TITLE: Conflict of Interest Reporting – Research and Sponsored Projects

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.
04/09/2020		Interim revision – Changes made for clarity purposes (especially in Section III.), and reference to CRI was changed to reflect new branding name (Children's Mercy Research Institute, CMRI).
05/03/2023	V 3.0	Re-assessment and republication – Changes were made to apply policy to all Research conducted at the Hospital and to reflect that this document is an addendum to the overall conflict of interest (COI) policy (*Reporting and Mitigation of Conflicts of Interest and Conflicts of Commitment*). Policy title was changed from "Conflict of Interest Reporting – Public Health Service Funded Research" to "Conflict of Interest Reporting – Research and Sponsored Projects" and sections were reorganized for clarity purposes. Some content moved to procedural documents.

PURPOSE:

Research conducted at the Hospital must be free from bias, promote objectivity and follow established standards that provide a reasonable expectation that the design, conduct, and reporting are transparent and accountable [42 CFR 50.601].

This policy applies to all Research. Public Health Service (PHS) funded research has specific requirements regarding Financial Conflicts of Interest (FCOI) [42 CFR 50.601] which are outlined in this policy.

PHS funded Research disclosure of conflict of interest (COI) applies to Investigators as defined by this policy to include Program Director/Principal Investigator (PD/PI), and any other person(s), regardless of title or position, who are responsible for the Research design, conduct, or reporting [42 CFR 50.602].

Note: Other federal and non-federal agencies (have slightly different policies. Investigators must comply with applicable policies.

LOCATION/SCOPE:

Children's Mercy Research Institute (CMRI)

DEPARTMENT RESPONSIBLE FOR POLICY MANAGEMENT & EXECUTION:

Corporate Compliance

REQUESTS FOR GUIDANCE:

Requests for guidance regarding this policy will be directed to the Vice President, Chief Compliance Officer.

POLICY STATEMENT:

The process detailed in this policy applies to all Research performed at the Hospital, except as otherwise noted. Where the policy references PHS funded Research, the requirements also apply to Research funded by entities that adopt PHS FCOI policies. For all other Research**,** the Hospital will abide by contractual or regulatory requirements of the individual sponsors and/or the regulatory agencies under which the Research falls.

I. Requirements for all CM Researchers

A. All Reportable Relationships/Interests must be reported, reviewed, and approved as set forth in the *Reporting and Mitigation of Conflicts of Interest and Conflicts of Commitment* policy.

B. For all studies overseen by a review committee (i.e. IRB, IAACUC, IBC, etc.), the Principal Investigator (PI) is responsible for notifying committee of Reportable Relationships/Interests.

II. Requirements for all PHS Funded CM Researchers

(Excluding Phase I Small Business Innovative Research (SBIR) or Small Business Technology Transfer (STIR) applications.)

A. PD/PI Responsibilities

The PD/PI is responsible for identifying individuals who have an obligation to submit conflict of interest disclosures (COI Disclosures). These individuals include 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, which may include, for example, collaborators or consultants (i.e., "Investigators"). The PD/PI or designee is responsible for identifying these individuals throughout the duration of the project. Study team additions or removals from the project must be done through the Hospital's electronic grants management system, myGrants. MyGrants will also be used to document those individuals who have an obligation to submit a COI Disclosure.

B. Educational Requirements

All Investigators are required to complete the Conflicts of Interest course before engaging in Research. This training must be completed via Collaborative Institutional Training Initiative (CITI) at the following intervals:

- Prior to initiating work on a PHS funded project;
- Prior to engaging in PHS funded Research at Hospital; and
- At least every four (4) years.

Training must also be completed when any of the following occur:

- Hospital revises this policy in a manner that affects Investigator requirements
- An Investigator is new to Hospital; or
- When an Investigator is determined to have been noncompliant with this policy

C. COI Disclosure Requirements - Timing
Investigators must complete or update COI disclosure in myCOI at the following intervals:
- As set forth in the *Reporting and Mitigation of Conflicts of Interest and Conflicts of Commitment* policy.
- Prior to performance of related activities (for example, at time of award or before being added to a PHS funded project).

D. COI Disclosure Requirements – Reportable Relationships
- All Reportable Relationships/Interests must be reported as set forth in the *Reporting and Mitigation of Conflicts of Interest and Conflicts of Commitment* policy.
- Additionally, PHS funded Investigators must also report Sponsored Travel as defined in Definitions section below.

