

MAINEHEALTH

Policy Title: Financial Conflicts of Interest in Research

INTRODUCTION

The purpose of this document is to set forth definitions, policies, and procedures to ensure that research conducted at MaineHealth (MH) is free from individual researcher bias. This policy seeks to ensure that the personal financial interests of Investigators conducting research at MH do not compromise the objectivity with which research is designed, conducted, and reported.

This policy applies to all investigators who are responsible for designing, conducting, or reporting research projects that are conducted at, or in affiliation with MH as well as all Key Personnel. Throughout the rest of the document, we use the term "Investigator" to encompass both Investigators and Key Personnel. MH has adopted the PHS requirements for financial disclosure in research *regardless of the source of project funding or whether the project has any external funding*. This policy is written to include portions of, and to adhere to, the Federal regulations governing financial conflicts of interest for PHS-funded activities. This policy specifically references 42 CFR Part 50 subpart F and 45 CFR Part 94.

In addition to the requirements set forth in this policy, as MH staff, investigators must comply with other MH policies relating to ethics and conflict of interest, including the Promoting Ethical Partnerships with Healthcare Vendors policy and the general Conflict of Interest policy.

DEFINITIONS

Investigator - the project director or principal Investigator (PD/PI) and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research

Key Personnel – includes the PD/PI but also includes any other personnel that are considered to be "essential to work performance" on a project. Furthermore, MH defines Key Personnel on human subjects protocols as 'Research personnel directly involved in conducting research specific interventions with study participants, or their private identifiable information (PII), or protected health information (PHI) and also includes faculty mentors/advisors providing direct oversight to research personnel.'

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).

Human Subjects Research and Clinical Investigations - any activity that meets either (a) the Department of Health & Human Services definitions of both "research" and "human subjects" or (b) the Food and Drug Administration definitions of both "clinical investigation" and "human subjects". These activities require review and approval by an Institutional Review Board (IRB).

Family Member - a spouse, domestic partner, and/or dependent child

Entity - an institution, organization, or business

Financial Interest - anything of monetary value, whether or not the value is readily ascertainable (e.g. equity, stocks, honorariums, travel reimbursement, etc.)

Significant Financial Interest (SFI) - a financial interest that exceeds a financial threshold; the amount as specified herein.

Financial Conflict of Interest (FCOI) - exists when an Investigator's Significant Financial Interest(s) (SFI, see above) could affect, or reasonably appear to affect, the Investigator's research.

Designated FCOI Official {DO} – the official who is responsible for soliciting and reviewing disclosures of significant financial interests and serves on the Research Financial Conflict of Interest Committee. The Director of Research Compliance serves in this role.

Vice President of Research -- has institutional authority to legally bind the institution in research matters.

Manage – to take action to address a FCOI, which can include reducing or eliminating the FCOI and/or to ensure, to the extent possible, that the design, conduct, and reporting of the research will be free from bias.

Outside Entity - any company or organization not affiliated with MaineHealth.

Prime Awardee – the institution that is awarded research funding through a grant or contract

Sub-recipient - an institution who is contracted by the “prime awardee” to carry out research activities (e.g., subawardees or consortium members) under a specific grant

Research - a systematic investigation designed to develop or contribute to generalizable knowledge. The term encompasses basic, translational, and applied research; it also includes product development

SBIR Program - the Small Business Innovation Research program: an extramural research program for small business established by the awarding component of the PHS under federal law. The SBIR Program also includes the **Small Business Transfer Technology Program (STTR)** program also established by Public Law

Sponsored Research - refers to research activities or projects that are financially supported by external funds awarded to MH.

POLICIES AND PROCEDURES

1. Investigator Education and Training

MH requires its Investigators to participate in FCOI training once per year at the same time they disclose their financial interests. The education and training is done by completing a) the CITI Financial Conflicts of Interest Training Module and b) by reviewing this Policy and attesting to having read it in the disclosure form. Such training must have been completed within 12 months prior to submission of a PHS grant proposal.

In addition to completing this education annually, such training is also required at the following times:

- Financial conflict of interest policies are revised in a manner that changes Investigator requirements
- An investigator is new to the organization
- An investigator is non-compliant with financial conflict of interest policies and procedures

Investigators will be held responsible for maintaining certification of completion of the CITI training tutorial, and must attest to both completion of training and of policy review on the Financial Interest Disclosure Form.

