Allina Health

System-wide Policy:

Research and Sponsored Programs Conflicts of Interest

Reference #: SYS-ADMIN-RA-004

Origination Date: December 2014
Next Review Date: April 2022
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Approval Date: **April 2019**
Approved By: **Ethics and Compliance Oversight Committee**

System-Wide Policy Ownership Group: Research Compliance
System Policy Information Resource: Director of Research Compliance

Stakeholder Groups
Research Administration
Research Directors
Institutional Review Board Members
Research Conflicts of Interest Committee

SCOPE:

Sites, Facilities, Business Units	Departments, Divisions, Operational Areas	People applicable to:
Abbott Northwestern Hospital, Buffalo Hospital, Cambridge Medical Center, District One Hospital, Mercy Hospital, New Ulm Medical Center, Owatonna Hospital, Phillips Eye Institute, River Falls Area Hospital, Regina Hospital, St. Francis Regional Medical Center, United Hospital; Orthopedic Institute Surgery Center at COC; Allina Health Group; Allina Health Home Care Services; All other business units	Research Compliance	See list below

The Research and Sponsored Projects Conflicts of Interest ("COI") Policy ("Policy") applies to the following groups:

1. All employed and non-employed research personnel who are responsible for the design, conduct, or reporting of research at Allina Health and/or research that is subject to the review of the Allina Health IRB or an external IRB requiring Allina Health to enter into an Inter-Institutional Authorization Agreement with such external IRB. This applies to all research regardless if it is publicly or privately funded. It also applies to Humanitarian Use Device (HUD) submissions and all other expanded access submissions.
2. Employees responsible for the design, conduct, or reporting of a Federal Project.
3. Non-Allina employees involved in the design, conduct, or reporting of research or a PHS-funded Federal Project when the employing organization or individual does not have a COI policy that meets the requirements set forth in the Public Health Service's Rule (42 CFR Part50, Subpart F)
4. Research Conflicts of Interest Committee members (Committee) and other Allina Health personnel designated by the Committee.
5. Members of Allina Health's Institutional Review Board (IRB).

POLICY STATEMENT:

Allina Health is committed to evaluating and appropriately addressing the relationships of personnel involved in research or Federal Projects to help ensure the work is free from potential or actual bias in order to focus on well-designed or scientifically sound discoveries and programs that will serve our patients and their communities. Review the definitions section for an explanation of terms used in this policy.

Section 1 Disclosure

A. Who Must Disclose?

All Investigators who apply for federal funding or submit an application to the IRB must disclose the information, interests and roles required on the disclosure form.

Generally, this includes all individuals listed on a grant budget, research protocol or IRB application. It always includes the Principal Investigator, Project Director, sub-investigators, study coordinators and key scientific personnel. In some cases the disclosure requirement will apply to other personnel (such as technologists or research fellows) if they are responsible for the design, conduct or reporting of the Federal Project or research.

When completing the disclosure form, Investigators must disclose all interests held personally, or by their Immediate Family Members.

B. Timing

Disclosures must be made prior to the submission of a proposal for federal funding, prior to the approval of a research protocol by the IRB, or as requested by Allina Health. Disclosures must be updated at least annually. Investigators are required to submit an updated disclosure of Significant Financial Interests or Significant Non-financial Interests

within thirty (30) days of discovery or acquisition (e.g., through purchase, marriage, or inheritance).

C. Travel Disclosures

Individuals involved in research or a Federal Project must, within ten (10) business days of returning from the travel, disclose the occurrence of any reimbursed or sponsored travel related to the Investigator's Institutional Responsibilities that is required by the COI Smart form.

Disclosures will include:

- The purpose of the trip, the identity of the sponsor / organizer, the destination and duration; and
- Sponsored or reimbursed travel for the Investigator or his/her Immediate Family Member.

All travel disclosed under this section will receive administrative review and may be reviewed by the Committee.

D. IRB or Committee Member Disclosures

Individuals serving on Allina's Institutional Review Board (IRB) or the Committee must disclose their financial and non-financial interests upon appointment and annually thereafter. IRB and Committee members must be recused from review of a project in which they have a conflict. The respective Committee Chair person is responsible for determining if there are attending members who may have a conflict of interest at the initiation of each duly convened committee meeting. If the individual has unique expertise or information that may assist the members in their review, the individual is permitted to provide the information. In no instances is the individual allowed to vote or otherwise participate in the approval or evaluation process of the research or Federal Project.