III. Evaluation of COI Disclosures for All Research

A. Corporate Compliance is responsible for evaluating external relationships in the Research study related disclosure. These evaluations are targeted reviews based upon the study, expenditure of any funds or the performance of the Research or Research-related activities. In addition to performing a research specific review, Corporate Compliance will review disclosures based upon the individual's other Hospital responsibilities. The findings from the two different reviews may differ.

B. When applicable, Corporate Compliance will work in conjunction with Research and Sponsored Projects 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 whether the Significant Financial Conflict of Interest (Research) represents a FCOI by assessing the following:
- If the Investigator's FI is related to the Research either because a) the FI could be affected by the Research; or (b) it is an external entity whose FI could be affected by the Research; and
- If the Investigator's FI could directly and significantly affect the Research.

The rationale for both determinations will be documented in writing.

C. If such an outside relationship is found to exist, the Investigator will be determined to have a FCOI and require further review to determine mitigation strategies. If there is a perceived FCOI, a mitigation plan may be required to prevent a conflict from occurring.

D. Management Plan Monitoring will be performed as described in the Management Plan.

IV. Evaluation of COI Disclosures for PHS-Funded Research

A. Prior to the expenditure of any funds or the performance of any related activities, the Hospital must determine whether Investigator disclosed Significant Financial Interest (SFI - Research) represents a FCOI. The evaluation of SFI - Research will most likely be performed 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. If a new disclosure is made after initiation of the project, the Hospital will have 60 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.

V. Reporting Financial Conflicts of Interest (FCOI) to NIH for PHS Funded Research

A. For any identified FCOI, the COI Team Member will provide content to Manager Grants Administration/Pre-Award or their designee who will either submit the report to PHS through the electronic Research and Sponsored Projects Administration (eRA) Commons FCOI module (where the Hospital is the Prime Awardee) or will submit a report to the Prime Awardee (where the Hospital is a Sub-Awardee). Such disclosures will be made prior to expenditure of NIH funds or 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 or to Prime Awardee, as applicable:
   - 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 FI relates to PHS funded Research and the basis for the Hospital's determination that the FI conflicts with such Research; and
   - Key elements of the Hospital's Management Plan.

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 or the Prime Awardee.

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 and Sponsored Projects Administration in conjunction with the COI Team Member 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

F. Corporate Compliance will be responsible for providing the following information regarding identified FCOI to applicable review committees
   - FCOI identified
   - Management Plans
   - Reports of Non-compliance with management plan
   - Updates regarding disclosures or management plans

VI. Public Disclosure of FCOIs for PHS Funded Research

A. Prior to the expenditure of any funds, the Hospital will ensure accessibility, via a written response to any requestor within five (5) business days of request of information concerning any identified FCOI held by individuals on PHS grants.

B. The written response to any requestor within five (5) business days of the request, shall include, at a minimum the following:
   - The Investigator's name;
   - The Investigator'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 significant FCOI; and
   - The approximate dollar value of the FCOI or a statement that the value cannot be readily determined.

VII. 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.

VIII. Sponsored Travel Reporting Requirements PHS Funded Research:

A. As part of the annual and study-specific disclosures completed in myCOI, PHS Investigators must disclose to the Hospital any reimbursed or sponsored travel (i.e., what is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their Hospital responsibilities.

B. Exception to reporting travel. The following types of travel does not require reporting:
   - travel is reimbursed or sponsored by domestic entities such as federal, state, or local government agency,
   - an institution of higher education [20 U.S.C. 1001(a)],
   - an academic teaching hospital,
   - a medical center, or a
   - research institute that is affiliated with an institution of higher education.

C. Travel costs provided by a foreign entity, including any government entity, must always be reported.

IX. Food and Drug Administration (FDA) Regulated Research

For FDA regulated research, CM research staff will make disclosures to sponsor as required by FDA regulations. Where CM staff hold an Investigational New Drug (IND), disclosures will be made to FDA as required by FDA regulations.

X. 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 submit disclosures. • Completes COI training prior to engaging in PHS funded Research. • Completes and updates COI disclosures in myCOI. • Reports to the IRB or other applicable regulatory review committees all applicable COIs of study members. • Complies with Management Plan, where applicable.
Investigators	• Completes COI training prior to engaging in PHS funded Research. • Completes and updates COI disclosures in myCOI. • Reports applicable COIs to PI for disclosure to review committees. • Complies with Management Plan, where applicable.
Corporate Compliance Department	• Determines whether a SFI (research) represents a FCOI prior to expenditure of any funds. • Develops a written Management Plan when a FCOI is identified. If needed, collaborates with Research and Sponsored Projects Administration and when necessary, the applicable regulatory review committee(s) and the Office of General Counsel. • For any identified FCOI, the Research Compliance Officer will provide content to the Manager, Grants Administration/Pre-Award or designee who will submit the report to PHS or Prime Awardee. • Issues final approval of the Management Plan as it relates to individual projects under review by the committee. • Provides review committee, where applicable, with specific FCOI information.