2. Disclosure Process

When to Report or Disclose Financial Interests:

Investigators planning to participate, or currently participating in, PHS or non-PHS funded research must disclose their significant financial interests (including those of their spouse and dependent children):

- a) Within the twelve months prior to the time of application for research funding;
- b) Each time human subject proposals are submitted to MH's Institutional Review Board (IRB) or to a Central IRB for research to be conducted at MH or under the auspices of MH, including initial submissions and each continuing review; and
- c) Annually, in accordance with the specific time period prescribed by MH; and
- d) Within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest

How are Financial Disclosures Made?

All research disclosures shall be made using a secure, electronic, financial interest disclosure form to be maintained by the Office of Research Compliance (ORC). Investigators will complete a confidential Financial Interest Form online which will be sent to investigators on an annual basis. If the investigator is new to research or new to the institution, the investigator will be sent the disclosure form separately prior to grant submission or IRB application.

What must be disclosed?

Any one (or more) of the following Significant Financial Interests of an Investigator (including the Investigator's spouse and dependent children) must be disclosed by way of the Financial Interest Disclosure Form:

- Financial interest in any **publicly traded entity**, if the value of remuneration (e.g., salary, payment for services such as consulting fees, honoraria, paid

authorship) and/or equity interest (including equity, stock, and/or ownership interest – value determined through reference to public prices or other measure of reasonable market value at the time of the disclosure), received in the 12-months preceding the disclosure, when aggregated exceeds \$5000.

- Financial interest in any ***non-publicly traded entity***, if the value of any remuneration (e.g., salary, payment for services such as consulting fees, honoraria, paid authorship) received from the entity in the 12-months preceding the disclosure, when aggregated, exceeds \$5000,
- Financial interest in any ***non-publicly traded entity*** when the Investigator (including spouse or dependent children) holds ANY equity interest (i.e., >\$0 value) such as stock, stock option, or other ownership interest.
- Intellectual Property (IP) rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and
- TRAVEL: The occurrence of any reimbursed or sponsored travel that **is related to the Investigator's Institutional responsibilities** and individually, or when aggregated from a single entity, exceeds \$5000 in value. *{This requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education (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.}*

*It DOES apply to a **foreign** government agency or institution of higher learning).*

- The following information must be provided in connection with any Travel disclosures that meet the above criteria:
 - Purpose of trip
 - Identity of the sponsor/organizer of the trip
 - Destination/Location
 - Duration of trip
 -

Exclusions (Items that do not need to be disclosed):

- Salary, or other remuneration paid by MaineHealth to the Investigator, if the Investigator is currently employed or otherwise appointed by MH; Any financial interest arising solely by means of investment in a mutual, pension, or other fund wherein the Investigator does not manage the assets;
- Income from seminars, lectures, or teaching engagements sponsored by a United States 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 United States 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, 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.
- SBIR and STTR Phase I federal grants are exempt.

- 3. Review Process:** The Director of Research Compliance will serve as the Designated FCOI Official (DO), and will oversee the solicitation and review of

disclosures under this policy. The DO will work closely with the **Research Conflict of Interest Committee (RCOIC)** in the review of potential conflicts and the creation of management plans. The RCOIC makes recommendations on courses of action designed to manage, reduce, or eliminate identified financial conflicts of interest in Research. The Office of Research Compliance provides support to the RCOIC by maintaining meeting minutes and preparing periodic reports for the Vice President of Research. It is the responsibility of the Vice President of Research in conjunction with the DO to appoint members to the Committee and to reassess its composition based on attendance, performance, required areas of expertise, and/or any other reason as deemed appropriate.

The DO oversees an initial review of submitted disclosures and will determine the presence of a SFI that may be an FCOI (as defined above):

