

Document Owner: Chief Compliance Officer	Reviewed By: Provider Services Legal	Approved By: Institutional Official
--	---	---

SCOPE

This Policy and Procedure applies to:

- Ambulatory Services
- Ambulance
- Clinics: <<state type of clinics in scope>>
- Home and Community
- Maple Grove Hospital
- North Memorial Health Hospital
- (Keep all locations in scope; delete the others and this statement in italics)*

PURPOSE

To guide the Organization in addressing conflicts of interest by articulating standards for identifying, addressing, managing and, if necessary, eliminating them. To implement the provisions of 42 CFR Part 50 and 45 CFR Part 94 (“PHS Objectivity in Research Rule”) for research supported by the U.S. Public Health Service (PHS) or any other Federal agency or extramural sponsor that has adopted the PHS Objectivity in Research Rule.

To maintain the public trust, to protect the integrity of professional judgment and to ensure appropriate stewardship of resources and compliance with applicable state and federal laws, it is important that external relationships not be or appear to be influenced by factors other than the pursuit of knowledge, the best interests of the customer and appropriate stewardship of resources.

This policy intends to balance the important medical and public benefit that external relationships can produce with the possibility that these relationships may cause a conflict of interest or the perception of a conflict of interest. Accordingly, while the Organization acknowledges that conflicts will exist, it expects for them to be proactively identified, robustly managed, and monitored or eliminated if they are inconsistent with the Organization’s expectations.

DEFINITIONS

- A. “Business interest”** means holding any position, such as officer, director, or membership on a board, including an advisory board, regardless of compensation.
- B. “Disclose” or “Disclosure”** means the act or process of making information available to a third party such as a patient or other relevant audience regarding the existence of a conflict of interest.
- C. “Researcher”** means any Organization employee and any non-employed medical staff member or other person conducting or participating in research in whole or in part at a NMH or MGH facility or using Organization non-public information, customer, or resources for purposes of research.

- D. **“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.
- E. **“FCOI Management Plan”** is a management plan prepared by the Organization in the event an Investigator is determined to have a Financial Conflict of Interest per this COI Research Policy.
- F. **“Financial Interest”** means anything of monetary value, whether or not the value is readily ascertainable.
- G. **“Immediate family”** means spouse, domestic partner, and each dependent child.
- H. **“Institutional Responsibilities”** means an Investigator’s professional responsibilities on behalf of the Organization, including but not limited to research, professional practice, and Organizational committee memberships.
- I. **“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. Investigator may include, for example, study coordinators, data managers, collaborators or consultants.
- J. **“Manage”** means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.
- K. **“Period of the Award”** means the time frame of the Organizational research project as stated in the award document, including any extensions.
- L. **“PHS-Funded Investigator”** means an Investigator who is participating or planning to participate in a research project funded by the U.S. Public Health Service or by an entity that has adopted the PHS Objectivity in Research Rule.
- M. **“Related”** A Significant Financial Interest (SFI) will be considered to be related to a research project if the relationship or SFI: (1) could be affected by the research project; or (2) is in an entity whose financial interests could be affected by the research project.
- N. **“Remuneration”** means salary and any form of payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship), including equity interests (e.g., stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value).
- O. **“Research”** means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social sciences research.
- P. **“Significant Financial Interest”** means:
- a. A financial interest consisting of one or more of the following interests of the Investigator or their Immediate Family that reasonably appears to be related to the Investigator’s institutional responsibilities:
 - i. 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 stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

- ii. 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 their Immediate Family holds any equity interest (e.g., stock, stock options, or other ownership interest);
 - iii. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests; or
 - iv. A Business Interest with any entity related to a research project, whether or not remuneration is received.
- b. For PHS-funded Investigators only, reimbursed or sponsored travel (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 the Investigator's institutional responsibilities. The details of the disclosure will include, at a minimum: the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The Organization will determine if additional information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI.
- c. Any other financial interest or external commitment that may interfere with an Investigator's ability to oversee or participate in research without bias.

POLICY

- I. Individual Financial Relationships in Non-PHS-Supported Research Projects**
- a. **Scope:** This section applies to Investigators planning to participate in non-PHS-supported research projects.
 - b. **Policy:** Investigators must fully disclose whether they or their Immediate Family have a Significant Financial Interest (SFI) related to the research. Such disclosures must be made as follows:
 - i. Prior to the initiation of non-PHS-supported research projects; and
 - ii. Within thirty (30) days of discovering or acquiring a new SFI (e.g., through purchase, marriage, or inheritance); and
 - iii. Annually updated during the Period of Award or duration of the research, to reflect any change in the value or status of the SFI.