Role	Responsibility
Research and Sponsored Projects Administration	• Confirms completion of annual award specific COI reporting at time of proposal submission and award acceptance respectively. • Confirms that Investigators have completed COI education in CITI. • Monitors COI training for ongoing compliance. • Reports any identified FCOI to PHS via eRA Commons FCOI module or to Prime Awardee prior to expenditure of NIH funds.
Research Compliance Officer/Corporate Compliance/Medical Administration	• Monitors adherence to Management Plans on an ongoing basis.
Research Regulatory Review Committees	• Reviews reported FCOI and proposed Management Plans. • IRB: Provides IRB specific mitigation measures as needed to uphold the ethical conduct of human subject research. • Works with Corporate Compliance Department on any revisions to the Management Plan.

DEFINITIONS:

Active – External activities where there is engagement in action or activity.

COI Team Member – The individual within Corporate Compliance who is responsible for conflict of interest activities, including but not limited to Research activities.

Financial Conflict of Interest (Research) – Significant Financial Interests that may affect research will be reported and reviewed in accordance with the Research COI Addendum.

Hospital – The Children's Mercy Hospital, including all of the Hospital's Affiliates. The term "Affiliates" shall refer exclusively to entities or organizations with respect to which the Hospital possesses (A) 100% of the legal or beneficial ownership interests, and (B) the unrestricted power to appoint all members of the governing body (board of directors or comparable governing body). "Unrestricted power" means the power to elect or appoint such members without any limitations (such as a requirement to appoint members from a list of candidates submitted by another party).

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, 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, and applicable to requirements posed by all regulatory oversight committees.

Public Health Service (PHS) – The Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health ("NIH").

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*.

Regulatory Review Committee – An overarching term that includes Institutional Review Board [IRB], Institutional Biosafety Committee [IBC], Institutional Animal Care and Use Committee [IACUC]) and Research Leadership. Reference to the Regulatory Review Committee in this policy will be identified by the type of research.

Reportable Relationship/Interest – Reportable Relationship/Interest: Any relationship with or interest in a Company or Other Organization that constitutes (i) a Significant Financial Interest (General) or a Significant Financial Interest (Research), whichever is applicable, or (ii) a Non-Financial Potential Conflict of Interest.

Research - A systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences Research (*42 CFR 50.603)*.

Significant Financial Interest (SFI – Research) – A consulting or other relationship with or interest in a Company or Other Organization which meets any of the following criteria:

- Interests in Public Companies: Remuneration received by the employee from the Company during the preceding 12 months plus the value of Equity held by the employee in the Company is greater than $5,000.
- Interests in Private Companies or Other Organizations: (i) Remuneration received by the employee from the Company or Other Organization during the preceding 12 months is greater than $5,000; or (ii) the employee holds any Equity interest in the Company (regardless of value).
- IP Rights: The employee has received any IP Rights from the Company or Other Organization. For avoidance of doubt, any inventor's share of an employee under the Intellectual Property Policy will not constitute a Significant Financial Interest.
- Foreign Activity: Any payments regardless of amount (such as awards, prizes, contributions, hospitality, or expense reimbursement) or any in-kind contributions such as materials and/or resources from any foreign entity.

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 60 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 and Sponsored Projects 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 Research project will be performed in order to determine whether any 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 and the Research is PHS funded, 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 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:

- *COI Disclosure and Financial Interest Review - Job Aid*
- *COI Management Plan - Job Aid*
- *Conflict of Interest Disclosure Review Process*
- *Outside Compensable Professional Services and Activities Request and Approval Policy*
- *Record Retention and Management*
- *Reporting and Mitigation of Conflicts of Interest and Conflicts of Commitment*

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:

- 20 U.S.C. 1001(a)
- 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 50.605(a)(2)
- 42 CFR 94.4(e)(2)
- NIH Regulations

KEYWORD SEARCH:

research conflicts, sponsor related travel, human subject research

POLICY CONTENT OWNER:

Program Manager, Research Policy

REVIEWED BY:

Executive Vice President, Physician-in-Chief
Research Leadership
Research Working Group
Vice President, Chief Compliance Officer

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