- If no SFI is disclosed, the Investigator's Financial Interest Form will be marked as reviewed, as having no conflict, and the submitted Form (with provided data) will be maintained as described below.
- If it is determined that a SFI is present and has **no potential** for the SFI to influence the design, conduct and/or reporting of a research study or a PHS-funded research grant, the Investigator's Financial Interest Form will be marked as reviewed, as having no conflict, and the provided data will be maintained as described below.
- If it is determined that a SFI is present and may possibly, or probably, **have potential** for the SFI to influence the design, conduct and/or reporting of a research study, the Investigator will be contacted by a RCOIC or ORC delegate and asked to provide additional information for committee review as needed.
- The completed Financial Interest Form AND supporting documentation, once provided by the Investigator will then be submitted for review by the RCOIC.
- At a convened meeting, the RCOIC will make a determination of one of the following:
 1. No Conflict: the determination will be documented in the RCOIC minutes and the Investigator (and Department Chief or direct supervisor) will be notified in writing of the determination
 2. Conflict:
 - Level of conflict will be determined based upon guidance below.
 - Management Plan will be drafted with terms that specify:
 - a. Required internal and/or external notifications and disclosures
 - b. Person(s) named who will provide oversight of management plan
 - c. Any restrictions on use of resources
 - d. Additional detail and considerations as deemed appropriate by the RCOIC

Research in which an Investigator is found to have a FCOI will not be permitted to proceed until the Investigator has agreed to implement an

executed (signed) Management Plan. If the identified FCOI is related to an investigator's NIH or PHS-agency funded grant, the management plan will be immediately submitted to NIH or other agency (see "reporting" below).

- Human Subjects Research: If the RCOIC determines that a financial conflict exists AND human subjects are involved, the RCOIC proposed Management Plan will be submitted to the IRB for further review and consideration. The IRB may include additional requirements but may not remove any requirements made by the RCOIC. A research project will not be approved unless, and until, the Management Plan has been approved by the, the RCOIC and the IRB. The plan will be submitted to the VP Research for final approval.

Out of Cycle Reviews: The DO will review out of cycle disclosures including disclosures of investigators new to the institution or new to a research project, and disclosures of an existing investigator who discloses a new SFI. The Office of Research Compliance is notified when a new disclosure is submitted and will take action to review the disclosure and will convene an RCOIC meeting if needed within 60 days of the disclosure if a potential conflict exists that must be reviewed and managed.

Retrospective Review/ Non-Compliance: Whenever an SFI is not disclosed or an identified FCOI is not managed in a timely manner, the RCOIC (via designee) shall complete a retrospective review of the Investigator's activities, and the research project, within 120 days of the determination of noncompliance. The RCOIC will determine whether any research, or portion thereof, was biased with regard to its design, conduct, or reporting during the time of noncompliance. If the retrospective review involves PHS funded research, the results of the review will be reported to the funding agency within 120 days of determination.

Guidance on Conflict Decisions and Considerations:

The DO and the RCOIC will be guided by the following principles in determining if an identified SFI is related to an investigator's research project (PHS funded or Non-PHS funded) and if so, if it constitutes a FCOI.

If the SFI is with any of the following entities, then a conflict of interest exists.

- the entity that sponsors the Investigator's research project;
- the entity that produces products (equipment, software, compounds, drugs, devices, etc.) or services used in the Investigator's research project;
- the entity that develops product or services the Investigator's research project intends to evaluate or develop; or
- an entity with whom the Investigator is consulting in an area that overlaps with or is the main subject of his/her research

Investigator Petition Process

Investigators may petition the RCOIC to allow participation in clinical research, or receive research support, if a potential conflict arises solely by virtue of the career pursuits of the Investigator's spouse or domestic partner. The RCOIC may allow the potential conflict of interest if it is one that the RCOIC finds can be managed adequately through a formal management plan.

4. Management of FCOIs

For all conflicts, the development of an FCOI Management Plan will include consideration of the potential risk to human subjects; the nature and significance of the conflict; the potential for adverse impact on the reputation of the Investigator and the Institution; and the level of difficulty involved in managing the conflict relative to the benefit of conducting the research.

Management strategies may include:

- Public disclosures of SFI (e.g., when presenting or publishing research);
- Disclosure of financial conflicts of interest directly to research participants;
- Monitoring of the research by independent reviewers;
- Modification of the research plan or the protocol to mitigate conflict;
- Change of personnel or responsibilities; disqualification of personnel from participation in all or a portion of the research;
- Divestiture by the Investigator of SFI related to the FCOI;
- Severance of relationships that create actual or potential conflicts

In cases where a significant FCOI cannot be effectively managed, the research will not be conducted at MH.

Further, the Institution may prohibit research that involves a conflict of interest even if the IRB approves the research. Such a decision will be made in consultation with the Vice President of Research, the DO, the Chief Academic Officer, and/or legal counsel.

