THE CHILDREN'S MERCY HOSPITAL
Children's Research Institute Policies and Procedures

TITLE: Conflict of Interest Reporting – Public Health Service Funded Research

VERSION/REVISION HISTORY:

Date	Version	Version/Revision Summary
08/24/2012	V1.0	Initial documentation/publication.
11/02/2018	V2.0	Re-assessment and republication. Changes were made for clarity purposes.

PURPOSE:

The Department of Health and Human Services (DHHS) final rule (2011) on Financial Conflicts of Interest (FCOI) requires transparency and accountability for those seeking Public Health Service (PHS) funding. The goal of this rule is to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research performed under National Institutes of Health (NIH) grants or cooperative agreements will be free from bias resulting from study team member's FCOI *[42 CFR 50.601]*.

This policy applies to Investigators as defined by this policy to include Program Director/Principal Investigator (PD/PI), and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS *[42 CFR 50.602]*. This policy does not apply to Phase I Small Business Innovative Research (SBIR) or Small Business Technology Transfer (STIR) applications.

This policy defines the responsibilities of both the Investigators and the Hospital in (1) identifying FCOI; (2) developing Management Plans when warranted; (3) reporting FCOI to PHS; (4) making FCOI disclosures publicly available; and (5) addressing Non-compliance with the policy/regulations. This policy is to be used in conjunction with the Hospital policy "*Conflict of Interest Disclosure Review Process"* and describes additional requirements for those individuals serving as Investigators on PHS-funded projects.

LOCATION/SCOPE:

Children's Research Institute (CRI)

DEPARTMENT RESPONSIBLE FOR POLICY MANAGEMENT & EXECUTION:

Corporate Compliance

REQUESTS FOR GUIDANCE:

Requests for guidance regarding this policy will be directed to the VP, Audit and Compliance.

POLICY STATEMENT:

I. Identification of Individuals Obligated to Report in Research

The PD/PI is responsible for identifying individuals who have an obligation to report (i.e., "Investigators"). The PD/PI or designee will document these individuals throughout the length of the project.

II. Education *[42 CFR 50.604(b)]*

All Investigators are required to complete training on FCOI before engaging in PHS-funded research. This training must be completed at the following intervals:

A. When training must be completed:
- Prior to initiating work on a PHS-funded project;
- Prior to engaging in research at Hospital; and
- At least every four years.

B. Training must also be completed when any of the following occur:
- Hospital revises its policy on conflict of interest in research;
- An Investigator is new to Hospital; or
- When an Investigator is determined to have been noncompliant with Hospital policy or Management Plan.

C. How training should be completed:
- Training is accessed via the Cornerstone Learning Management System.

III. Disclosure by Investigators to Hospital

A. Identified individuals are required to report their Financial Interest (FI) related to health care or research activities and **including interest of their Immediate Family members**. The reporting period is potential COIs that were active in the previous 12 months.

B. All individuals identified must complete a FCOI disclosure in MyCOI at the following intervals:
1. Annually: Completed as part of the mandatory requirements for employees within July 1st to September 30th. This disclosure will meet the requirement for submission of grants to PHS *[42 CFR 94.4(e)(2)]*.
2. At Time of Award (includes prime and subaward) and Prior to Initiating Any Study Activities: Required to review, update and acknowledge that their FCOI disclosure is up to date.
3. New FCOIs or Changes in FCOI's: New FCOI or changes in FCOI must be reported through MyCOI within 30 days of discovering or acquiring a new FI.
4. Changes in Investigators: The above reporting periods (Section III.B) are required for new Investigators before their study activities begin and annually.

C. Sponsored Travel Report Requirements: DHHS regulations require that Investigators disclose any reimbursed or sponsored travel.
1. Sponsor travel that is paid on behalf of the Investigators to the Hospital does not require disclosure by the Investigator.
2. If the Investigator has had reimbursed/sponsored travel by an outside entity, they are required to include and enter the following information in MyCOI:
- the purpose of the trip;
- the identity of the sponsor/organizer;
- the destination;

- estimated monetary value; and
- total number of days.

