shall supply CMI with a copy of (1) a training certificate and (2) a disclosure of financial interests submitted by each investigator from the subawardee institution.

(2) Depend on CMI's FCOI Policy

If the subrecipient is unable or unwilling to certify that its FCOI policy complies with the Code of Federal Regulations—or if CMI prefers to depend on its own FCOI policy—then the written agreement between the two parties shall state that the subrecipient's Investigators must comply with CMI's FCOI policy. The agreement shall also specify

time period(s) for the subrecipient to submit all Investigator disclosures of significant financial interests to Child Mind Institute. Such time period(s) shall be sufficient to enable CMI to complete its review, management, and reporting obligations prior to the expenditure of any funds by the subrecipient and within 60 days of any subsequently identified FCOI.

The procedure for implementing this policy shall consist of adding an attachment to CMI's standard form for formalizing subawards.

IX. Institutional Official

Child Mind Institute designates the Vice President of Research as the Institutional Official responsible for FCOI compliance. The Institutional Official shall solicit and review disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in, the PHS-funded research. The Vice President of Research may delegate any or all of these responsibilities by writing a letter that documents the delegation.

X. Disclosures Required of Investigators

A. Initial Disclosure

Each Investigator who is planning to participate in research described in a grant application submitted to the PHS must disclose his or her financial interests (and those of the Investigator's spouse and dependent children) no later than the time of application for PHS funded research. Form A shall be used for this disclosure.

If, within the 12 months prior to an application for PHS funding, an investigator has already disclosed all financial interests in an Annual Disclosure, a Disclosure of New Financial Interest(s), or a Retrospective Disclosure, then no Initial Disclosure is required at the time of the application.

B. Annual Disclosure

Each Investigator who is participating in research funded by PHS must submit an updated disclosure of financial interests to CMI's Institutional Official at least annually during the period of the award. Such disclosure shall include any information that was not included in the Initial Disclosure or in a subsequent disclosure of financial interests (e.g. any financial conflict of interest identified on a PHS-funded project that was transferred from another Institution), and shall include updated information regarding any previously disclosed financial interest (e.g. the updated value of a previously disclosed equity interest). Form A shall be used for this disclosure.

Annual disclosures are due by September 30 of each year.

C. Disclosure of New Financial Interest(s)

Each Investigator who is participating in research funded by PHS must submit an updated disclosure of financial interests to CMI's Institutional Official within thirty days

of discovering or acquiring (e.g. through purchase, marriage, or inheritance) a new financial interest. Form A shall be used for this disclosure.

D. Retrospective Disclosure

If CMI determines that an investigator (who may be a subrecipient) failed to deliver timely disclosure of a financial interest, the investigator shall be required to submit a Retroactive Disclosure. Form A shall be used for this disclosure.

XI. Guidelines for Analyzing Financial Interests

A. Identifying SFI's

Upon receipt of Form A – Part 2 (and before CMI expends any funds on a newly-awarded grant from the PHS) the Institutional Official shall use the following decision rule to identify SFI's: If a disclosed financial interest reasonably appears to be related to the investigator's institutional responsibilities, then that financial interest is a SFI. Form B shall be used to document the Institutional Official's analysis and conclusion. A copy of the completed Form B shall be sent to the investigator.

B. Identifying FCOI's

After determining that a financial interest is a SFI, the Institutional Official shall use the following two criteria to determine whether each SFI is a Financial Conflict of Interest:

1. The SFI is related to PHS-funded research.
The SFI is related to PHS-funded research if either of the following two conditions is met:
 - a. The SFI could be affected by the PHS-funded research.
 - b. The SFI is in an entity whose financial interest could be affected by the research.
2. The SFI could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

If both criteria are true of a given SFI, then the Institutional Official shall determine that the SFI is a Financial Conflict of interest. Form B shall be used to document the Institutional Official's analysis and conclusion. A copy of the completed Form B shall be sent to the investigator. A decision by the Institutional Official may be appealed to the Executive Director within 30 days of the date of notification of the Institutional Official's decision.

