

		POLICY TITLE Financial Conflict of Interest for Investigators Conducting Research		
POLICY #	VERSION	CATEGORY	SUB-CATEGORY	
11564	5	<input checked="" type="checkbox"/> Organizational	Research	Medical Staff Only -Choose a Policy Type
KEY WORDS Conflict, Disclosure, Research		<input type="checkbox"/> Divisional	Choose a Division.	Administrative
		<input type="checkbox"/> Departmental	Choose a Department.	Administrative
CURRENT EFFECTIVE DATE: 7/21/2022 LAST APPROVAL DATE: 7/19/2019 ORIGINAL DATE: 9/9/2013			THIS POLICY REPLACES: Click here to enter text.	
APPLICABILITY: Choose an item. <input checked="" type="checkbox"/> Akron Children's Hospital & Affiliates <input checked="" type="checkbox"/> ACH Foundation <input type="checkbox"/> Akron Children's Health Collaborative (ACHC) <input type="checkbox"/> Child Dimensions Insurance Company				
Contact Person/Position: Research Integrity Manager			Pages: 6	
SPECIAL REVIEW			ADMINISTRATIVE REVIEW	
<input type="checkbox"/> Environment of Care/Safety	<input type="checkbox"/> Medical Staff		<input type="checkbox"/> Administrative Staff	
<input type="checkbox"/> Health Information Management	<input type="checkbox"/> Nursing Guidelines		<input type="checkbox"/> ACH Board of Directors	
<input type="checkbox"/> Human Resources	<input type="checkbox"/> Patient Services		<input type="checkbox"/> ACHC Board of Directors	
<input type="checkbox"/> Infection Control	<input type="checkbox"/> Pharmacy & Therapeutics		<input type="checkbox"/> Interdisciplinary Care Committee	
<input type="checkbox"/> Information Services	<input type="checkbox"/> Radiology		<input type="checkbox"/> Medical Staff Executive Committee	
<input type="checkbox"/> Laboratory/Pathology	<input checked="" type="checkbox"/> Research		<input type="checkbox"/> Click here to enter text.	
REFERENCES AND ACCREDITATION STANDARDS: See Appendix B				
APPROVAL Michael Forbes, MD Chief Academic Officer			APPROVAL Bruce Cohen, MD Interim Medical Director	
APPROVAL Click here to enter text. Click here to enter Title of Authorized Representative			APPROVAL Click here to enter text. Click here to enter Title of Authorized Representative	

Original signature on file in Accreditation Office

PURPOSE:

This Policy defines Akron Children's Hospital's ("Hospital") and its Investigators' responsibilities and procedures regarding conflicts of interest (as defined in Appendix A), in relationship to research. Its purpose is to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research will be free from bias resulting from Investigator conflicts of interest and to ensure compliance with federal and state regulations. Where there is a discrepancy, the applicable federal or state law or rule of the funding agency will take precedence, unless the law or rule is less restrictive than the Hospital's standard.

SCOPE:

This policy pertains to individuals involved in the design, conduct or reporting of research, or proposed research, through Akron Children's Hospital. This is not limited to those titled or budgeted as the Principal Investigator or Co-Investigator on a particular project, and may include Post-Doctoral Associates, Senior Scientists, Research Nurses, Research Coordinators, Residents, and Students. The definition may also include Collaborators or Consultants, as appropriate. This Policy applies to all research regardless of the funding source.

POLICY:

In accordance with federal regulations and other guidelines, the Hospital has a responsibility to manage Financial Conflicts of Interest. Thus, the Hospital requires that all Investigators disclose all Financial Interests annually, prior to submitting a proposal for external funding, and again at the time of award if there is a status change. Conflict of Interest Training will be required of all Investigators and must be updated every 3 years. Definitions of words/phrases used herein are printed in Appendix A to this policy.