D. Non-Reportable Travel Costs: Disclosures are not required when travel costs are provided by 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.

IV. Evaluation of FI

A. The Compliance Program Manager is responsible for determining whether a FI related to PHS-funded research represents a FCOI prior to expenditure of any funds. In most cases, this evaluation will not be performed until after a Just in Time notice (JIT) or a Notice of Award (NOA) has been received from the sponsoring agency *[42 CFR 50.604(b)]*.

B. When applicable, the Compliance Program Manager will work in conjunction with Research Administration, the regulatory review committees (e.g., Institutional Review Board [IRB], Institutional Biosafety Committee [IBC], Institutional Animal Care and Use Committee [IACUC]) and Research Leadership, to determine the following:

1. When the Investigator's Financial Interest is related to PHS-funded research either because a) the Financial Interest could be affected by the PHS-funded research; or (b) it is an entity whose Financial Interest could be affected by the research; and
2. When the Investigator's Financial Interest directly and significantly affects the PHS-funded research.

The rationale for both determinations will be documented in writing.

C. If such a relationship is found to exist, the Investigator will be determined to have a FCOI and require further review to determine mitigation strategies.

V. Management Plans for FCOI

A. When a FCOI has been identified, the Compliance Program Manager will work in conjunction with the Investigator, Research Administration, and when necessary the applicable regulatory review committee(s), to develop a written Management Plan to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias. The Management Plan must include the following components:

- Role and principal duties of the conflicted Investigator in the research project;
- Conditions of the proposed Management Plan;
- Management Plan design to protect the integrity of the research project;
- Confirmation of the Investigator's agreement to the Management Plan;
- Monitoring of the Management Plan and assignment of the monitor; and
- Other information as needed.

B. Conditions of the Management Plans may include, but are not limited to:

- Public disclosure of FCOI (e.g., when presenting or publishing research);
- When research involves human subjects, disclosure of FCOI to study subjects via informed permission/assent or informed consent process;
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI;
- Modification of the research plan if FCOI is determined;

- Change of personnel or reduction in personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- Reduction or elimination of the FCOI (such as sale of an equity interest); and/or
- Severance of relationships and/or employment that create actual or potential FCOI.

C. When, in the course of the project, a new Investigator discloses a FI, or an existing Investigator discloses a new FI, the Hospital will have 30 days to review the disclosure, determine whether it is related to the PHS-funded research, determine whether a FCOI exists, and implement (at least on an interim basis) a Management Plan.

D. Disclosures are referred to the FCOI Committee when the following occur:
- The Management Plan is not accepted by the discloser;
- Management Plan recommendation is the removal of the individual from the study, or
- Complex financial relationships affecting the reported financial interest.
  - The FCOI Committee extends an invitation for the individual to attend, to clarify and/or present additional information.

VI. Reporting Financial Conflicts of Interest (FCOI) to NIH

A. For any identified FCOI, the Research Compliance Officer will provide content to Manager Grants Administration/Pre-Award or their designee who will submit the report to PHS through the electronic Research Administration (eRA) Commons FCOI module, prior to expenditure of NIH funds and within 60 days of any subsequently identified FCOI, including any FCOI identified for newly added Investigators. Hospital must, at the same time, certify that a Management Plan has been implemented.

B. The following information must be provided to the PHS Awarding Component:
- Grant/Contract Number;
- Name of Program Director/Principal Investigator (PD/PI);
- Name of individual with FCOI;
- Name of the entity with which the individual has the FCOI;
- Value of the FCOI or a statement that the value cannot be readily determined;
- Nature of the FCOI (e.g. equity, consulting fees, honoraria);
- A description of how the Financial Interest relates to PHS-funded research and the basis for the Hospital's determination that the Financial Interest conflicts with such research; and
- Key elements of the Hospital's Management Plan (as outlined in Section IV.A).