Timing of Analysis by the Institutional Official:

Type of Disclosure	Required Completion Date of Analysis
Initial	Prior to expenditure of funds
Annual	Within 60 days of disclosure
New Financial Interest	Within 60 days of disclosure
Retrospective	Within 60 days of discovery of noncompliance

XII. Management of Financial Conflicts of Interest

Once a FCOI has been identified and documented, Child Mind Institute shall be responsible for developing and implementing a management plan that shall specify the actions that have been, and shall be, taken to manage such financial conflict of interest. The Institutional Official shall develop this management plan in consultation with the investigator. Form C shall be used to document the management plan.

A management plan shall include the following key elements:

- (1) Role and principal duties of the conflicted Investigator in the research project;
- (2) Conditions of the management plan (see below);
- (3) How the management plan is designed to safeguard objectivity in the research project;
- (4) Confirmation of the Investigator's agreement to the management plan;
- (5) How the management plan will be monitored to ensure Investigator compliance; and
- (6) Other information as needed.

Conditions specified by the plan may include any or all of three options: manage, reduce, or eliminate the FCOI. Examples of each type of action include, but are not limited to the following:

Manage

Public disclosure of financial conflicts of interest:

- in publications and/or presentations in which the research results are circulated,
- to other staff working on the project,
- to human research subjects participating in the research (this information is usually provided in consent forms), and/or
- to the grantee institutions' Institutional Review Boards (these boards ensure the rights and safety of people participating in clinical trials).

Ensure that protections are in place to prevent the exertion of inappropriate pressure on other staff working on the grant-funded project:

- ensuring that staff who work on the grant knew where to bring any concerns about the impact of the conflict on them or the research,
- ensuring that students and trainees were not involved with the company with which the researcher had a relationship, and/or

- gaining prior approval before allowing students and trainees to conduct research related to the company.

Other common methods to manage conflicts include:

- requiring researchers to notify the grantee institution when and how relationships with the outside companies changed (this included changes in equity amounts, changes in the nature of the researchers' relationship with the outside companies, changes in any funding of the research provided by the outside companies, and accrual of royalties),
- requiring researchers to ensure that an open exchange of research results would take place,
- monitoring or oversight of the grant research by grantee institution staff not related to the grant research, and
- limiting or prohibiting researchers from research involving human subjects.

Reduce

Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest

Modification of the research plan

Change of personnel or personnel responsibilities, or disqualification of personnel from participating in all or a portion of the research.

Reduction of the financial interest (e.g. by sale of equity interest)

Eliminate

Elimination of the entire financial interest (e.g. by sale of equity interest)

Severance of relationships that create financial conflicts

CMI shall monitor the Investigator's compliance with the management plan on an ongoing basis until the completion of the PHS-funded project. Form D shall be used to document the monitoring of the management plan.

Depending on the nature of the significant financial interest, the Institutional Official may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date of disclosure and the completion of the Institution's review.

A decision by the Institutional Official may be appealed to the Executive Director within 30 days of the date of notification of the Institutional Official's decision.

XIII. Handling Noncompliance

Noncompliance with FCOI policy includes (but is not limited to) several possibilities: (1) failure by the Investigator to disclose a significant financial interest that is determined by CMI to constitute a financial conflict of interest; (2) failure by the CMI to review or manage such a financial conflict of interest; (3) failure by the Investigator to comply with CMI's FCOI policy or with a FCOI management plan; or (4) bias is found in the design, conduct, or reporting of PHS funded research even if such bias was created with a management plan in place.

In the event that CMI receives evidence of noncompliance with the organization's FCOI policy or with an FCOI management plan, CMI shall promptly undertake two actions: (1) Within 14 days of receipt of the evidence, the Institutional Official shall review the evidence and draw a conclusion as to whether noncompliance, in fact, occurred. (2) Within 7 days of conclusion of the Institutional Official's review, CMI shall notify the PHS Awarding Component if noncompliance has occurred.