Section 2 Review of Disclosures

A. Review Criteria and Determination Process

All disclosed interests will be reviewed. The review will include a determination of whether the disclosed interests constitute a Significant Financial Interest or a Significant Non-financial Interest. Significant Financial Interest and Significant Non-financial Interests will be reviewed to determine if they:

- Are related to the research or Federal Project (i.e., could the interest be affected by the research or Federal Project or is the interest in an entity whose financial interest could be affected by the research or Federal Project?): and
- Constitute a conflict of interest (i.e., could the interest directly and significantly affect the design, conduct or reporting of the research or Federal Project?).

If they are related to the research or Federal Project and constitute a conflict of interest, the Committee shall manage the COI pursuant to Section 3 of this Policy.

The Committee may also determine that a disclosed interest does not constitute a Significant Financial Interest or a Significant Non-financial Interest that is related to the research or a Federal Project, or that it is related but it does not constitute a COI, however, the disclosed interest nonetheless warrants management.

B. Disclosures Not Reviewed in a Timely Manner

The following applies only to research or Federal Projects funded by the Public Health Service.

When SFIs are not reviewed in a timely manner, for whatever reason, the Committee shall, within sixty (60) days of identifying the SFI; review the SFI to evaluate whether it is related to the research or Federal Project and determine if an FCOI exists.

If there is an FCOI, then Allina Health shall:

(1) Implement, on at least an interim basis, a management plan that specifies the actions that have been, and will be, taken to manage the FCOI going forward; and
(2) Complete, within 120 days, a retrospective review of the Investigator's activities and the research or PHS-funded project consistent with the requirements in 42CFR50.605.

Section 3 Management

A. Committee Determinations

The Committee shall determine the appropriate response to manage an identified COI. Approaches may include:

(1) finding that the research or Federal Project may not proceed because of the COI, in which case the COI must be eliminated through divestiture of the SFI, severance of the Significant Non-financial Interest relationship causing the conflict, or other action; or
(2) finding that the research or Federal Project may proceed if the COI is managed in accordance with the plan approved by the Committee; or
(3) finding that the Investigator must not participate in the research or Federal Project

For disclosures that do not constitute a SFI or a Significant Non-financial Interest, the Committee may impose administrative requirements to manage the potential or actual conflict.

If the research or Federal Project is subject to the jurisdiction of an IRB, the Committee determination shall be provided to such IRB and the IRB may impose further management or restrictions.

If the research or Federal Project is funded by the Public Health Service or another federal funding source, that agency will be notified of a financial conflict of interest (FCOI) as specified in federal regulations pursuant to Section 4 of this policy.

B. Undisclosed Interests and Clinical Trials

In any case in which the Department of Health and Human Services determined that an NIH-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an investigator with a conflicting interest that was not managed or reported as required by the regulation, Allina Health must require the investigator(s) involved to disclose the conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

Section 4 Reporting

A. PHS and Other Governmental Agencies

Allina Health will submit reports to governmental agencies as required by the individual awarding components.

Prior to expenditure of any PHS funds under an award, Allina Health will report to the PHS Awarding Component the existence of a FCOI and assure that the FCOI has been managed, reduced or eliminated in accordance with Section 50.604(g)(c); and, for any SFI that Allina Health identifies as conflicting subsequent to Allina Health's initial report under the award, the report will be made and the conflicting interest managed, reduced, or eliminated, at least on an interim basis, within sixty (60) days of that identification.

For any FCOI previously reported by Allina Health with regard to an ongoing PHS-funded research project, Allina Health shall provide to the PHS Awarding Component an annual FCOI report that addresses the status of the FCOI and any changes to the management plan for the duration of the PHS-funded research project. The annual FCOI report shall specify whether the FCOI is still being managed or explain why the FCOI no longer exists. Allina Health shall provide annual FCOI reports to the PHS Awarding Component for the duration of the project period (including extensions with our without funds) in the time and manner specified by the PHS/NIH Awarding Component.

B. The Public

Prior to expenditure of any funds under PHS-funded research, Allina Health, in compliance with federal regulations, must ensure public accessibility of information concerning senior/key personnel who have any SFI determined to be a FCOI. Requests for information must be submitted in writing to Allina's Research Compliance division of the Integrity and Compliance Department at researchcompliance@allina.com and must specify the name of the senior/key personnel and the name or number of the PHS-funded grant. Allina Health will respond to written requests received by Research Compliance within five (5) working days.