C. In the event the Hospital identifies a FCOI and eliminates it prior to the expenditure of PHS awarded funds, a report will not be submitted to PHS. The evaluation and elimination of FCOI will be documented and retained in the grant file.

D. For a FCOI that was previously reported to PHS, Hospital will provide an annual FCOI report at the same time Hospital is required to submit the annual progress report. This report must address the status of the FCOI and any changes to the

Management Plan. This report will specify whether the FCOI is still being managed or explain why the FCOI no longer exists.

E. Research Administration in conjunction with the Research Compliance Officer will report to PHS any changes to a previously submitted FCOI report, including the following:
   - Project Number
   - Individual with the FCOI
   - Name of the entity
   - Nature of the FCOI

VII. Public Disclosure *[42 CFR 50.604(a)]*

A. Prior to the expenditure of any funds, the Compliance Program Manager will coordinate online posting of all FCOI held by individuals on the grant. The following information will be included in the posting:
   - The individual's name;
   - The individual's title and role with respect to the research project;
   - The name of the entity in which the FCOI is held;
   - The nature of the FCOI;
   - The date reported online; and
   - The approximate dollar value of the FCOI or a statement that the value cannot be readily determined.

B. Such information will be updated at least annually or within 60 days of the following:
   1. Hospital's receipt or identification of additional FCOI for individual that was not previously disclosed.
   2. Upon disclosure of FCOI of an individual.
   3. Upon the disclosure of a FCOI of an individual new to the PHS-funded research.

C. When Hospital is the awardee (prime and subaward), Hospital will make FCOI information publically available for all individuals. This information will remain online for 3 years from the date on which the information was most recently updated.

VIII. Monitoring

The Corporate Compliance's Research Compliance Officer will monitor, or oversee monitoring, of adherence to Management Plans on an ongoing basis.

IX. Human Subjects Research

A. For PHS-funded studies involving human subjects research, the Principal Investigator (PI) is responsible for reporting all FCOIs to the IRB. The Compliance Program Manager will be responsible for providing the following information regarding the specific FCOI to the Office of Research Integrity:
   - FCOI identified
   - Management Plans (proposed or accepted)
   - Reports of Non-compliance
   - Updates regarding the above

B. If the study has been designed, conducted, or reported by a study team member with a FCOI that was not reported or managed as required by this policy, then the following steps must be taken:

1. The FCOI must be disclosed in each public presentation of the results of the research, and
2. An addendum disclosing the FCOI must be submitted for previously published presentations.

X. Requirements for Sub-Recipients of PHS Funded Research

A. The Hospital may from time to time carry out aspects of PHS-funded research through a subrecipient with which the Hospital contracts with through a subaward agreement or other similar contract to provide research funding.

B. The Hospital will grant such subawards where the subrecipient has its own policy on FCOI's and certifies through the subaward agreement or other contract, that the policy complies with applicable PHS regulations.

C. Organizations who do not have their own FCOI policy that complies with the NIH regulations, will be considered ineligible to be a sub-recipient for PHS awards until such time as they develop, adopt, and implement their policy and can demonstrate compliance with it in the conduct on the PHS funded research. In rare circumstances, the Hospital will make an exception and allow the subrecipient to apply the Hospital policy as its own for purposes of the subaward. The subaward agreement or other contract type will specify the time period for the subrecipient to report all identified FCOI's to the Hospitals, which will be sufficient to allow the Hospital to provide timely reporting to PHS as applicable.