Within 120 days of CMI's determination of noncompliance, the organization shall complete a retrospective review. Such a review shall examine all of the Investigator's activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research. The Vice President of Research shall be responsible for conducting the retrospective review and may appoint a review panel to participate in the review.

CMI shall document a retrospective review with at least the following key elements:

- (1) Project number;
- (2) Project title;
- (3) PD/PI or contact PD/PI if a multiple PD/PI model is used;
- (4) Name of the Investigator with the financial interest;
- (5) Name of the entity with which the Investigator has a (potential) FCOI;
- (6) Nature of the financial interest (e.g. equity, consulting fee, travel reimbursement, honorarium);
- (7) Value of the financial interest—
Value will be reported in dollar ranges: \$0–\$4,999; \$5,000–\$9,999; \$10,000–\$19,999; amounts between \$20,000–\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a 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;
- (8) Reason(s) for the retrospective review;
- (9) Detailed methodology used for the retrospective review (e.g. methodology of the review process, composition of the review panel, documents reviewed);
- (10) Findings of the review, including a description of how the financial interest relates to the PHS-funded research and, if the financial interest is determined to conflict with the research, the basis for the Institution's determination.

(11) Conclusions of the review.

(12) If the conclusion is that the investigator's financial interest is an FCOI, then

The Institutional Official may conclude that the findings and conclusions of the retrospective review warrant further action(s). In such cases, CMI shall update any relevant FCOI report that was submitted to the PHS. The update shall specify the actions that will be taken to manage the financial conflict of interest going forward. If bias is found, CMI is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report must include, at a minimum, the key elements documented in the retrospective review and a description of the impact of the bias on the research project and CMI's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g. impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, CMI will annually submit FCOI reports to the PHS.

Depending on the nature of an identified financial conflict of interest, CMI may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date that the financial conflict of interest or the Investigator's noncompliance is determined and the completion of the Institution's retrospective review.

If the failure of an Investigator to comply with this policy or a financial conflict of interest management plan appears to have biased the design, conduct, or reporting of the PHS-funded research, CMI shall promptly notify the PHS Awarding Component of the corrective action taken or to be taken.

In any case in which PHS determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was not managed or reported by CMI as required by this policy, CMI shall require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

XIV. Reporting FCOI's to the Public

Prior to expenditure of any funds under a PHS-funded research project, CMI shall ensure public accessibility of FCOI information to any requestor within five business days of a written request. Information shall be available about any financial interest that meets the following three criteria:

- (1) The significant financial interest was disclosed and is still held by the senior/key personnel;
- (2) CMI determines that the significant financial interest is related to the PHS-funded research; and
- (3) CMI determines that the significant financial interest is a financial conflict of interest.

The information that the CMI makes available shall include, at a minimum, the following:

- (1) the Investigator's name;
- (2) the Investigator's title and role with respect to the research project;
- (3) the name of the entity in which the significant financial interest is held;
- (4) the nature of the significant financial interest; and
- (5) the approximate dollar value of the significant financial interest or a 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.

Such information shall remain available to all written requests for three years from the date that the information was most recently updated.

XV. Reporting FCOI's to the PHS

A. Reporting requirements

There are five circumstances that require submission of a report to the PHS component that awarded a grant to CMI.

1. FCOI identified for investigator(s) on a new award:

Prior to expenditure of any funds under a new PHS-funded research project, CMI shall provide to the PHS Awarding Component an FCOI report regarding any Investigator's significant financial interest which CMI has found to be conflicting. The report shall document that CMI has implemented a management plan in accordance with section XII. In cases in which CMI identifies a financial conflict of interest and eliminates it prior to the expenditure of PHS-awarded funds, CMI shall not submit an FCOI report to the PHS Awarding Component.

