Table of Contents

Allegheny Health Network Research Institute: Research Conflict of Interest Policy

POL-8501167

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Overview Statement

I. PURPOSE:

The purpose of this Policy is to maintain the objectivity and integrity of Research at Allegheny Health Network Research Institute (the "Institute") and to ensure transparency in relationships with outside Entities and individuals as they relate to the care, academic and scholarly mission of the Institute. Among its many missions, the Institute seeks to foster interactions between the private sector and research, as interdisciplinary and translational research is of ever-increasing importance in transforming newfound knowledge into useable technologies that benefit the public. There is, however, the potential for financial conflicts of interest in such collaborations. In most cases those conflicts can be managed appropriately, rather than eliminated, thereby enabling those involved in Institute Research to engage in that Research objectively and with integrity and at the same time maintain acceptable financial relationships with outside Entities and individuals. Disclosure of financial interests to the Institute will protect both investigators and Institute from potential criticism or even government sanctions in the event such relationships are subsequently called into question.

II. POLICY:

All Significant Financial Interests ("SFI") (defined below) shall be disclosed annually, and within thirty (30) days of the discovery or acquisition (e.g. through purchase, marriage, or inheritance) of a new SFI, to the Conflict of Interest Official("COIO"), who reports to the President of the Institute. All SFI shall be disclosed prior to an application for funding as required by this Policy and/or by the sponsoring agency (see, e.g., Department of Health and Human Services, 42 C.F.R. § 50.

If the SFI is evaluated by the COIO or the Research Conflict of Interest Committee ("Committee") and found to present a Financial Conflict of Interest ("FCOI"), the FCOI shall be properly managed or eliminated, and the Investigator shall agree to the FCOI Management Plan, if one is implemented, before any related clinical trial agreement, contract, grant, sponsored project (e.g., research, instruction or outreach), dedicated gift, or other transaction is executed, any relationship is initiated, or any action is taken that could be influenced by the SFI. All Investigators shall be required to complete FCOI training identified by the Institute at least every four (4) years or immediately upon the occurrence of one of the three circumstances referenced in Section IV.E below.

Terms and Definitions

III. DEFINITIONS

Research Conflict of Interest Committee ("Committee") means the committee(s) established by the Institute to assist the Conflict of Interest Official ("COIO") in implementing and enforcing this Policy. The Institute shall establish at least one Research Conflict of Interest Committee but may establish more than one. Members shall be appointed by the President of AHN RI. The membership of each Committee shall represent the diversity of disciplines at the Institute, but shall include at least one individual who conducts Research at the Institute involving human participants. The COIO (or the individual to whom this responsibility has been delegated) shall serve on each Committee as member, and also shall serve as the liaison to the Institute's Institutional Review Board(s) ("IRB"). Responsibilities of the Committee shall include:

- Review of all SFI disclosures referred to it by the COIO;
- FCOI determinations (as outlined below);
- Development and implementation of FCOI Management Plans (as outlined below);
- Review of noncompliance issues brought to it by the COIO and recommendations for sanctions to ensure compliance with this Policy and federal regulations.

Conflict of Interest Official ("COIO") means the Director of the Institute's Clinical Research and Regulatory Affairs, who shall be responsible for overseeing the implementation and enforcement of this Policy and shall report directly to the President of AHN RI. The COIO is responsible for developing, promulgating, and updating procedures and guidelines for the implementation of this Policy and for providing administrative support to the Research Conflict of Interest Committee. The COIO also shall be responsible for ensuring compliance with all federal regulations and requirements concerning conflicts of interest (see, e.g., 42 C.F.R. §§ 50.604(d) and 50.605(A)(1) – (3)), including but not limited to: conflict of interest training, FCOI management (as more fully described below), FCOI reporting to sponsoring agencies, monitoring for compliance with FCOI Management Plans, enforcement of sanctions for noncompliance with this Policy and/or federal regulations, and maintenance of all records relating to disclosures and FCOI management. The COIO may delegate responsibilities under this Policy to staff within the Clinical Research and Regulatory Affairs department.

"***Dependent Child(ren)***" means a natural or adopted child of the Investigator who is under the age of 18.

"***Entity***" means any domestic or foreign, public or private, for-profit or not for-profit, business, organization, or association; including but not limited to, a sole proprietorship, partnership, corporation, limited liability company (excluding U.S. federal, state, and local government agencies).