- II. Individual Financial Relationships in PHS-Supported Research Projects**
- a. **Scope:** This section applies only to Investigators engaging in or proposing to engage in PHS-supported research, including Investigators engaging in research funded by agencies and extramural sponsors that have adopted the U.S. Public Health Service (PHS) Objectivity in Research Rule.
 - b. **Policy:** PHS-Funded Investigators must fully disclose whether they or their Immediate Family have a Significant Financial Interest (SFI) related to the research. Such disclosures must be made as follows:
 - i. No later than the date of submission of a proposal for a PHS-funded research project;
 - ii. Updated at the time of Notice of Award;
 - iii. Within thirty (30) days of discovering or acquiring a new SFI (e.g., through purchase, marriage, or inheritance); and
 - iv. Annually updated during the Period of Award to reflect any change in the value or status of the SFI.
 - c. **Training:** PHS-Funded Investigators must complete training as follows:
 - i. Prior to submitting a proposal for PHS-funded research;
 - ii. At least every four years during the Period of the Award; and
 - iii. Immediately when any of the following apply:
 - 1. The Organization revises the COI Research Policy or its associated procedures in any manner that affects PHS-funded Investigators;
 - 2. A PHS-Funded Investigator is new to the Organization; or
 - 3. The Organization finds that a PHS-Funded Investigator is in non-compliance with the Organization's COI Research Policy or a Financial Conflict of Interest (FCOI) Management Plan.
- III. PHS-Funded Subrecipient Responsibilities:** Where any portion of a PHS-funded research project is carried out through a PHS-funded Subrecipient Investigator, the terms of this section will apply:
- a. When a PHS-funded research project is funded, in whole or in part, by a PHS agency, or an entity that has adopted the PHS Objectivity in Research Rule, the Organization will incorporate terms into the written agreement with the subrecipient institution that establish whether the Organization's or the subrecipient institution's COI policy will apply to Subrecipient Investigators.
 - i. Subrecipient institution COI policy applies: When the subrecipient agreement stipulates that the subrecipient institution's COI policy will apply, the subrecipient institution must also certify in the subrecipient agreement that its COI policy complies with the PHS Objectivity in Research Rule. Further, the written agreement will specify the time period within which the subrecipient institution must report all identified FCOIs to the Organization, which time period shall be sufficient to enable the Organization to provide timely reporting of the FCOI to the funding agency pursuant to the timelines set forth in this Policy.
 - ii. Organization COI Research Policy applies: PHS-funded Subrecipient Investigators will be subject to the Organization's COI Research Policy if the Subrecipient Investigator is not affiliated with an institution that

maintains a COI policy that is compliant with the PHS Objectivity in Research Rule. If the Organization's COI Research Policy applies:

1. The subrecipient agreement will specify the time period (both prior to proposal submission and throughout the Period of Award) wherein the Subrecipient Investigators will be required to disclose SFIs related to the proposed research. Such time periods must be sufficient to enable the Organization to comply in a timely manner with review, management, and reporting obligations set forth in this Policy.
2. Subrecipient Investigators shall complete the North Memorial Health Research Conflict of Interest Disclosure Form.

IV. Organization Responsibilities for PHS-Funded Research

- a. The Organization will make this COI Research Policy available to the public on its website at: www.northmemorial.com
- b. The Organization shall:
 - i. Inform each Investigator of the requirements of this Policy, the Investigator's responsibilities regarding disclosure of SFIs, and of the requirements of 42 CFR Part 50 and 45 CFR Part 94;
 - ii. Require each Investigator to complete training related to this Policy and the requirements of 42 CFR Part 50 and 45 CFT Part 94:
 1. Prior to engaging in any PHS-funded research;
 2. At least every four years; and
 3. Immediately when any of the following circumstances apply:
 - a. The Organization revises its COI Research Policy or related procedures in any manner that affects the requirements of Investigators;
 - b. An Investigator is new to the Organization; or
 - c. The Organization finds that an Investigator is not in compliance with this COI Research Policy or a management plan.
- c. The Chief Compliance Officer or designee shall solicit and review disclosures of SFIs from each Investigator who is planning to participate in, or is participating in, PHS-funded research.
- d. The Organization shall maintain records relating to all PHS-supported Investigator disclosures of financial interests and the Institution's review of, and response to, such disclosure (whether or not a disclosure resulted in the Institution's determination of a Financial Conflict of Interest) and all actions under the Organization's COI Research Policy or retrospective review, if applicable, for at least three (3) years from the date the final expenditure report is submitted to the PHS or, where applicable, from other dates specified in 45 CFR 75.361.