XI. Retention of Records

Retention of records will be in accordance with the Hospital's policy *Record Retention and Management.*

IMPLEMENTATION – ROLES AND RESPONSIBILITIES

Role	Responsibility
Program Director/ Principal Investigator (PD/PI)	• Identifies Investigators who are required to report. • Completes FCOI training prior to engaging in PHS-funded research (as outlined in Section II). • Completes FCOI disclosure in MyCOI (as outlined in Section III.B). • Reports to the IRB or other review committees all FCOIs of study members for grants involving human subjects research.
Investigators	• Completes FCOI training prior to engaging in PHS-funded research (as outlined in Section II). • Completes FCOI disclosure in MyCOI (as outlined in Section III.B and Section III.C). • Reports FI related to health care or research activities, including interest of their Immediate Family members.

Role	Responsibility
Compliance Program Manager/Corporate Compliance Department	• Determines whether a FI related to PHS-funded research represents a FCOI prior to expenditure of any funds. • Works in conjunction with the Investigator, Research Administration and when necessary, the applicable regulatory review committee(s) to develop a written Management Plan when a FCOI is identified. • Coordinates online posting of all FCOI held by individuals on the grants (as outlined in Section VII). • Provides the Office of Research Integrity with specific FCOI information (as outlined in Section IX).
Research Administration	• Reports any identified FCOI to PHS via eRA Commons FCOI module prior to expenditure of NIH funds (as outlined in Section VI). • Certifies FCOI training has been completed before account set-up.
Research Compliance Officer/Corporate Compliance Department	• Monitors adherence to Management Plans on an ongoing basis. • Reports any identified FCOI to PHS via eRA Commons FCOI module prior to expenditure of NIH funds (as outlined in Section VI).
Research Review Committees	• Reviews reported FCOI and proposed Management Plans. • Works with Corporate Compliance Department on any revisions to the Management Plan. • Issues final approval of the Management Plan as it relates to individual projects under review by the committee.

DEFINITIONS:

Financial Conflict of Interest (FCOI) – A financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

Financial Interest (FI) – One or more of the following financial interests of an Investigator and/or his/her immediate family member received in the twelve months preceding the disclosure which appear to be related to the Investigator's institutional responsibilities:

- Payments or remuneration including salary and any non-salary (e.g. consulting fees, honoraria, paid authorship).
- Equity interest including stock, stock option, or other ownership interest.
- Income related to intellectual property rights and interest, such as patents and copyrights.
- Any reimbursed or sponsored travel related to their institutional responsibilities. (Sponsor travel that is paid on behalf of the Investigators to the Hospital does not require disclosure by the Investigator.) This includes any entity (including non-profits) **except** 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.

Financial interests do not include the following:

- Salary, royalties, or other remuneration paid by Hospital to the Investigator if the Investigator is currently employed or appointed by Hospital.
- Intellectual property rights assigned to Hospital and agreements to share in royalties related to such rights.
- Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.
- Income from seminars, lectures, or teaching, and service on advisory or review panels for federal, state, or local government agencies, institutions of higher education, academic teaching hospitals, medical centers, or research institutes affiliated with an institution of higher education.
- Payment made directly to Hospital. However, if payment for services is paid directly to the Investigator, the remuneration must be disclosed regardless of whether the money will be turned over to Hospital or will be used to support the Investigator's future research activities.

Hospital – The Children's Mercy Hospital and all affiliates of such entity.

Immediate Family – In accordance with *42 CFR 50.603*, this includes spouse and dependent children.

Institutional Responsibilities – An Investigator's professional responsibilities on behalf of the Hospital including, but not limited to, activities such as research, research consultation, teaching, professional practice, Hospital committee memberships, and service on panels such as Institutional Review Boards and Data Safety Monitoring Boards.

Investigator – The Program Director/Principal Investigator (PD/PI), and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.

Management Plan – Plan of action to address a financial conflict of interest which can include reducing or eliminating the conflict, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

Non-compliance – Failure to comply with federal regulations, Hospital policies or procedures including those governing human research, or Institutional Review Board (IRB) determinations.