Details

Applicability
AHN Entity

Content Type
Policy

Responsible Area
Research

Executive Sponsor
Tariq Cheema

Owner
Defazio, Dawnmarie

Former Numbers

Effective Date
8/9/2024

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Next Review Date
8/9/2026

Related Authoritative Sources

Related Content

Related Documents
Appendix A - Recommendations for management reduction or elimination of the conflict of interest.pdf

"***Equity Interest***" means any ownership interest in an Entity, including but not limited to, stock or stock option, or partnership interest, as determined through reference to public prices or other reasonable measures of fair market value.

"***Financial Interest" ("FI")*** means anything of monetary value, whether or not that value is readily ascertainable.

"***Financial Conflict of Interest" ("FCOI")*** means any situation in which an SFI could directly and significantly affect the design, conduct, or reporting of Research.

"***FCOI Management Plan***" means the action(s) taken to address an FCOI, which may include reducing or eliminating the FCOI to ensure, to the extent possible, that the design, conduct and reporting of Research will be objective and free from bias.

"***Institutional Responsibility(ies)" ("IR")*** means an Investigator's professional responsibilities on behalf of the Institute. Examples of an IR include, but are not limited to:

- Research (regardless of whether or not it is funded);
- Research consultation;
- Teaching;
- Outreach;
- Professional practice (e.g., clinical medical practice)
- Institute committee memberships (e.g., AHN Board, Purchasing Committees); and
- Service on Institute panels, such as an Institutional Review Board ("IRB").

"***Investigator***" means any individual, regardless of his or her title or position, whether medical staff, faculty, staff, resident or student, who has the ability to make independent decisions related to the design, conduct or reporting of Institute Research, but not including individuals who perform only incidental or isolated tasks related to a Institute Research project.

"***Remuneration***" means salary and any payment for services not otherwise identified as salary, including, but not limited to, consulting fees, honoraria, and paid authorship.

"***Research***" means systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge. The term encompasses basic and applied research that may or may not be published in an article, book or book chapter and product development (e.g., a diagnostic test or drug). As used in this Policy, the term includes, but is not limited to, any such activity for which research funding is available from a federal, state or local government agency, or a public or private Entity, through a grant, contract or cooperative agreement (e.g., a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award). As used in this Policy, Research also includes research activities that are not funded or sponsored.

"***Senior or Key Personnel***" means the project director or principal Investigator and any other person identified as senior or key personnel in the grant application, progress report, or any other report required to be submitted by law or regulation.

"***Significant Financial Interest" ("SFI")*** means an FI consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent child(ren)) that reasonably appears to be related to the Investigator's Institutional Responsibilities:

a. **For publicly traded Entities**, if the value of any Remuneration received from the Entity in the twelve months preceding the disclosure combined with the value of any Equity Interest of the Investigator in the Entity as of the date of disclosure, when aggregated, exceeds $5,000. Remuneration includes salary and any payments for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock options, or other ownership interests.
b. **For non-publicly traded Entities** (including but not limited to private "start-up" companies, closely held corporations, partnerships or sole proprietorships), if either:

    i. the value of any Remuneration received from the Entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or
    ii. the Investigator holds any Equity Interest (i.e., there is no *de minimis* amount for Equity Interests in a non-publicly traded Entity) in the Entity;

c. **Intellectual property rights and interests** (e.g., patents, copyrights) upon receipt of income related to such rights and interests (including but not limited to royalties, or licensing revenues) that exceeds $5,000 in the previous twelve months;
d. **All reimbursed or Sponsored Travel;** however, travel that is reimbursed or sponsored by a federal, state, or local government agency in the United States, an American institution of higher education as defined at 20 U.S.C. 1001(a), an American academic teaching hospital, an American medical center, or a research institute that is affiliated with an American Institution of higher education does not need to be disclosed as an SFI. Reimbursed or Sponsored Travel paid to an Investigator's spouse and/or dependent child(ren) does not need to be disclosed under this Policy

Significant Financial Interest (SFI) does NOT include the following types of FI:

i. salary, royalties, or other remuneration paid by the Institute (this includes any intellectual property rights assigned to the Institute and any agreements to share in royalties or licensing revenue related to the intellectual property rights) provided that the remuneration was not routed to the Institute by an Entity and intended for the Investigator at the direction of the Investigator in order to avoid disclosure as required by this Policy;
ii. 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;
iii. income from seminars, lectures, or teaching engagements sponsored by a U.S. federal, state, or local government agency, an American institution of higher education as defined at 20 U.S.C. §1001(a), an American academic teaching hospital, an American medical center, or a research institute that is affiliated with an American institution of higher education; or
iv. income from service on advisory committees or review panels for a federal, state, or local government agency in the United States, an American institution of higher education as defined at 20 U.S.C. §1001(a), an American academic teaching hospital, an American medical center, or a research institute that is affiliated with an American institution of higher education.