PROCEDURE

- I. **Organization Review and Management of Disclosures for Non-PHS-Supported Research:** If the Organization determines that any SFI may affect the design, conduct, or reporting of non-PHS-supported research, steps will be taken to manage or eliminate the conflict. If the Organization determines that a management plan is required in order for the non-PHS-supported research to proceed, then the project may be monitored by the Organization to ensure compliance with the management plan.
- II. **Organization Review and Management of Disclosures for PHS-Funded Research**
 - a. **Organization Review and Management of SFI Disclosures and FCOI Reporting:** Prior to the expenditure of funds for any PHS-funded research, the Organization, through its COI review, management, and reporting process, will:
 - i. Determine, in consultation with the Investigator, whether any SFI disclosed is related to PHS-funded research.
 - ii. If so, the Organization will determine whether the SFI constitutes an FCOI.
 - iii. Take appropriate action to manage FCOIs, including creating an FCOI Management Plan.
 - iv. Report any FCOIs and associated FCOI Management Plans to the PHS Awarding Component in the manner directed by such component initially and annually for the duration of the related Period of the Award (including extensions with or without funds).
 1. In cases where the Organization identifies an FCOI related to PHS-funded research and eliminates such FCOI prior to the expenditure of funds, the Organization shall not submit an FCOI report to the funding agency.
 - b. **Organization Review of SFIs not Timely Disclosed or Reviewed:** Whenever the Organization identifies an SFI that was not disclosed by a PHS-funded Investigator in accordance with the timeframes specified in this Policy and the PHS Objectivity in Research Rule or, for whatever reason, was not previously reviewed by the Organization, the Organization shall, within sixty (60) days:
 - i. Review the SFI and determine whether it is Related to the Research; and if so,
 - ii. Determine whether an FCOI exists;
 - iii. If so, implement, at least on an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage the FCOI going forward; and
 - iv. Submit an FCOI report to PHS.
 - c. **Organization Retrospective Review:** If, during the course of reviewing an SFI not timely disclosed or reviewed, the Organization determines that an FCOI exists for a PHS-funded project, or that a PHS-funded Investigator has failed to comply with an FCOI Management Plan, the Organization shall, within one hundred twenty (120) days:

- i. Complete a Retrospective Review of the Investigator's activities and the project to determine whether any portion of the research was biased in the design, conduct, or reporting prior to the identification and management of the FCOI or during the period of the Investigator's non-compliance with the FCOI Management Plan; and if so,
- ii. Document the Retrospective Review, including but not limited to:
 1. Project number;
 2. Project title;
 3. Principal Investigator/Project Director or contact PI/PD if a multiple PI/PD model is used;
 4. Name of the Investigator;
 5. Entity with which the Investigator has an FCOI;
 6. Reason(s) for the Retrospective Review;
 7. Detailed methodology used for the Retrospective Review (e.g. methodology of the Retrospective Review process, composition of the Retrospective Review panel, documents reviewed, etc.);
 8. Findings of the Retrospective Review (i.e. facts and observations); and
 9. Conclusions of the Retrospective Review (i.e. determination and recommended actions).
- iii. If bias is found during the Retrospective Review, the Organization shall:
 1. Promptly notify the funding agency of the corrective action taken or to be taken;
 2. Submit a mitigation report to the funding agency, which shall include, at a minimum:
 - a. The elements enumerated above (for documenting a Retrospective Review);
 - b. A description of the impact of bias on the PHS-funded research project; and
 - c. The Organization'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).
 3. Thereafter, submit FCOI reports annually for the Period of Award for the related research.
- d. **Organization monitoring of FCOI Management Plans:** Whenever the Organization identifies an FCOI and implements an FCOI Management Plan, the Organization shall monitor the Investigator's compliance with the FCOI Management Plan on an ongoing basis until completion of the PHS-funded research project.
- e. **Public Accessibility to FCOI Information for PHS-Funded Projects:** For PHS-funded projects, the Organization will make information about FCOIs it has identified through its COI review and management process publicly available by responding in writing to requests for such information within five (5) business

days of receipt of such requests. Public disclosures of a PHS-funded Investigator's FCOI information shall include the following:

- i. Name, title, and role of the Investigator;
- ii. Name of the entity in which the SFI is held; and
- iii. Nature and approximate dollar value or range of the SFI, 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.

SANCTIONS

- I. **All Research:** Failure to submit disclosures as required by this Policy and related procedures may be grounds for disciplinary action under the provisions of any applicable Organization policy. Failure to comply with Policy requirements may also result in the termination of current awards or contracts or ineligibility of the Investigator to receive future awards or contracts for research.
- II. **PHS-Supported Research:**
 - a. In cases in which the failure of an Investigator to comply with this policy or an FCOI Management Plan appears to have biased the design, conduct, or reporting of PHS-funded research, the Organization shall promptly notify the PHS Awarding Component.
 - b. In any case in which the Department of Health and Human Services determines that a PHS-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 FCOI that was not managed or reported by the Organization as required by 42 CFR Part 50 or 45 CFR Part 94, the Organization will require the conflicted Investigator to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

REFERENCES

42 CFR Part 50
45 CFR Part 94

ATTACHMENTS

Conflict of Interest in Research Disclosure Form

TABLE OF REVISIONS

Date	Description of Change(s)