

POLICY ON CONFLICT OF INTEREST IN RESEARCH



Policy Description and Purpose:

The purpose of this document is to set forth definitions, policies, and procedures to ensure that the personal financial interests of Investigators or Key Personnel do not compromise the objectivity with which research is designed, conducted, and reported, nor to allow interests to compromise the safety or welfare of human research subjects.

This policy applies to all Investigators and Key Personnel, here-forward referred to as “Investigator” who are responsible for designing, conducting, or reporting research projects that are conducted at, or in affiliation with Maine Medical Center (MMC). This policy additionally refers to any Program Director/Principal Investigator (PD/PI) and any other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they request salaries or compensation.

MMC (“Institution”) has adopted the PHS requirements for financial disclosure in research *regardless of the source of project funding*. This policy shall apply to Investigators on any sponsored research agreement that is in preparation, has been submitted to a sponsor, or that is currently funded. Further, this policy applies to Investigators involved in any institutionally-sponsored research.

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 and 45 CFR Part 94.

I. 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, MMC 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 Conflict of Interest Official {DCOIO} – 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.

Institutional Official {IO} - has institutional authority to legally bind the institution in grants administration matters and is responsible for institutional compliance with FCOI

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 or Maine Medical Center

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

Sub-recipient - an institution or investigator who is contracted by the “prime awardee” to carry out research activities (e.g., subcontractors 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 MMC

II. Investigator Education and Training Requirements:

The Institution 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 NIH Financial Conflict of Interest Training Tutorial](#) and attesting to having completed the training; and b) by reviewing this Policy and attesting to having read it in the disclosure form.

Investigator education is required by the Institution immediately when:

- 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

This training and education requirement must have been fulfilled within twelve months prior to submission of a new research grant proposal and annually thereafter.

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

III. 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):

1. Within the twelve months prior to the time of application for research funding; and/or
2. Each time human subject proposals are submitted to MMC's Institutional Review Board (IRB) or to a Central IRB for research to be conducted at MMC or under the auspices of MMC; including initial submissions and each continuing

- review; and
3. Annually, in accordance with the specific time period (e.g., May 1 through April 30) prescribed by Maine Medical Center; and
 4. Within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest

IV. How are Financial Disclosures Made?

Investigators will complete a Financial Interest Form online which will be sent on an annual basis or, if the investigator was not included in the annual disclosure list, will be sent separately at time of grant submission or IRB application.

V. 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 interests *{This requirement does not apply if the IP rights and income are held by the Institution and the investigator shares in royalties through the institution}*
- TRAVEL: The occurrence of any reimbursed or sponsored travel that **is related to the Investigators 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.}*
 - 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:

- Salary, royalties, or other remuneration paid by Maine Medical Center or by MaineHealth to the Investigator, if the Investigator is currently employed or otherwise appointed by Maine Medical Center, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights;
- 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 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; 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.

VI. Research Conflict of Interest Committee (RCOIC):

The RCOIC is a committee that makes recommendations on courses of action designed to manage, reduce, or eliminate financial conflicts of interest in Research. The MMC RCOIC is comprised of the following members: Director of Research Administration (chair), Director of Clinical Ethics, Director for the Office of Technology Transfer, Institutional Review Board (IRB) Chair, Physician Representative, Senior Faculty Scientist(s), the Manager of Research and Grant Accounting, the Director of Research Compliance, and ad hoc members.

The RCOIC shall maintain meeting minutes and shall prepare periodic reports for the Institutional Official. It is the responsibility of the Institutional Official 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.

VII. Disclosure Review Process:

All research disclosures shall be made using a secure, electronic, financial interest disclosure form to be maintained by the Office of Research Compliance (ORC). The ORC will perform an initial review of submitted disclosures and will determine the presence of a SFI (as defined in Section V 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 in Section XIII of this policy
- 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, the Investigator's Financial Interest Form will be marked as reviewed, as having no conflict, and the provided data will be maintained as described in Section XIII of this policy
- 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 and their Department Chief (or direct supervisor) will be contacted by a RCOIC delegate and asked to provide, for committee review, one or both of the following:
 1. Documentation, to include specific detail, addressing factors that may contribute to, or negate, a potential finding by the RCOIC of an actual (or perceived) conflict of interest
 2. A proposal to include actions or methods to be taken to prevent, or manage, an actual (or perceived) conflict of interest
- The completed Financial Interest Form AND supporting documentation (or mitigation proposal), once provided by the Investigator and Department Chief (or direct supervisor), 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 the MMC Conflict Level guidance document (attached)
 - 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.**
- 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 and may also make modification requests. A research project will not be approved unless, and until, the Management Plan has been approved by the IO, the RCOIC Committee, and the IRB.

