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Administration -  
Clinical Practice  
Location CSHC, NWCH,  
RGH  
+ 2 more

**Financial Conflicts of Interest in Research**

## Scope

This policy applies to all Rochester Regional Health’s (RRH) sponsored research, and to all individuals involved in the design, conduct, reporting, review, administration, and/or supervision of research at RRH.

## Purpose

The purpose of this policy is to guide RRH in addressing conflicts of interest (COI) by articulating standards for identifying, addressing, managing, and, if necessary, eliminating conflicts. This policy also serves 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 not appear to be, influenced by factors other than the pursuit of knowledge, the best interests of the patients and individuals participating in RRH research, 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 COI or the perception of a COI. Accordingly, while RRH acknowledges that conflicts will exist, it expects for them to be proactively identified, robustly managed, and monitored or eliminated if they are inconsistent with RRH 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. **“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 research funded by an entity that has adopted the PHS Objectivity in Research Rule.
- D. **“FCOI Management Plan”** is a management plan prepared by RRH in the event an Investigator is determined to have a Financial Conflict of Interest per this COI Research Policy.
- E. **“Financial Interest”** means anything of monetary value, whether or not the value is readily ascertainable.
- F. **“Immediate family”** means spouse, domestic partner, and each dependent child.
- G. **“Institutional Responsibilities”** means an Investigator’s professional responsibilities on behalf of RRH, which may include for example: research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.
- H. **“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.
- I. **“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.
- J. **“Period of the Award”** means the time frame of a RRH research project as stated in the award document or contract, including any extensions.
- K. **“PHS”** means the Public Health Service of the US Department of Health and Human Services (HHS), and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).
- L. **“PHS Awarding Component”** means the organizational unit of the PHS that funds the research or sponsored program that is subject to this policy.
- M. **“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.
- N. **“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.

- O. **“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).
- P. **“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.
- Q. **“Researcher”** means any RRH employee and any non-employed medical staff member or other person conducting or participating in research in whole or in part at a RRH facility or using RRH non-public information, customer, or resources for purposes of research.
- R. **“Significant Financial Interest” (SFI)** means:
  - 1. 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:
    - 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 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 their Immediate Family holds any equity interest (e.g., stock, stock options, or other ownership interest);
    - c. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests; or
    - d. A Business Interest with any entity related to a research project, whether or not remuneration is received.
  - 2. 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 RRH 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.
  - 3. Any other financial interest or external commitment that may interfere with an

Investigator's ability to oversee or participate in research without bias,

- S. **"Sponsored Project"** means externally-funded activities in which a formal written agreement (i.e., a grant, contract, or cooperative agreement) is entered into by the Institution and by the sponsor. A sponsored project may be thought of as a transaction for which there is a specific statement of work with a related, reciprocal transfer of something of value.
- T. **"Senior/Key Personnel"** means the Project Director/Principal Investigator and any other person identified as senior/key personnel by RRH in the application, budget, progress report, or any other report submitted to the PHS or other sponsor by RRH. For the purposes of clarity, these individuals are to be considered Investigators within the meaning of this policy.

## Policy

- A. RRH encourages its Medical, Dental, and other Department/Division staff, researchers, and where appropriate, employees to seek and participate in sponsored research or programs that may benefit not only the participants, but also RRH and the public. It is understood that COI sometimes naturally occur during the course of conducting RRH's daily affairs, because the many persons associated with RRH have multiple interests and affiliations and various positions of responsibility within the community.
- B. A potential COI exists when an individual's personal or private interest might lead an independent observer to question whether the individual's professional actions or decisions are determined by considerations of significant personal interest, financial or otherwise. In accordance with the federal regulations, RRH has a responsibility to manage, reduce or eliminate any actual or potential COI that may be presented by a financial interest of an Investigator.
- C. RRH requires that all Investigators disclose any Significant Financial Interest (SFI) that could reasonably appear to affect or be affected by a Sponsored Project.
- D. Investigators of Sponsored Projects must fully disclose whether they or their Immediate Family have a SFI related to the research. Such disclosures must be made as follows:
  - 1. No later than the date of submission of a proposal for a Sponsored Project;
  - 2. Updated at the time of Notice of Award or execution of the contract for funding;
  - 3. Within thirty (30) days of discovering or acquiring a new SFI (e.g., through purchase, marriage, or inheritance); and
  - 4. Updated annually during the Period of Award to reflect any change in the value or status of the SFI.
- E. Investigators must complete training as follows:
  - 1. Prior to submitting a proposal for a Sponsored Project;
  - 2. At least every four years during the Period of the Award; and
  - 3. Immediately when any of the following apply:
    - a. RRH revises the COI Research Policy or its associated procedures in any manner that affects sponsored Investigators;
    - b. An Investigator is new to RRH; or

- c. RRH finds that an Investigator is in non-compliance with RRH's COI Research Policy or a Financial Conflict of Interest (FCOI) Management Plan

F. 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:

1. 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, RRH will incorporate terms into the written agreement with the subrecipient institution that establish whether RRH or the sub-recipient institution's COI policy will apply to subrecipient Investigators.
  - a. 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 RRH, which time period shall be sufficient to enable RRH to provide timely reporting of the FCOI to the funding agency pursuant to the timelines set forth in this Policy.
  - b. RRH's COI Research Policy applies: PHS-funded subrecipient Investigators will be subject to RRH 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 RRH COI Research Policy applies:
    - i. 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 RRH to comply in a timely manner with review, management, and reporting obligations set forth in this Policy.
    - ii. Subrecipient Investigators shall complete RRH's Sponsored Programs & Research Disclosure form

G. RRH Responsibilities for Sponsored Research

1. RRH will make this COI Research Policy available to the public on its website at Research & Accounting | Rochester Regional Health.
2. RRH shall:
  - a. 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;
  - b. Require each Investigator to complete training related to this Policy and the requirements of 42 CFR Part 50 and 45 CFT Part 94:

- i. Prior to engaging in any PHS-funded or other sponsored research;
  - ii. At least every four years; and
  - iii. Immediately when any of the following circumstances apply:
    - a. RRH revises its COI Research Policy or related procedures in any manner that affects the requirements of Investigators;
    - b. An Investigator is new to RRH; or
    - c. RRH finds that an Investigator is not in compliance with this COI Research Policy or a management plan.
3. The Director, Office of Sponsored Programs/Research or designee shall solicit and review disclosures of SFIs from each Investigator who is planning to participate in, or is participating in, sponsored research.
4. RRH shall maintain records relating to all sponsored 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 RRH'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.