2. FCOI identified for an investigator who is newly participating on an existing project:

For any significant financial interest that CMI identifies subsequent to CMI's initial FCOI report during an ongoing PHS-funded research project (e.g. upon the participation of an Investigator who is new to the research project), CMI shall provide to the PHS Awarding Component, within sixty days, an FCOI report regarding the financial conflict of interest and ensure that CMI has implemented a management plan.

3. New or newly-identified FCOI for existing investigator(s):

This circumstance shall be handled in the same manner specified in section X.A.2.

4. Ongoing awards:

For any financial conflict of interest previously reported with regard to an ongoing PHS-funded research project, CMI shall provide to the PHS-Awarding Component 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. The annual FCOI report shall specify whether the financial conflict is still being managed

or explain why the financial conflict of interest no longer exists. CMI shall provide annual FCOI reports to the PHS Awarding Component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS Awarding Component.

5. Noncompliance:

Initial reporting of noncompliance is covered in section XIII. Follow-up with a retrospective review can be prompted by any of the circumstances listed in section XIII. Following completion of a retrospective review, CMI shall submit a report of findings to the PHS Awarding Component if the review identifies an FCOI. The findings shall include a Mitigation Report if this report is required by section XIII.

B. Process for reporting

The process of reporting to the PHS is implemented by use of Form B. One section of this form is devoted to documenting the need for reporting. Another section includes a signature line in order to verify that reporting to the PHS has been completed.

C. Reporting elements

Any FCOI report submitted to the PHS shall include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the financial conflict, and to assess the appropriateness of the CMI's management plan.

Elements of the FCOI report shall include at least the following elements:

- (1) Project number;
- (2) PD/PI or contact PD/PI if a multiple PD/PI model is used;
- (3) Name of the Investigator with the FCOI;
- (4) Name of the entity with which the Investigator has a financial conflict of interest;
- (5) Nature of the financial interest (e.g. equity, consulting fee, travel reimbursement, honorarium);
- (6) Value of the financial interest (dollar ranges are permissible) or a 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;
- (7) A description of how the financial interest relates to the PHS-funded research and the basis for the Institution's determination that the financial interest conflicts with such research;
- (8) A description of the key elements of the Institution's management plan, as specified in section XII of CMI's policy.

XVI. Maintenance of Records

CMI shall maintain records relating to all Investigator disclosures of financial interests and the CMI's review of, and response to, such disclosures (whether or not a disclosure resulted in the Institution's determination of a financial conflict of interest) and all actions under the Institution's policy or retrospective review, if applicable, for at least three years from the date

the final expenditures report is submitted to the PHS or, where applicable, from other dates specified in 45 CFR 74.53(b) and 92.42 (b) for different situations.

The procedure to implement this policy shall consist of filing all relevant records in the Research Program. Files shall not be retained for at least three years from the date on which the final expenditures report is submitted to the PHS.

XVII. Enforcement mechanisms and sanctions

CMI's FCOI policy is formalized with an internal governing policy. Enforcement mechanisms and sanctions will be determined by the process that is used whenever a violation of an internal governing policy has occurred.

XVIII. Policy Changes

The Institutional Official may change this policy document, provided the change is documented with a memo to the Executive Director and the General Counsel.

FCOI File No.: _____
Date received: _____

Form A – Part 1

**Confidential
Child Mind Institute
Financial Conflict of Interest (FCOI) Disclosure Form**

1. Investigator Name: _____

Status: Faculty Student Staff Other—specify: _____

Mailing address: _____

Phone: _____ E-mail: _____

Department or Unit _____

2. PHS Project Title: _____

3. Check one box to indicate the type of disclosure you are making:

Initial Annual New Financial Interest Retrospective

4. Disclosure of Financial Interests

A. In making this disclosure, do not include any of the following items:

1. Salary, royalties or other remuneration paid by CMI to the investigator.
2. Intellectual property rights that have been assigned to CMI and agreements to share in royalties produced by such rights.
3. Income from investment vehicles such as mutual funds and retirement accounts, provided the investigator does not control the investment decisions made in these vehicles.
4. 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.
5. Income from service on advisory committees or review panels for a federal, state, or local government agency, institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

B. Check all of the following that were true of you, your spouse, and/or any dependent children at any time during the past 12 months or since you last submitted an FCOI disclosure, whichever is shorter.