"***Sponsored Travel***" means travel that is paid for on behalf of an Investigator and not reimbursed to the Investigator directly.

Administration
IV. IMPLEMENTATION:

a. Disclosure:

Investigators shall disclose all SFI (i) prior to the submission of an application for Research funding, (ii) at least annually and (iii) within thirty (30) days of the discovery or acquisition (e.g., through purchase, marriage, or inheritance) of a new SFI. Disclosures of reimbursed or Sponsored Travel shall include the following details:

- Purpose of the travel;
- Identity of the sponsor or source of reimbursement;
- Destination; Duration of the travel; and Conflict of Interest (COI System") (Archer Prod | Contains Confidential Information (synergy.local). All SFI must be disclosed **prior** to an application for Research funding when the proposed Research is related to the SFI (see below for more information on relatedness to Research) and when required by the funding agency (see generally 42 C.F.R. § 50.605(a) – (b)). This requirement for prior disclosure applies to all Investigators, including principal investigators, project directors and any other person who is responsible for the design, conduct or reporting of the Research. Thus, all Investigators should disclose in a timely manner according to this Policy so they do not delay the submission of funding applications.

All disclosures submitted are first routed electronically by the COI System to the Investigator's department/unit head for review. If the Investigator has no SFI to disclose, then his/her disclosure will bypass department/unit head review and be electronically routed directly to the COIO. Department/unit heads may view such disclosures within the COI System but need not review them. Once department/unit head review, if required, is completed, all disclosures will be electronically routed by the COI System to the COIO.

Disclosures made under this Policy shall be reported by the Institute to governmental agencies or to the general public as required by law or regulation.

Investigators Unaffiliated with AHN RI will complete and return the Significant Financial Interest Disclosure Form for Unaffiliated Investigators. All Unaffiliated investigators must abide by all AHN RI Standard Operating Procedures and Guidances.

b. FCOI Review and Determination:

The COIO shall be responsible for (i) the review of all SFI disclosed in order to determine whether the SFI is related to Research and (ii) if so related, referral to the Committee in order to determine whether the SFI is a FCOI, unless the Committee has delegated its authority to the COIO to make this determination.

i. Related to Research: An SFI will be deemed to be related to Research if the SFI could be affected by the Research or is in an Entity or individual whose financial interest could be affected by the Research. The COIO may seek the input of the Investigator and/or his/he department/unit head in the determination of whether the SFI is related to Research.

The COIO shall refer SFI disclosures related to Research to the Committee for review and determination of whether an FCOI is present; provided, however, that the Committee is authorized to delegate to the COIO its authority to determine whether an SFI constitutes an FCOI, and in the event the Committee has delegated that authority to the COIO through specific guidelines set forth in a Standard Operating Procedure, the COIO may determine whether the SFI constitutes an FCOI without referral to the Committee.

ii. FCOI Determination: The Committee or the COIO, under authority granted by the Committee, shall determine whether the SFI **could** directly and significantly affect the design, conduct or reporting of related Research. If the Committee or COIO shall find that an FCOI exists, then it shall also determine whether the FCOI shall be managed or eliminated prior to the expenditure of funds for the related Research.

If, in the course of on-going Research, an Investigator who is new to the Research discloses an SFI or an existing Investigator discloses a new SFI, then the COIO or Committee shall review the SFI, make an FCOI determination, as provided in the previous paragraph and, if the SFI is determined to constitute an FCOI, implement an FCOI Management Plan (see Section IVc. below) within sixty (60) days of the date of the disclosure. If, in the course of on-going Research, an Investigator discloses an SFI that was not disclosed in a timely manner as required by this Policy (see Section IVa above), the COIO or Committee shall review the SFI, make an FCOI determination, as provided in the previous paragraph and, if the SFI is determined to constitute an FCOI, implement an FCOI Management Plan (see Section IVc. below) within sixty (60) days of the date of the disclosure. See Section vi below for more details on failure to properly disclose according to this Policy.