Publicly accessible information will include:

- Investigator's name;
- Investigator's title and role with respect to the research project;
- Title of the research project;
- Name of entity in which the SFI is held;
- Nature of the significant financial interest; and
- Approximate dollar amount, in one of the following categories:
    - $0 - $4,999
    - $5,000 - $9,999
    - $10,000 - $19,999
    - Amounts between $20,000 - $100,000 by increments of $20,000
    - Amounts above $100,000 by increments of $50,000; or

- Statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

Section 5 Subrecipient Requirements

When carrying out PHS-funded research or Federal Projects through a subrecipient, Allina Health must take reasonable steps to ensure that any subrecipient complies with federal regulations by:

1. Incorporating as part of a written agreement with the subrecipient, terms that establish whether the Research and Sponsored Projects Conflicts of Interest Policy of Allina Health or that of the subrecipient will apply to the subrecipient's investigators.
2. Providing FCOI reports to the PHS Awarding Component regarding all FCOIs of all subrecipient Investigators prior to the expenditure of funds and within sixty (60) days of any subsequently identified FCOI.
3. If an FCOI is identified for a subrecipient Investigator who must comply with Allina Health's Research and Sponsored Projects Conflicts of Interest Policy, Allina Health will monitor compliance with the required management plan on an ongoing basis until completion of the PHS-funded research or Federal Project.

Section 6 Training

All Investigators must complete training regarding conflicts of interest prior to engaging in any research or Federal Project. Successful completion of the CITI Program's COI module is the required training. Other training may be required and/or conducted by Allina Health Research Compliance division of the Integrity and Compliance Department.

Exceptions to the CITI COI training requirement may be granted if an investigator has completed training determined to be sufficient by the Allina Health Research Compliance division.

For all Investigators who are responsible for the design, conduct or reporting of PHS-funded research or a Federal Project, and as required by the Allina Health IRB and/or Allina, CITI COI Training must be renewed every four years and immediately when:

- Allina Health revises its policies and/or procedures regarding financial conflicts of interest in any manner that affects the requirements of the Investigators;
- An Investigator is new to Allina Health; or
- Allina Health finds that an Investigator is not in compliance with this Policy or a management plan.

Section 7 Record Retention

Allina Health must maintain records relating to all disclosed interests and the Institution's review of, and response to, such disclosures (whether or not a disclosure resulted in the Institution's determination of a COI), and all actions under the Institution's policy or retrospective review, if applicable, for at least three years from the date of final payment or, where applicable, for the

time periods specified in 48 CFR Part 4, Subpart 47 (4 years) or Allina Health's Retention Policy, whichever is longer.

Section 8 Sanctions

Failure to file a completed disclosure form for each PHS-funded project or to update this information on an annual basis, in addition to within thirty (30) days when the status of the disclosure may change, in compliance with this policy may be grounds for termination of the award. When appropriate, further sanctions may apply.

DEFINITIONS:

Committee means Allina Health's Research Conflicts of Interest Committee.

Conflict of Interest (COI) means a Significant Financial Interest or a Significant Non-financial Interest that could directly and significantly affect the design, conduct, or reporting of research or a Federal Project.

Federal Project means Federal financial assistance and Federal cost-reimbursement contracts that Allina Health receives directly from Federal awarding agencies or indirectly from pass-through entities. It does not include procurement contracts, under grants or contracts, used to buy goods or services from vendors.

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 or a Federal Project.

Immediate Family Member means spouse and dependent children.

Institution means Allina Health.

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 research, irrespective of funding source, or a Federal Project.

Institutional Responsibilities means research, education, clinical practice, service on institutional committees and panels, administrative activities and other professional activities.

PHS Rule means the regulation that applies to federal funding by certain federal agencies that the Department of Health and Human Services categorizes as the Public Health Service (PHS), such as National Institutes of Health or the Centers for Disease Control. The PHS Rules are comprised of the following two regulations: Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 C.F.R. Part 50, Subpart F) and Responsible Prospective Contractors (45 C.F.R. Part 94).