Financial Interest in a publicly traded entity:
exists if the total of remuneration from and equity in the entity exceeds \$5,000.

Financial Interest in a non-publicly traded entity:
exists if there is any equity at all or if total remuneration from the entity exceeds \$5,000.

Financial Interest in intellectual property rights (e.g. patents and copyrights):
exists if there is more than \$5,000 of income related to such rights that are not assigned to CMI.

Financial Interest in travel:
exists if you travelled and received reimbursement or sponsorship from a source other than CMI.

C. No Financial Interest
Check if none of the types of Financial Interest listed in Part B were true of you, your spouse, and/or any dependent children during the past 12 months or since you last submitted an FCOI disclosure, whichever is shorter.

5. Investigator Assurance

I agree to abide by CMI's Financial Conflict of Interest Policy. In submitting this form and any other required documents I certify that the information provided is true to the best of my knowledge. I supply this information for confidential review by Child Mind Institute and for such other limited purposes as are required by law, regulation, or contract. I do not authorize release of it for any other purpose. I understand and agree that if there is a material change (an acquisition of a significant financial interest) to this information, I must submit a new disclosure and attachment within 30 days of that change.

Signature: _____ Date: _____

What should I do next?

If you checked only box 4. C., no further disclosure is required. Please submit this form to the Vice President of Research.

If you checked any box in 4. B., then complete a separate Form A – Part 2 for each financial interest covered by the criteria in 4. B. Please submit both Form A – Part 1 and all copies of Form A – Part 2 to the Vice President of Research.

What response can I expect?

If you checked only box 4. C., no response will be sent to you.

If you checked any box in 4. B. the Vice President of Research will review your information. The Vice President of Research will review your information and, if necessary, contact you for discussion. If any of your financial interests meet the criteria for a Financial Conflict of Interest (FCOI), the Vice President of Research will help you develop a management plan. You will receive written communication of all conclusions that result from review of your information.

Form A – Part 2

Confidential
Child Mind Institute
Financial Conflict of Interest (FCOI) Disclosure Form

1. Investigator Name: _____

2. PHS Project Title: _____

3. Check the type of financial interest that was true of you at any point in the past 12 months. (Check only one.)

- A. Equity worth at least \$5,000 in a publicly traded organization.
- B. Remuneration of at least \$5,000 from a publicly traded organization.
- C. Any equity in a non-publicly traded organization.
- D. Remuneration of at least \$5,000 from a non-publicly traded organization.
- E. Income of at least \$5,000 from intellectual property rights assigned to an organization other than CMI.
- F. Travel sponsored or reimbursed by an organization other than CMI.

4. Name of the organization in which the financial interest exists:

5. Describe the type of business conducted by the organization:

6. The organization is:

- For profit (publicly-owned) For profit (privately-held) Non-profit
- Governmental

7. The financial relationship is between the organization and (Check all that apply.)

- Self Spouse Dependent Child(ren)

8. Estimated value of the financial interest:

- \$0 - \$4,999
- \$5,000 - \$9,999
- \$10,000 - \$19,999
- \$20,000 - \$100,000 by increments of \$20,000: _____
- more than \$100,000 by increments of \$50,000: _____
- Value cannot be readily determined from public prices or other reasonable measures of fair market value

9. In the box below, answer only one of the following questions:

If you checked 3.B. or 3.D., describe the work for which the organization paid you or your family member.

