



Category:	Administrative
Organizational or Department:	Organizational
Policy No.:	A00240
Former Policy No.:	
Page:	1:5

TITLE: FINANCIAL CONFLICT OF INTEREST – INSTITUTIONAL REVIEW BOARD

PURPOSE:	To promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under Public Health Service (PHS) grants or cooperative agreements will be free from bias resulting from Investigator Financial Conflict of Interest (FCOI).
SCOPE:	This policy applies to investigators engaged in PHS - funded, human subjects research reviewed by the East Tennessee Children's Hospital's (ETCH) Institutional Review Board (IRB).

POLICY:

DEFINITIONS:

Disclosure of significant financial interests means an Investigator's disclosure of significant financial interests to an Institution.

Financial conflict of interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS funded research.

FCOI report means an Institution's report of a financial conflict of interest to a PHS Awarding Component.

Financial interest means anything of monetary value, whether or not the value is readily ascertainable.

HHS means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

Institution means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, PHS research funding.

Investigator means the project director or principal investigator and any other person regardless of title or position, who is responsible for the design, conduct, or reporting of PHS funded research, or proposed for such funding, which may include collaborators or consultants.

Institutional responsibilities means an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution, but not limited to, activities such as research, research consultation, teaching, professional practice, institutional committee membership, and service on panels such as the Institutional Review Board.

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

PHS means 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).

PHS Awarding Component means the organizational unit of the PHS that funds the research.

S:\nsgadmin\P&P MASTER\Administration\FINANCIAL CONFLICT OF INTEREST – INSTITUTIONAL REVIEW BOARD.docx

Disclaimer Message

Date/Time Generated
Jun 17, 2019 10:24

Generated By
shuckc



Category:	Administrative
Organizational or Department:	Organizational
Policy No.:	A00240
Former Policy No.:	
Page:	2:5

TITLE: FINANCIAL CONFLICT OF INTEREST – INSTITUTIONAL REVIEW BOARD

Public Health Service Act or PHS Act means the statute codified at 42 U.S.C. 201.

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 a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

Senior/Key Personnel means the Project Director/Principal Investigator and any other person identifies as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS by the Institution under the regulation.

Significant Financial Interest means:

- (1) Anything of monetary value - aggregated for the Investigator and the Investigator's spouse, domestic partner, and dependent children - that reasonably appears to be related to the Investigator's institutional responsibilities including but not limited to the following:
 - (a) Salary or other payment for services (e.g. consulting fees) that exceeded in the previous twelve months or is reasonably expected to exceed in the next twelve months \$5,000
 - (b) Equity interests (e.g. stocks, stock options or other ownership interests) that meet the following tests:
 - i. exceeds \$5,000 in value as determined through reference to public prices or other reasonable measures of fair market value (e.g. most recent sales price recognized by the company), or
 - ii. constitutes more than a 5% ownership interest in any single entity.
 - (c) Intellectual property rights (e.g. patents, copyrights and royalties from such rights) upon receipt of income related to such rights and interests.
 - (d) Services as an officer, director, or in any other executive position in an outside business, whether or not remuneration is received for such service.
 - (e) Reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and is not reimbursed)
- (2) If compensation or equity interests may be influenced by a particular outcome in sponsor-funded research, such interests are significant financial interests even if the identified thresholds are not met or if the monetary value of interests is not immediately ascertainable.

S:\nsgadmin\P&P MASTER\Administration\FINANCIAL CONFLICT OF INTEREST – INSTITUTIONAL REVIEW BOARD.docx

Disclaimer Message

Date/Time Generated
Jun 17, 2019 10:24

Generated By
shuckc



Category:	Administrative
Organizational or Department:	Organizational
Policy No.:	A00240
Former Policy No.:	
Page:	3:5

TITLE: FINANCIAL CONFLICT OF INTEREST – INSTITUTIONAL REVIEW BOARD

PROCEDURE:

Review of PHS-funded human subjects research by the ETCH IRB must take into consideration financial interests that may be relevant to the conduct of the research. In cases when the IRB determines that there is a financial conflict of interest that could affect or otherwise be relevant to the research, the IRB must determine that the conflict is either eliminated or appropriately managed to ensure that the rights and welfare of human subjects are protected. The IRB, in its discretion, may consult or coordinate with other committees at ETCH in making such determinations. The ETCH IRB has final authority to make decisions regarding resolution of the conflict and the conduct of the research.