For research funded by a PHS agency, the management plan will be reported to the federal agency within 60 days of learning of the financial conflict of interest. Federal grant applications may be submitted while MH is considering a possible FCOI with the understanding that the research will not be conducted unless the FCOI is managed, or eliminated. There will be no expenditure of funds until such time as the Management Plan has been executed and reported to the funding agency.

For off-cycle disclosures, when there is a new investigator at MH or when an investigator discloses a new SFI during the year, the Office of Research Compliance will review the disclosure and if there is a potential FCOI, will call a meeting of the RCOIC to discuss and to develop a management plan, if needed. This process will take place within 60 days of learning of the disclosure.

5. Monitoring Management Plans

All management plans will be monitored by the Vice President of Operations for Academic affairs who will oversee compliance. The plan will specify time periods during

which the monitor must review reports from the investigator on progress and compliance steps. The monitor will report on compliance with the plan on an annual basis; if the monitor finds noncompliance issues, he/she will report them immediately to the RCOIC for review and action.

6. PHS Reporting Responsibilities

For all FCOIs on projects funded with PHS awards, prior to expenditure of funds, MH will report to the PHS awarding agency the existence of any FCOI, the nature of the conflict, and details of the management plan. Reports to the PHS will be submitted initially within 60 days of learning of the conflict, annually during the award period, and within 60 days of learning of any subsequently identified FCOI. It is the responsibility of the Director of Research Grant Services to submit such reports.

The report will include:

1. Project number;
2. Project title;
3. Project PD/PI or contact (local) PD/PI
4. Name of the Investigator with FCOI
5. Name of the entity with which the Investigator has a FCOI
6. Reason for the retrospective review;
7. Detailed methodology use for the review
8. Findings and Conclusions of the review

If the conflict was identified after the research had begun, MH will conduct a retrospective review and will report the results to the federal funder. If bias is found MH will notify the PHS Awarding Component and submit a mitigation report (see below, noncompliance).

NOTE: for any FCOI that is eliminated prior to the expenditure of PHS-awarded funds, the Institution is NOT required to submit a report). For any subsequent or newly identified FCOI, an amendment to the FCOI report will be filed with the PHS funding agency, or the FCOI will be eliminated, within sixty (60) days of the disclosure.

7. Record Retention:

Records of all financial interest forms, disclosures and any actions taken by MH with respect to financial interest disclosures and any actions taken regarding management plans will be retained electronically in a secure fashion.

- i. For grants or cooperative agreements – at least three years from the submission date of the final expenditures report or, where applicable, from other dates specified in 45 C.F.R. 74.53(b) and 92.42(b) for different situations; and
- ii. For research contracts – for three years after final payment to MMC or sub-recipient, or where applicable, for the other time periods.

8. Enforcement Mechanisms, Remedies, and Non-Compliance

Retrospective Review:

Whenever a financial conflict of interest is not identified or managed in a timely manner including failure by the Investigator to disclose a significant financial interest that is determined by MH to constitute a financial conflict of interest; failure by MH to review or manage such a financial conflict of interest; or failure by the Investigator to comply with a financial conflict of interest management plan, MH will, within 120 days of the determination of noncompliance, complete a retrospective review of the Investigator's activities and the research project, including a PHS-funded research project, to determine whether any research conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.

MH will document this review and, if PHS-funded, will report the following elements within 120 days of learning of the noncompliance:

- (1) Project number;
- (2) Project title;
- (3) PD/PI or contact PD/PI if a multiple PD/PI model is used;
- (4) Name of the Investigator with the FCOI;
- (5) Name of the entity with which the Investigator has a financial conflict of interest;
- (6) Reason(s) for the retrospective review;
- (7) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
- (8) Findings of the review; and
- (9) Conclusions of the review.

Based on the results of the retrospective review, if appropriate, MH shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward. If bias is found, MH will notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report will include, key elements documented in the retrospective review above and a description of the impact of the bias on the research project and the Institution's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, MH will submit FCOI reports annually, as specified in this policy. Depending on the nature of the financial conflict of interest, MH may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date that the financial conflict of interest or the Investigator's noncompliance is determined and the completion of the Institution's retrospective review.

Failure to comply with a management plan: In this case, the DO will call a meeting of the RCOIC within 14 days of learning of non-compliance to review the situation and take action. If the failure is related to a PHS-funded grant, notification will be sent to the funding agency of the noncompliance and a management plan, within 60 days of identification of the noncompliance.