PROCEDURE:

A. Disclosure Procedure

1. Soliciting and Reviewing Disclosures.

- a. All Investigators are required to complete a Financial Disclosure form for research annually. The disclosure form is in the electronic IRB submission system.
- b. All Investigators are required to complete a Financial Disclosure form when submitting a proposal for a grant and at the time of award for each study.
- c. All Investigators are required to update the Financial Disclosure form within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new reportable financial interest during the life of the research and for one (1) year following completion of the research.
- d. The Research Integrity Manager (RIM) will review all affirmative disclosures to determine whether a conflict or potential conflict of interest exists as defined in Appendix A.
- e. If a potential conflict of interest exists, the RIM will prepare a letter to the investigator explaining the potential conflict with instructions for actions to take if an actual conflict develops. This letter will be signed by the Chief Academic Officer (CAO), the investigator and the investigator's supervisor, and kept on file in the Office of Research Integrity.
- f. If an actual conflict of interest exists, the RIM will notify the CAO and the Chief Legal Officer (CLO) who will determine, in writing, what actions should be taken by the Hospital to manage the conflict of interest.
- g. The management plan will be signed by the CLO, the Investigator and the Investigator's supervisor, and kept on file in the Office of Research Integrity and with the CLO.
- h. The Investigator must comply with the management plan.
- i. The RIM or designee will upload a copy of the written management plan (watermarked "Confidential"), to the Investigator's user profile in the electronic IRB submission system.

- Annual Disclosures. All Investigators must complete the Financial Conflict of Interest disclosure by January 31st of each year. The IRB Administration Office will verify the COI form has been submitted before releasing approval letters or study documents. The Regulatory Compliance Specialist(s) will perform regular audits of COI records to identify affirmative disclosures and will notify the RIM of affirmative disclosures.
- Ad Hoc Disclosures. Upon a change in circumstance, all Investigators must revise their Financial Disclosure Form in the electronic IRB submission system within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new reportable Financial Interest during the life of the Research and for one (1) year following completion of the Research.
- Subrecipients. Institutions participating as subrecipients on Hospital grant proposals must have policies compliant with Federal guidelines or agree to comply with ACH's policy. The written agreement between the Hospital and the subrecipient must incorporate terms that establish whether the financial conflict of interest policy of the Hospital or that of the subrecipient will apply to the subrecipient's investigators.

B. Management of Conflicts.

1. Development of Management Plan.
 - a. The Research Integrity Office will review COI records as submitted to identify affirmative disclosures and will notify the RIM.
 - b. If the RIM determines there is a conflict of interest that must be managed, a management plan will be developed in the best interest of the Hospital, in consultation with the Investigator and the CLO.
 - c. The management plan will specify the actions that have been and shall be taken to address the conflict of interest, which may include reducing or eliminating the conflict.
 - d. If a conflict of interest is not disclosed or managed in a timely manner, the CLO shall, within 120 days of the Hospital's determination of noncompliance, complete and document a retrospective review of the investigator's activities and the research project to determine if there was bias in the design, conduct, or reporting of such research. A Mitigation Report is required if bias is found.
 - e. An interim management plan may be developed for time critical situations and approved by the CLO and the CAO. The plan should be updated as more information becomes available.
2. Examples of possible conflict management include:
 - a. Public disclosure of Significant Financial Interests.
 - b. Monitoring of research by independent reviewers.
 - c. Modification of the research plan.
 - d. Disqualification from participation in all or a portion of the funded research.
 - e. Divestiture of Significant Financial Interests.
 - f. Severance of relationships that create actual or potential conflicts.
 - g. Oversight by an objective employee of the Hospital, of any financial transactions in which the conflict may be relevant.
3. Final Authority. In any instance in which the CLO and the individual in conflict do not agree regarding the management of the conflict, the CLO will have final authority.

C. Reporting to Sponsor

1. Prior to expenditure of Public Health Service (PHS) funds under an award, the Office of Sponsored Projects (OSP), working in conjunction with the RIM and CLO, will report to the Sponsor the existence of any conflict of interest (but not the nature of the interest or other details) to assure that the interest has been managed in accordance with applicable regulations. Upon request, the Hospital will make available information regarding how existing conflicts of interests have been managed to protect the research from bias.
2. The OSP, in conjunction with the CLO, will report the existence of any actual or potential conflict of interest influencing PHS awards that the Hospital has been unable to manage prior to expenditure of funds.
3. The OSP, in conjunction with the CLO, will report on the existence of any actual or potential conflict of interest influencing external sponsor awards as required by sponsors.
4. For any conflicts of interest that are identified subsequent to the Hospital's initial report under the award, a report will be made, and the conflict of interest will be managed at least on an interim basis, within sixty (60) days of that identification.