## Procedures

- A. If RRH determines that any SFI may affect the design, conduct, or reporting of sponsored research, steps will be taken to manage or eliminate the conflict. If RRH determines that a management plan is required in order for the sponsored research to proceed, then the project may be monitored by RRH to ensure compliance with the management plan.
- B. RRH Review and Management of Disclosures for Sponsored Research
  - 1. RRH Review and Management of SFI Disclosures and FCOI Reporting: Prior to the expenditure of funds for sponsored research, RRH, through its COI review, management, and reporting process, will:
    - a. Determine, in consultation with the Investigator, whether any SFI disclosed is related to sponsored research.
      - i. If so, RRH will determine whether the SFI constitutes an FCOI.
    - b. Take appropriate action to manage FCOIs, including creating an FCOI Management Plan.
    - c. For PHS-supported research, 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).
    - d. In cases where RRH identifies an FCOI related to PHS-funded research and eliminates such FCOI prior to the expenditure of funds, RRH shall not

submit an FCOI report to the funding agency.

- C. RRH Review of SFIs not Timely Disclosed or Reviewed: Whenever RRH 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 RRH, RRH shall, within sixty (60) days:
1. Review the SFI and determine whether it is Related to the Research; and if so,
  2. Determine whether an FCOI exists;
  3. 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
  4. Submit an FCOI report to PHS.
- D. RRH Retrospective Review: If, during the course of reviewing an SFI not timely disclosed or reviewed, RRH 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, RRH shall, within one hundred twenty (120) days:
1. 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,
  2. Document the Retrospective Review, including but not limited to:
    - a. Project number;
    - b. Project title;
    - c. Principal Investigator/Project Director or contact PI/PD if a multiple PI/PD model is used;  
Name of the Investigator;
    - d. Entity with which the Investigator has an FCOI;
    - e. Reason(s) for the Retrospective Review;
    - f. Detailed methodology used for the Retrospective Review (e.g. methodology of the Retrospective Review process, composition of the Retrospective Review panel, documents reviewed, etc.);
    - g. Findings of the Retrospective Review (i.e. facts and observations); and
    - h. Conclusions of the Retrospective Review (i.e. determination and recommended actions).
  3. If bias is found during the Retrospective Review, RRH shall:
    - a. Promptly notify the funding agency of the corrective action taken or to be taken;
    - b. Submit a mitigation report to the funding agency, which shall include, at a minimum:
      - i. The elements enumerated above (for documenting a Retrospective Review);

- ii. A description of the impact of bias on the PHS-funded research project; and
    - iii. RRH'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).
  - c. Thereafter, submit FCOI reports annually for the Period of Award for the related research.
- E. **RRH monitoring of FCOI Management Plans:** Whenever RRH identifies an FCOI and implements an FCOI Management Plan, the RRH shall monitor the Investigator's compliance with the FCOI Management Plan on an ongoing basis until completion of the sponsored research project.
- F. **Public Accessibility to FCOI Information for PHS-Funded Projects:** For PHS-funded projects, RRH 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:
  - 1. Name, title, and role of the Investigator;
  - 2. Name of the entity in which the SFI is held; and
  - 3. 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

- A. All persons subject to this policy are expected to comply with it fully and promptly. Whenever an Investigator has violated this policy, the Director, Office of Sponsored Programs/Research shall report such violation to the appropriate RRH Official and, where appropriate, sanctions will be imposed in accordance with the applicable RRH policies.
- B. Failure to submit disclosures as required by this policy and related procedures may be grounds for disciplinary action under the provisions of any applicable RRH 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.
- C. For PHS-Supported Research:
  - 1. 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, RRH shall promptly notify the PHS Awarding Component.
  - 2. 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 RRH as required by 42 CFR Part 50 or 45 CFR Part 94, RRH 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.

Individuals involved in the design, conduct, reporting, review, administration, or supervision of research at Rochester Regional Health are responsible for knowing and understanding this policy and familiarizing themselves with its contents and provisions. If you have questions about this policy, please contact the Rochester Regional Health Office of Human Research Protection.

## References

[42 CFR Part 50 Subpart F “Responsibility of Applicants and Institutions for Promoting Objectivity in Research”](#)

[45 CFR Part 94 “Responsible Prospective Contractors”](#)

## Approval Signatures

Step Description	Approver	Date
Final Policy Posting	Mike Fitzsimmons: Policy Program Manager	05/2024
Associate CMO Reviewer	Richard Alweis: Associate CMO, Education / DIO, ACGME	05/2024
Chair to Clinical Investigation Committee	Lynda Dimitroff: Chair fo Clinical Investigation Committee	05/2024
IRB Manager	Renee Capizzi: Institutional Review Board Manager	05/2024
	Lauren Fenclau: Administrative Coordinator	05/2024

## Applicability

Clinical Practice, RRH Administrative

## Location

CSHC, NWCH, RGH, UMMC, Unity