- Non-Human Subjects Research: The IO may agree or disagree with the RCOIC proposed Management Plans.
 1. If the IO disagrees with the Management Plan, the comments will be brought back to the RCOIC for revision until mutual agreement is achieved
 2. Upon IO agreement with a proposed RCOIC Management Plan, the plan will then be provided for signature by the Investigator, the Department Chief, who will oversee implementation of the plan, and the IO. An electronic copy of the signed plan will be maintained as described in Section XIII.

VIII. Conflict Decisions and Considerations:

For any identified FCOI, with guidance from the RCOIC, the designated financial conflict of interest official will take appropriate action to mitigate or remove the potential for any financial conflict to compromise the safety of human subjects or to negatively impact the validity of the proposed research.

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.

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.

Per the regulations, 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 by utilizing the means outlined above, the research will not be conducted at the Institution.

For all FCOIs on projects funded with PHS awards, prior to expenditure of funds, the Institution is required to report to the PHS awarding agency the existence of any FCOI. (See section XII). Reports to the PHS will be submitted initially, annually during the award period, and within 60 days of any subsequently identified FCOI. For any FCOI previously reported by the Institution with regard to an ongoing PHS-funded research project, the Institution shall provide to the PHS an annual FCOI report that addresses the status of the FCOI and any changes to the Management Plan – for the duration of the project. It is the responsibility of the Senior Grant Administrator to submit such reports.

An approved Management Plan must be in place before the research begins. In human subjects research, IRB approval will not be granted until the conflict of interest management plan has been established and approved. 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 IO, the IRB Chair, the Senior Vice President for Medical and Academic Affairs, and/or legal counsel.

Federal grant applications may be submitted while MMC 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.

Once a management plan is in place for a specific FCOI, it will be reviewed annually. Investigators are required to notify MMC's Office of Research Compliance of any changes that occur related to the FCOI.

IX. 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.

Per Federal Regulations, the Institution is required to document the retrospective review; such documentation shall include, at a minimum, all of the following key elements:

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 bias is found and the research is funded with PHS funds, the Institution is required to notify the PHS Awarding Component and submit a mitigation report. The Senior Grant Administrator will notify the PHS awarding component and ensure fulfillment of this requirement.

The Investigator is required, at a minimum, to disclose the FCOI in each public presentation of the results of the research and to submit an addendum to any previously published presentations. Employee sanctions or other administrative actions may apply.

X. PHS Funded Sub-recipient Agreements:

When MMC research is to be funded by PHS and carried out through a sub-recipient, the Institution 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; if the application is funded, the subaward agreement will specify the time frames within which the sub-recipient must provide any information necessary to ensure that MMC is able to meet its reporting obligations to the PHS awarding agency.

When MMC Investigators are sub-recipients on grants awarded to other institutions, the Investigator will follow the requirements of this policy regarding disclosing, managing, and reporting of FCOIs, unless otherwise specified by the agreement with the prime awardee Institution. The Senior Grants Administrator is responsible for reporting any FCOI to the prime recipient within 30 days of learning of the conflict.

XI. Transparency/Public Accessibility for PHS Funded Research:

By regulation, it is the responsibility of the Institution to make this policy available via a publicly accessible web-site. MMC will ensure that any FCOI has been managed, reduced, or eliminated in accordance with 42 CFR Part 50 and 45 CFR Part 94. Prior to the Institution's expenditure of any funds under a PHS-funded research project, the Institution shall ensure public accessibility via written response to any requestor within five business days of a request for information concerning any SFI that is disclosed to the Institution that meets the following three criteria:

1. The SFI was disclosed and is still held by key personnel;
2. The Institution determines that the SFI is related to the PHS-funded research; and
3. The Institution determines that the SFI is a FCOI

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The information to be made available shall include:

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.

XII. PHS Reporting Responsibility:

The Institution shall provide to the PHS Awarding Component an FCOI report regarding any SFI found to be an FCOI. The report will include documentation that the Institution has implemented a Management Plan in accordance with the regulations (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.

XIII. Record Retention:

Records of all financial interest disclosures (whether or not a disclosure resulted in the Institution's determination of a FCOI) and any actions taken by the Institution, with respect to FCOI, will be retained electronically and managed by Office of Research Compliance for at least three years from the date the final expenditures report is submitted to the PHS or, where applicable, from other dates specified in 45 CFR 75.361.

XIV. Other Considerations:

Students/Trainees: An important part of the training of graduate students and postdoctoral fellows is research mentoring. MMC 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 MMC 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.

XV. Regulatory Compliance:

The review of all financial conflicts will be conducted according to this policy regardless of the funding source. MMC 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).

XVI. 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](#)

[Human Research Protection Policy on the Resolution and Management of Investigator Conflicts of Interest](#)

[Reporting Misconduct of Science](#)

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