If human participants are involved in the related research, the Committee also shall determine whether the SFI will adversely affect the protection of participants. If the Committee has determined that the SFI will adversely affect the protection of human participants, then disclosure to potential participants or the public cannot be used as the sole method of FCOI management (see Section IV.c.below).

c. FCOI Management Plans:

The Committee or COIO shall document its FCOI Management Plan, which shall specify the actions that have been, and/or shall be, taken to manage the FCOI. The Investigator's input regarding what actions should be included in the FCOI Management Plan shall be considered by the Committee or COIO. Examples of conditions and restrictions that may be imposed to manage an FCOI, either as a single condition or restriction, or as a combination of conditions and restrictions, and on either an interim or permanent basis include, but are not limited to:

- Public disclosure of the FCOI (e.g., in public presentations or publications of the related Research);
- Disclosure of the FCOI to human participants, if applicable;
- Appointment of an independent monitor capable and willing to take appropriate measures to protect the design, conduct and reporting of the Research against potential bias resulting from the FCOI;
- In instances in which students are involved in the Research, given the educational mission of the Institute, taking steps, to the extent possible, to protect the students' academic progress, intellectual property interests, and welfare (e.g., appointment of an independent monitor);
- Modification of the Research plan;

- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the Research, including interim disqualification of personnel from the Research between the date of disclosure and the completion of the Institute's review of the matter;
- Reduction or elimination of the SFI (e.g., sale of an equity interest); or
- Severance of the relationship giving rise to the FCOI.

The COIO shall communicate to the IRB summary information about the nature and amount of any SFI related to human participants in research, along with the Committee's findings, FCOI determination and any FCOI Management Plan approved by the Committee. Investigators conducting Research involving human participants should note that review of SFI and implementation of an FCOI Management Plan, if such a Plan is necessary, by the Committee or the COIO does not constitute approval of the Research proposed. The IRB has final authority on whether the proposed Research should be approved and shall not render its decision until after the Committee has reviewed the SFI and implemented any necessary FCOI Management Plan. The IRB shall consider the FCOI Management Plan, if any, in its final determination and also may include additional protections to the FCOI Management Plan if it deems they are necessary for the protection of human participants.

The Investigator shall document his/her agreement to abide by the FCOI Management Plan before the FCOI Management Plan may be finalized. This documentation of agreement may be recorded within the COI System. The Investigator may request changes to the provisions set forth in the FCOI Management Plan, **if** such changes are requested **within five (5) days** of the FCOI Management Plan being sent electronically to the Investigator by the COI System. The COIO or Committee shall consider the changes requested and make a determination whether to accept any of them.

Funding for the related Research shall not be released unless and until the FCOI Management Plan has been implemented and agreed to by the Investigator. If funding has already begun, the COIO or Committee may request the funding to be held pending the FCOI determination and the Investigator's agreement to the FCOI Management Plan, if any.

The Committee established standard recommendation for management plans that the COIO or designee will follow. (Appendix A)

d. Required Updates:

All SFI disclosures shall be updated at least annually and within thirty (30) days after any new SFI is discovered or acquired.

e. Required FCOI Training:

The Institute shall identify appropriate training regarding this Policy that shall be completed by all Investigators at least once every four (4) years or immediately upon the occurrence of one of the circumstances listed below. The training shall inform each Investigator of this Policy, the Investigator's responsibilities regarding disclosure of his/her SFI, and of the federal regulations pertaining to FCOI (e.g., 42 C.F.R. § 50.601 *et seq.*). Immediate training for Investigators shall be required under the following circumstances:

i. When the Institute makes revisions to this Policy that impact an Investigator's responsibilities under this Policy;
ii. When an Investigator is new to the Institute; and
iii. When the Institute finds that an Investigator is not in compliance with this Policy or with his/her FCOI Management Plan