D. Records Retention. The RDCRI will retain all disclosure forms, conflict management plans and related documents for a period of at least three (3) years after completion of the relevant research (submission of final expenditure reports) or three (3) years after the conflict has ended, whichever is longer.

E. Remedies and Sanctions.

1. Failure to submit the required Financial Disclosure Form will delay submission of the proposal to the funding agency or sponsor until after the Form is submitted.
2. Failure of an Investigator to comply with this conflict of interest policy or to comply with any management plan will be referred to the CLO, CAO and RIM. If applicable, failure to comply also must promptly be reported to the Sponsor, and corrective action must be taken, which may affect the award process.
3. In the event an identified conflict of interest was not disclosed, the Hospital will require the Investigator(s) involved to disclose the conflict of interest in each public presentation of the results of the research.

F. Education, Training and Information.

1. The Office of Research Integrity will be responsible for providing information and training on this Policy and the applicable federal and state regulations.
2. Training shall be completed by all key study personnel at the following times:
 - a. Prior to engaging in any research, and at least every three years thereafter, as tracked by the IRB Administrators.
 - b. Immediately upon any of the following:
 - (i) The Hospital revises this Policy in any manner that affects the requirements of Key personnel.
 - (ii) Key personnel new to the Hospital.
 - (iii) The Hospital finds that Key personnel are not in compliance with this Policy or the Hospital's management plan.

Questions involving this Policy, regulations, guidelines, precedents, and practice in this context, and particularly as they may relate to sponsored programs, may be directed to the RDCRI Office of Research Integrity.

Appendix A

Definitions

Conflict of Interest: a situation in which a person is in a position to derive personal benefit from actions or decisions made in their official capacity. For the purpose of this policy, a financial conflict of interest exists when the Chief Legal Officer reasonably determines that a disclosed Financial Interest could directly and significantly affect the design, conduct, or reporting of the research.

Institution: any domestic or foreign public or private entity or organization (excluding Federal agencies)

Chief Legal Officer (CLO): The individual within the Institution who is responsible for the solicitation and review of disclosures of significant financial interests including those of the Investigator's Family, related to the Investigator's Institutional responsibilities.

Institutional Responsibilities: The Investigator's professional responsibilities associated with his or her Institutional appointment or position, such as research, teaching, clinical activities, administration, and institutional, internal, and external professional committee service.

Investigator: an individual who is involved in the design, conduct or reporting of research or results of research or proposed research. This definition is not limited to those titled or budgeted as the Principal Investigator or Co-Investigator on a particular project, and may include Post-Doctoral Associates, Scientists, Research Coordinators/Nurses, Residents, and Graduate Students. The definition may also include Collaborators or Consultants, as appropriate, including an individual who is involved in the design and conduct of proposed research, and/or reporting of research results.

Investigator's Family: The Investigator's spouse/domestic partner and dependent children

Management Plan: A document that outlines and dictates measures to actively reduce, mitigate, or eliminate an actual, potential, or perceived conflict of interest held by an employee.

Research: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. The term encompasses basic and applied research that is biomedical or social behavioral in nature.

Appendix B

Applicable Regulations, Guidelines and Resources Include but are not limited to:

[21 CFR Part 312.53 \(c\) \(4\)](#)

[21 CFR 54](#)

[42 CFR part 50, subpart D](#)

[42 CFR part 50, subpart F](#)

[45 CFR part 16](#)

[45 CFR part 74](#)

Food and Drug Administration (FDA) Financial Disclosure

FDA Financial Disclosure by Clinical Investigators

Public Health Service (PHS) grant appeals procedures

PHS Promoting Objectivity in Research

PHS Procedures of the Departmental Grant Appeals Board

PHS Uniform Administrative Requirements for Awards and Subawards to Institution of Higher Education, Hospitals, Other Non-Profit Organization and Commercial Organizations; and Certain Grants and Agreements with States, Local Governments and Indian Tribal Governments.

PHS Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments

Government-wide debarment and suspension (non-procurement)

Program Fraud Civil Remedies

Responsible Prospective Contracts

[45 CFR part 92](#)

[45 CFR part 76](#)

[45 CFR part 79](#)

[45 CFR part 94](#)

[NIH FCOI Website](#)

[FDA Policy on COI](#)