Significant Financial Interest (SFI):

(1) A financial interest consisting of one or more of the following interests of the Investigator, or the Immediate Family Member(s), that reasonably appears to be related to the Investigator's Institutional Responsibilities:

a. With regard to any publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. For purposes of this definition, remuneration includes salary, and any payment for services not otherwise identified

as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

b. With regard to any non-publicly traded entity, a *significant financial interest exists* if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Immediate Family member) holds an equity interest (e.g., stock, stock option, or other ownership interest); or

c. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

(2) Investigators also must disclose the occurrence of any reimbursed or sponsored travel that is required by the COI Smart disclosure form (i.e., that which 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 Institutional Responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 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.

(3) The term significant financial interest does not include the following: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights, assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; 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 engagements sponsored by a Federal, state, or local government agency, and Institution of higher education as defined at 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; or income from service on advisory committees or review panels for a Federal, state, or local government agency, and Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

Significant Non-financial Interest means a fiduciary relationship (e.g. Board Member), an advisory relationship (e.g., Scientific Advisory Board member), or the instances when an Investigator is the inventor of a product.

PROCEDURES: Not applicable.
PROTOCOL: Not applicable.
FORMS: Not applicable.
ALGORITHM: Not applicable.
ADDENDUM: Greater than Minimal Risk Research Financial Interest Thresholds and FAQs.
FAQs: Not applicable.

REFERENCES:
NIH Financial Conflict of Interest
42 CFR Part 50, Subpart F
45 CFR Part 94
COI Smart
Allina Health Conflicts of Interest webpage
CITI Program

Alternate Search Terms:
COI, Conflicts of interest, PHS, IRB, conflict, financial interest, FCOI, disclosure

Related Policies:

Name of Policy	Content ID	Business Unit where Originated
N/A		

Policies Replacing:

Name of Policy	Content ID	Business Unit where Originated
N/A		

Allina Health

Greater than Minimal Risk Research Financial Interest Thresholds and FAQs
Approved by the Research Conflicts of Interest Committee, May 14, 2018

Overview

Effective April 1, 2019, Investigators[1] with financial interests exceeding threshold (as outlined below) in the sponsor (or a company that makes the test article) of a new greater than minimal risk research study must show that compelling circumstances justify allowing the investigator to participate in the research study. If the Committee determines that compelling circumstances justify allowing the investigator to participate, the investigator would be permitted to participate in the research study subject to any management imposed by the Committee and/or other institutional oversight (e.g., IRB).

Thresholds for Financial Interests

Compelling circumstances are required when an investigator has a financial interest in the sponsor (or company that makes the test article) equal to or exceeding these thresholds:

- Compensation of $25,000 in the last 12 months (e.g., consulting, speaking engagements)
- Equity in a publicly-traded company valued at $25,000
- Income from intellectual property licensing arrangements (e.g., royalties) of $25,000 in the last 12 months
- Any equity in a privately-held company

Compelling Circumstances

When determining whether compelling circumstances justify allowing an investigator to participate in a greater-than-minimal risk clinical research study when they have a financial interest exceeding the above thresholds, the Committee will consider:

- the nature of the research,
- the magnitude of the Investigator's financial interest and the degree to which it is related to the research,
- the extent to which the Investigator's financial interest could be directly and substantially affected by the research,
- the degree of the risk to the human subjects involved that is inherent in the research protocol,

[1] Consistent with the Research and Sponsored Programs Conflicts of Interest Policy, "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 research, irrespective of funding source, or a Federal Project. Allina Health defines "investigator" to mean all study personnel.

- whether there are other investigators participating in the research who have similar interests,
- the extent to which the Investigator is uniquely qualified to perform a research study with important public benefit,
- the extent to which the removal of the Investigator would put patient safety at risk, and
- the extent to which the financial interest is amenable to effective oversight and management.

Scenarios

Scenario #1: Consulting interest in sponsor, Committee would not find compelling justification

Dr. Marcus is nationally known in the field of allergy clinical research, and has submitted an application to the IRB to serve as PI on a multi-site, open-label, pivotal study comparing a new drug with the standard of care therapies. The study is sponsored (and the experimental drug is manufactured) by AllergyAversion, Inc. The IRB has determined that this study is greater than minimal risk.

Over the last several years, Dr. Marcus has consulted with AllergyAversion, helping them develop rigorous study designs, identify new treatment opportunities, speaking about allergy research at national conferences, and, most recently, she has served on AllergyAversion's scientific advisory board. In the past 12 months, Dr. Marcus has received $74,000 from AllergyAversion, Inc.