To manage this policy, ETCH's IRB will

- (1) Make this policy available upon request.
- (2) Maintain records of all Investigator disclosures of financial interests and the Institution's review of, and response to such disclosures per 42 CFR 50.605 .
- (3) Inform each applicable Investigator of the Institution's policy on financial conflicts of interest, the Investigator's responsibilities regarding disclosure of significant financial interests, and the applicable federal regulations.
- (4) Require each Investigator to complete FCOI training prior to engaging in research related to any PHS-funded grant and at least every four years, and immediately when any of the following circumstances apply:
 - (a) ETCH revises its financial conflict of interest policies or procedures in any manner that affects the requirements of Investigators;
 - (b) An Investigator is new to ETCH; or
 - (c) ETCH finds that an Investigator is not in compliance with the financial conflict of interest policy.
- (5) Solicit and review disclosure statements from each investigator planning to participate in, or participating in PHS/NIH-funded research.
- (6) Review applications for funding and provide required information per 42 CFR 50.605 as applicable. If ETCH carries out the PHS funded research through a sub-recipient (e.g., subcontractors or consortium members), the awardee Institution must take reasonable steps to ensure that any sub-recipient Investigator is in compliance pursuant to 42 CFR 50.605.
- (7) Take such actions as necessary to manage financial conflicts of interest.
- (8) Establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance as appropriate.
- (9) Prior to the Institution's expenditure of any funds under a PHS-funded research project, the IRB Staff Associate and/or Vice President of Legal Services shall, consistent with 42 CFR 50.604(f): review all Investigator disclosures of significant financial interests; determine whether any significant financial interests relate to PHS-funded research; determine whether a financial

S:\nsgadmin\P&P MASTER\Administration\FINANCIAL CONFLICT OF INTEREST – INSTITUTIONAL REVIEW BOARD.docx

Disclaimer Message

Date/Time Generated
Jun 17, 2019 10:24

Generated By
shuckc



Category:	Administrative
Organizational or Department:	Organizational
Policy No.:	A00240
Former Policy No.:	
Page:	4:5

TITLE: FINANCIAL CONFLICT OF INTEREST – INSTITUTIONAL REVIEW BOARD

conflict of interest exists; and, if so, develop and implement a management plan that shall specify the actions that have been, and shall be taken to manage such financial conflict of interest.

- (10) Ensure public accessibility by written response to any requestor within five business days of a request of information concerning any significant financial interest disclosed to the Institution that meets the following three criteria:
 - (a) The significant financial interest was disclosed and is still held by the senior/key personnel as defined by this subpart;
 - (b) The Institution determines that the significant financial interest is related to the PHS funded research; and
 - (c) The Institution determines that the significant financial interest is a financial conflict of interest.
- (11) Whenever, in the course of an ongoing PHS-funded research project, an Investigator who is new to participating in the research project discloses a significant financial interest or an existing Investigator discloses a new significant financial interest to the Institution, the IRB Staff Associate and/or Vice President of Legal Services shall, within sixty days: review the disclosure of the significant financial interest; determine whether it is related to PHS-funded research; determine whether a financial conflict of interest exists; and, if so, implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest. Depending on the nature of the significant financial interest, an Institution 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.

PRECAUTIONS:

N/A

SUPPORTIVE DATA:

N/A

Policy Owner:	IRB Staff Assistant
References:	42 CFR 50; 45 CFR 95; 20 U.S.C. 1001(a), 42 U.S.C. 201 45 CFR46, 21 CFR 50, 21 CFR 56, 21 CFR 812
Related Policies:	Institutional Review Board - #A00309

S:\nsgadmin\P&P MASTER\Administration\FINANCIAL CONFLICT OF INTEREST – INSTITUTIONAL REVIEW BOARD.docx

Disclaimer Message

Date/Time Generated
Jun 17, 2019 10:24

Generated By
shuckc



Category: Administrative
Organizational or Department: Organizational
Policy No.: A00240
Former Policy No.:
Page: 5:5

TITLE: FINANCIAL CONFLICT OF INTEREST – INSTITUTIONAL REVIEW BOARD

Related Documents:

Origination Date: 08/12
Revision Dates: 01/17
Last Review Date: Institutional Review Board: 08/12, 01/15, 12/16
Next Review Date: 01/20
Date Retired:
Approved By: Vice President – Operations – 01/03/2017
Institutional Review Board – 12/14/2016
Policy Review Committee – 01/27/2017

S:\nsgadmin\P&P MASTER\Administration\FINANCIAL CONFLICT OF INTEREST – INSTITUTIONAL REVIEW BOARD.docx

Disclaimer Message

Date/Time Generated
Jun 17, 2019 10:24

Generated By
shuckc