V. RESPONSIBILITIES:

a. Investigators:

i. Investigators are responsible for complying with the requirements of this Policy.
ii. Investigators are responsible for making disclosures, both annually and as they arise (within 30 days), as outlined in this Policy (see Sections I and IV above).
iii. Investigators are responsible for completing FCOI training at least once every three (3) years or as outlined above (see Section IV.e above).
iv. Investigators are responsible for providing to the COIO and/or Committee information requested in order for the COIO or Committee to review and make an FCOI determination regarding the Investigator's disclosure.
v. Investigators are responsible for accepting the FCOI Management Plan, or making a timely request for any changes to the FCOI Management Plan as outlined above (see Section IV.C above), and for providing documentation of his/her agreement to abide by the FCOI Management Plan. Investigators are responsible for abiding by all the terms, conditions and actions set forth in the FCOI Management Plan. This responsibility carries with it the responsibility to respond to requests from the COIO or Committee for information and/or meetings related to the Institute's responsibility to monitor compliance with this Policy, the applicable FCOI Management Plan, if any, and applicable federal regulations.
vi. If the Institute finds the Investigators is not in compliance with this Policy, his/her FCOI Management Plan, if any, and/or federal FCOI regulations and rules, the Investigator is responsible for complying with all corrective actions, enforcement mechanisms and/or sanctions imposed by the Institute.

b. The Institute:

i. The Institute is responsible for maintaining this Policy, making it available publicly as required by law or regulation, and ensuring it complies with all applicable federal FCOI regulations and rules.

ii. The Institute shall make available FCOI training to Investigators that complies with this Policy and all applicable federal FCOI regulations and rules.

iii. The Institute shall provide all FCOI reports to Research sponsors as required by federal FCOI regulations and rules, sponsor terms and conditions, and/or as may be required by an FCOI Management Plan.

vi. The Institute shall be responsible for establishing enforcement mechanisms (See Section VI below) to ensure Investigator compliance with this Policy and federal FCOI regulations and rules.
vii. The institute shall maintain records relating to Investigator SFI disclosures and the Institute's review and determination related to each disclosure (whether or not an FCOI was found and any FCOI Management Plan required) as is required by federal FCOI regulations.
viii. The Institute shall be responsible for making information relating to Investigator SFI disclosures and the Institute's review and determination related to each disclosure (whether or not an FCOI was found and any FCOI Management Plan required) available upon request to the sponsoring agency as outlined in federal FCOI regulations and rules.

Exceptions

Violations

VI. Noncompliance/Investigator Failure to Disclose or To Abide by FCOI Management Plan:

Any suspected non-compliance with this Policy, including but not limited to an Investigator's failure to disclose according to this Policy and an Investigator's failure to abide by an applicable FCOI Management Plan, shall be handled by the COIO in accordance with any applicable regulatory requirements or Institute policies. The COIO or Committee is authorized to stop Research or hold Research funding in order to ensure compliance with this Policy, an FCOI Management Plan and/or applicable federal FCOI regulations. If the Investigator has no active, funded Research, the COIO or Committee shall recommend other appropriate sanctions, including but not limited to actions related to the Investigator's employment at the Institute, to the appropriate administrator for action.

Additional References

This policy is in compliance with:

- Title 42 Code of Federal Regulations (CFR), Part 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought
- Title 45 Code of Federal Regulations (CFR), Part 94, Responsible Prospective Contractors
- Title 21 Code of Federal Regulations (CFR), Part 54, Financial Disclosure by Clinical Investigators
- 13.7 Enterprise Conflict of Interest Policy
- Intellectual Property Policy

People Applicability

Independent credentialed/privileged providers (including physicians, nurse practitioners, physician assistants, certified registered nurse anesthetists, and midwives); Employees (including residents and fellows); Contracted/embedded workforce personnel (including independent contractors and agency staff); Volunteers; Vendors; Students; Visitors; Researchers; Vendors:Onsite; Vendors:Offsite

Entity Applicability

Contact(s)

List of Approver(s)

MARK RUBINO - PHYSICIAN PRESIDENT / 74 - 8/9/2024,
ALLAN KLAPPER - PHYSICIAN PRESIDENT - 8/2/2024,
CHONG PARK - PHYSICIAN PRESIDENT / 74 - 8/5/2024,
IMRAN QADEER - PHYSICIAN PRESIDENT / 74 - 8/9/2024,
BRIAN JOHNSON - PHYSICIAN PRESIDENT / 74 - 8/9/2024,
CHRISTOPHER CLARK - PHYSICIAN PRESIDENT - 8/5/2024

Back to List