If you checked 3.E., describe the intellectual property to which payments are related and how it is or is not related to your work at CMI.

If you checked 3.F., describe the purpose of the travel, the destination, and the duration of the travel.

10. Investigator Assurance

I agree to abide by CMI’s Financial Conflict of Interest Policy. In submitting this form and any other required documents I certify that the information provided is true to the best of my knowledge. I supply this information for confidential review by Child Mind Institute and for such other limited purposes as are required by law, regulation, or contract. I do not authorize release of it for any other purpose. I understand and agree that if there is a material change (an acquisition of a significant financial interest) to this information, I must submit a new disclosure and attachment within 30 days of that change.

Signature: _____ Date: _____

What response can I expect?

The Vice President of Research will review your information and may contact you for discussion. If any of your financial interests meet the criteria for a Financial Conflict of Interest (FCOI), the Vice President of Research will help you develop a management plan. You will receive written communication of all conclusions that result from review of your information.

Form B

**Child Mind Institute
Financial Interest Review Form**

1. Investigator Name: _____
2. PHS Project Title: _____
3. Disclosed Financial Interest: _____
-

Part 1: Identifying a Significant Financial Interest

4. Does the disclosed financial interest appear to be reasonably related to the investigator's institutional responsibilities?

Yes No

Briefly explain the reasoning behind the conclusion:

If the answer is yes, then the financial interest is a Significant Financial Interest (SFI). Proceed to 5.

If the answer is no, then the financial interest is not a Significant Financial Interest. Skip all remaining parts of this form except the signature.

Part 2: Identifying a Financial Conflict of Interest (FCOI)

5. Determine relatedness by answering both questions A. and B.

- A. Could the SFI be affected by the PHS-funded research?

Yes No

- B. Is the SFI in an entity whose financial interest could be affected by the research?

Yes No

6. Could the SFI directly and significantly affect the design, conduct, or reporting of PHS-funded research?

Yes No

If the answer to either question 5. A. or 5. B. is yes AND if the answer to question 6 is yes, then the SFI is a FCOI.

7. Conclusion (check one):

The SFI is an FCOI The SFI is not an FCOI.

Part 3: Reporting to the PHS

8. A report to the PHS

is required. is not required.

Part 4: Verification of Analysis (Parts 1 – 3) by Institutional Official

Signature: _____ Date: _____
Institutional Official

Part 5: Verification of Reporting to the PHS

9. A report to the PHS was submitted on _____.
Date

Signature: _____ Date: _____
Institutional Official

Form C

**Child Mind Institute
Financial Conflict of Interest Management Plan**

1. Investigator Name: _____

2. PHS Project Title: _____

3. Disclosed Financial Conflict of Interest: _____

4. Role and principal duties of the Investigator in the research project:

5. Conditions of the management plan include (check all that apply)

- Reduce Manage Eliminate

6. List and describe all detailed actions that will be taken in order to accomplish the conditions of the management plan. Describe how each action will contribute to the objectivity of the research.

7. List and describe all detailed actions that will be taken in order to accomplish the conditions of the management plan. Describe how each action will contribute to the objectivity of the research.

8. List and describe all actions that will be taken in order to monitor this management plan. Include dates by which actions are to be accomplished.

9. Assurances:

We agree to the management plan as it is described on this form.

Signature: _____ Date: _____
Investigator

Signature: _____ Date: _____
Institutional Official

FCOI File No.: _____

Date received: _____

Form D

**Child Mind Institute
Monitoring Report on
Financial Conflict of Interest Management Plan**

1. Investigator Name: _____

2. PHS Project Title: _____

3. Disclosed Financial Conflict of Interest: _____

4. List and describe all actions that were required by the financial management plan. Indicate whether the actions have been completed. Add explanations as necessary.

5. Conclusion: The management plan has has not been followed to date.

Signature: _____ Date: _____

Institutional Official