Program Director/Principal Investigator (PD/PI) – The person responsible to the applicant organization for the scientific and technical direction of the project, for the management of project funding, and for compliance with award terms and conditions, as well as applicable policies and regulations. The PD/PI is included in the definitions of Senior/Key Personnel and Investigator under *42 CFR 50 Subpart F*.

BUSINESS CONTINUITY AND DISASTER (BCD) PLAN:

Unless otherwise indicated, requirements in this document remain applicable during a Business Continuity and Disaster (BCD) event.

RECOURSE FOR NON-COMPLIANCE:

I. In the event the Hospital discovers that a FI was not disclosed by the individual in a timely manner, and/or was not previously reviewed by the Hospital, Corporate Compliance Department will, in the manner described above and within 30 days, review the FI and determine whether a FCOI exists.

II. If a FCOI does exist, a Management Plan will be implemented on a going forward basis.

III. A retrospective review will be completed by Corporate Compliance in conjunction with the individual's Section Chief/Supervisor, Research Administration, and Research and Medical Administration within 120 days of identifying the following incidents of Non-compliance:

A. A FCOI is not identified or managed because the individual failed to disclose, or failed to disclose in a timely manner, a financial interest that was determined by Hospital to represent a FCOI;
B. The Hospital failed to review or manage a FCOI; or
C. The individual failed to comply with this policy or a Management Plan.

IV. The retrospective review of the Investigator's activities and the PHS-funded research project will be performed in order to determine whether any PHS-funded research conducted during the time period of noncompliance was biased in the design, conduct, or reporting of such research. If deemed necessary, an ad-hoc committee may be convened to make the necessary determinations. This review must be documented by noting the following information:

- Project Number;
- Project Title;
- PD/PI or contact PD/PI if the multiple PD/PI model is used;
- Name of the Investigator with the FCOI;
- Name of the entity with which the individual has a FCOI;
- Reason for the retrospective review;
- Detailed methodology used for the retrospective review;
- Findings of the review; and
- Conclusions of the review, specifically whether any PHS-funded research conducted during the period of Non-compliance was biased in the areas of design, conduct, or reporting.

V. Based upon the results of the review, the Hospital will, if appropriate, update the previously submitted FCOI report, including any Management Plan.

VI. If bias is found, the Hospital is required to notify the PHS awarding component promptly and submit a mitigation report. This report must include the information identified above in IV. in addition to a description of the impact of the bias on the research project and the Hospital's plan of action or actions taken to eliminate or mitigate the effect of the bias.

VII. In the event of Non-compliance, a follow-up review will be completed and documented by Corporate Compliance within 120 days of the determination.

VIII. Failure to comply with this policy may result in counseling, up to and including termination of the individual's relationship with the Hospital.

IX. If Investigators are non-compliant with reporting requirements, they may not be involved in any grant related activities.

RELATED POLICIES, PROCEDURES and STANDARDS:

- *Conflict of Interest Disclosure Review Process*
- *Record Retention and Management*

REFERENCES:

- NIH Frequently Asked Questions: Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 CFR Part 50 Subpart F) applicable to grants and cooperative agreements (2011 Revised Regulations)
- NIH Online Tutorial on Financial Conflicts of Interest

REGULATIONS:

- 42 CFR Part 50, Subpart F - Promoting Objectivity in Research
- 42 CFR 50.601
- 42 CFR 50.602
- 42 CFR 50.604(a)
- 42 CFR 50.604(b)
- 42 CFR 94.4(e)(2)

KEYWORD SEARCH:

research conflicts, sponsor related travel, human subject research

POLICY CONTENT OWNER:

Program Manager, Research Policy

REVIEWED BY:

Privacy Officer, Corporate Compliance – Corporate Compliance
Research Leadership
Research Working Group
Senior Post-Award Grant Specialist – Research Administration

REVIEW PERIOD:

3 years
Reassessment of this policy will occur once every 3 years; interim revisions will be incorporated as needed.

APPROVED BY:

Research Leadership