Dr. Marcus submitted the Compelling Justification Form, arguing that compelling circumstances justified her participation. She argued that she has unique expertise as a nationally known leader in allergy research. She also argued that this study would not proceed at Allina Health without her involvement, since no other Allina allergist is interested in serving as PI.

The Committee would not likely find compelling circumstances justifying Dr. Marcus's involvement in this study. Although Dr. Marcus is a nationally recognized expert in allergy research, that expertise is not required to conduct this study; many PIs from across the country are leading this study at their sites.

Scenario #2: Consulting interest in sponsor, Committee would find compelling justification

Dr. Rose would like to serve as national PI, as well as local PI, on a study on a new device used with individuals who have had a stroke, sponsored by NeuroCo. This device addresses strokes in an innovative manner that differs from other products on the market or that are currently being researched by other companies). The device has not been used widely; Dr. Rose has served as a proctor on similar devices, and has had significant experience—likely more than virtually any other clinician in the country—using this particular device in previous clinical trials. Dr. Rose has a consulting relationship with NeuroCo; he reports receiving $50,000 from NeuroCo in the past 12 months.

Dr. Rose submitted the Compelling Justification Form, arguing that compelling circumstances justified his participation in this study. He argued that he has unique expertise to implant this experimental device, given his experience implanting similar devices that are FDA-approved, as well as this particular device in other clinical trials (or approved as compassionate use). Due to his reputation and expertise, he has a higher percentage of patients with complicating medical factors, and these patients are prime candidates to benefit from this research study. If he was not participating in this study, these patients may not have access to this research study. Given the level of expertise needed to carry out this study, if Dr. Rose wasn't permitted to participate, it is not likely that another local investigator would have the expertise to serve as PI in the study. Local patients would not likely be able to participate in this research study within Dr. Rose's involvement.

The Committee would likely find compelling circumstances justifying Dr. Rose's involvement in this study, subject to a management plan designed to insulate the study from actual or perceived influence. Management strategies might include disclosure to all participants in the informed consent form, disclosure in all publications and presentations, periodic reports to the Committee by a study team member (or leader) without a conflict regarding oversight of the study, and limitation of Dr. Rose's involvement in the consent process.

Scenario #3: Salary and stock held by investigator's spouse, Committee would find compelling justification

Dr. Thomas's husband is a human resources executive at MedDevice, Inc. As a MedDevice employee, he receives salary from, and holds stock in, MedDevice. MedDevice is a large device company with a broad portfolio of products targeting a wide variety of medical conditions. Dr. Thomas is a cardiovascular surgeon interested in serving as PI on a new device study, sponsored by MedDevice. She has reported on her COI disclosures that her husband receives salary and holds MedDevice stock obtained through his employment.

Dr. Thomas submitted the Compelling Justification Form, arguing that compelling circumstances justified her participation in this study. First, her husband's interest in MedDevice is related to his work in human resources, and is not directly related to MedDevice's cardiovascular research. Furthermore, his interest in MedDevice would not be directly and substantially affected by this research, since MedDevice has a large portfolio of research studies and products.

The Committee would likely find compelling circumstances justifying Dr. Thomas's involvement in this study, subject to a management plan designed to insulate the study from actual or perceived influence. Management strategies might include disclosure to all participants in the informed consent form, disclosure in all publications and presentations, periodic reports to the Committee by a study team member (or leader) without a conflict regarding oversight of the study, and limitation of Dr. Thomas's involvement in the consent process.

FAQs

How does an investigator go about showing compelling circumstances?

After submitting an IRB application and all COI-related requirements (e.g., disclosure forms, trainings), a member of the Research Compliance team will reach out to investigators who have financial interests exceeding the above thresholds. If the investigator believes compelling circumstances are present, he or she would complete the Compelling Justification Form for Committee review.

What happens if the Committee does not find compelling circumstances?

The study could proceed at Allina with a different investigator.

Some studies are able to be restructured so that they are not greater than minimal risk (e.g., retrospective chart review). If that's a possibility, the study could be restructured as minimal risk, and an investigator with a financial interest exceeding the above thresholds could participate in that study.

Allina Health Research Compliance is available to help researchers understand and identify other options at researchcoi@allina.com or 612-262-6009.

Are there resources available to investigators who want to better understand this policy?

If you have any questions about these requirements, please contact Allina Health Research Compliance at researchcoi@allina.com or 612-262-6009.