Failure to disclose a new SFI in a timely manner: The DO and RCOIC shall review the newly identified SFI and determine if an FCOI exists. If it does, a management plan will be instituted and reported to the PHS Agency, if applicable, within 60 days of identifying the FCOI.

Clinical Research Non-compliance: If a PHS funded clinical research project 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 financial conflict of interest that was not managed or reported by MH, MH will require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

9. Sub-Recipient Requirements

When MH is the prime recipient of a PHS-funded research grant, and a portion of the research is carried out through a sub-recipient, MH will establish in writing, at the time of proposal submission, whether this policy, or that of the sub-recipient, will apply to the sub-recipient's Investigators. The sub-recipient must certify in writing that it has a policy that is compliant with CFR 42 subpart 50 and MH will obtain the policy or confirm on the FDP clearinghouse that the institution has a compliant policy. If the sub-recipient cannot provide such certification, the sub-recipient investigators will comply with the MH policy. If the application is funded, the subaward agreement shall specify which policy is to be followed. If sub-recipient policy is followed, the agreement shall specify time period(s) for the sub-recipient to report all identified financial conflicts of interest to MH to enable MH to provide timely FCOI reports, to the PHS. If MH policy is followed, the agreement will so state, and time periods for sub-recipient investigators to disclose interests will be specified.

When MH Investigators are sub-recipients on grants awarded to other institutions, the Investigator will follow the requirements of this MH policy regarding disclosing, managing, and reporting of FCOIs, unless otherwise specified by the agreement with the prime awardee Institution. The Director of Research Grant Services is responsible for reporting any FCOI to the prime recipient within 30 days of learning of the conflict. These terms will be incorporated in the sub-recipient agreement.

10. Transparency/Public Accessibility Requirements

This policy is available on our public website at <http://mmcri.org/grantspolicies>.

MH will also ensure public accessibility to any identified FCOIs of a senior/key personnel on a PHS-funded grant, via written response to any requestor within five business days of a request for information concerning the FCOIs.

Prior to MH's expenditure of any funds under a PHS-funded research project, MH shall ensure public accessibility, via a 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;
- (B) MH determines that the significant financial interest is related to the PHS-funded research; and
- (C) MH determines that the significant financial interest is a financial conflict of interest.

MH will make available the following information upon request:

1. Investigator's name
2. Investigator's title and role on the project
3. Name of the entity in which the SFI is held
4. Nature of the SFI
5. Approximate value (dollar 'range' permissible – e.g., \$0-\$4,999, \$5,000-\$9,999, etc.), or, a 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.

11. Other Considerations:

Students/Trainees: An important part of the training of graduate students and postdoctoral fellows is research mentoring. MH and the staff who oversee student research must ensure that the educational interests of these trainees are not compromised by FCOIs. Care must be taken to ensure that the source of research funding does not cause a change in the training experience. Students and fellows should not be placed in a situation where the financial interests of MH or the mentor will influence the direction of the research project. Furthermore, agreements with sponsors should not compromise the rights of students to publicly present and publish dissertations and manuscripts reporting their research.

12. Regulatory Compliance:

The review of all financial conflicts will be conducted according to this policy regardless of the funding source. MH will comply with all applicable federal, state and institutional regulations, standards and requirements including those of Public Health Service (PHS) agencies, the National Science Foundation (NSF), Department of Defense (DoD), and the Association for the Accreditation of Human Research Protection Programs (AAHRPP).

Conflict of Interest Websites:

NIH <http://grants.nih.gov/grants/policy/coi>
FAQ <http://grants.nih.gov/grants/policy/coifaq.htm>

Other Related Documents or Policies:

[Research Conflict of Interest Committee Charter](#)
[Promoting Ethical Partnerships with Health Care Vendors Policy](#)

References:

42 CFR Part 50 Subpart F
45 CFR Part 94

*Within the Department of Health and Human Services (HHS), eight agencies are designated components of the U.S. Public Health Service (PHS):

- the Agency for Healthcare Research and Quality (AHRQ),
- the Agency for Toxic Substances and Disease Registry (ATSDR),
- the Centers for Disease Control and Prevention (CDC),
- the Food and Drug Administration (FDA),
- the Health Resources and Services Administration (HRSA),
- the Indian Health Service
- the National Institutes of Health (NIH), and
- the Substance Abuse and Mental Health Services Administration (SAMHSA).