

ROGERS BEHAVIORAL HEALTH

POLICY/PROCEDURE TITLE: Individual Financial Conflict of Interest in Research	
POLICY NUMBER: QUA-RES-101	REPLACES: NEW
EFFECTIVE: 01/01/2023	LAST REVIEWED DATE: 05/03/2023
TJC/CMS:	STATES/OTHER: 42 CFR 50
SCOPE: Rogers Behavioral Health System, Inc., Rogers Memorial Hospital, Inc., and all subsidiaries and affiliates of both corporations	PRIMARY CONTACT: Sponsored Programs Lead REVIEWED BY: Sponsored Programs Lead, Chief Compliance Officer, Legal Counsel APPROVED BY: Vice President of Research
APPROVAL SIGNATURE AND DATE:	 Oct 5, 2023

PURPOSE:

The purpose of this policy is to establish guidelines for disclosure of Significant Financial Interests and management of Financial Conflicts of Interests for individuals involved in the conduct of research. This policy applies to situations in which financial or other personal considerations may compromise or have the appearance of compromising an individual's professional judgement in conducting or reporting research. All conflicts of interest will be reviewed and managed as outlined in this policy. This policy is meant to supplement, not replace, the System-wide Conflict of Interest Policy (ADM-COR-102).

DEFINITIONS:

Entity: Any domestic or foreign, public, or private, for profit or not-for-profit legal entity or organization other than Rogers, any state agency, or the federal government.

Institutional Responsibilities: A Key Study Personnel's professional responsibilities on behalf of the institution, and as defined by the institution in its policy on financial conflicts of interest, which may include for example: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Financial Conflict of Interest (FCOI): A significant financial interest that could directly and significantly affect the design, conduct, or reporting of research, including PHS-funded research.

Key Study Personnel: The project director or Principal Investigator (PI) and any other person, regardless of title or position, whose responsibilities affect study design, conduct of the study, including adherence to study protocols, collection or analysis of data or engagement with study participants, or reporting of the research, or whose responsibilities or actions may impact study quality or compliance. For research funded by Public Health Service (PHS), this also includes any staff responsible for research reporting or proposals for such funding, and may include, for example, collaborators or consultants.

Manage: To take action to address a financial conflict of interest (e.g., through implementation of a management plan), which includes reducing or eliminating the financial conflict of interest, to ensure that the design, conducting, and reporting of research are free from bias or the appearance of bias.

Principal Investigator (PI): The individual designated by Rogers to have the appropriate level of authority, experience and overall responsibility to conduct a Research Project as specified on the IRB application (i.e., "under whose immediate direction the test article is administered or dispensed to, or used involving a subject or, in the event of a research project conducted by a team of individuals, is the responsible leader of that team" (21 CFR 50.3(d)).

Public Health Service (PHS): Refers to 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).

Research: Systematic investigation, including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. 45 CFR 46.102(l)

Systematic Investigation: Activity that involves a prospective plan that incorporates data collection (quantitative or qualitative) and data analysis to answer a question.

Generalizable Knowledge: Knowledge gained from activities designed to draw conclusions, inform policy, or generalize findings beyond a single individual or an internal program or procedure.

Research Project: Discrete scientific endeavor to answer a research question or a set of research questions. It includes a PI, defined protocol, objectives, methods and outputs, a defined set of activities, and a start and end date.

Significant Financial Interest: Per Federal Regulations (42 CFR 50.603), this means anything of monetary value or potential monetary value held by Key Study Personnel (and by their spouse and dependent children), and that reasonably appears to be related to the individual's institutional responsibilities:

- a) With regard to any publicly traded Entity, a significant financial interest exists if remuneration received from the entity in the twelve (12) 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 the definition of Significant Financial Interest, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship), equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.
- b) With regard to any non-publicly traded Entity, a significant financial interest exists if the value of any remuneration received from the entity in the calendar year preceding the disclosure, when aggregated, exceeds \$5,000, or any equity interest (e.g., stock, stock option, or other ownership interest; 42 CFR § 50.603);
- c) With regard to any Entity, intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests; or,
- d) With regard to any Entity, a position giving rise to a fiduciary duty, such as director, officer, partner, trustee, employee, or any position of management.
- e) With regard to any Entity, Key Study Personnel applying for or conducting research funded by the PHS, also must disclose the occurrence of any reimbursed or sponsored travel (i.e., travel is paid on behalf of the individual and not reimbursed to the individual so that the exact monetary value may not be readily available), related to their institutional responsibilities. Disclosure of this interest shall include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

The term "Significant Financial Interest" generally does not include salary, royalties, or other remuneration paid by Rogers to Key Study Personnel if the individual is currently employed or otherwise appointed by Rogers, including intellectual property rights assigned to Rogers and agreements to share in royalties related to such rights; any ownership interest in Rogers held by individuals; income from investment vehicles, such as mutual funds and retirement accounts, as long as the individual does not directly control the investment decisions made in these vehicles; income from seminars, lectures, teaching engagements, or travel reimbursed, if sponsored by a United States federal, state, or local government agency, a United States institution of higher education, an academic teaching hospital, medical center, or research institute affiliated with a United States institution of higher education; or income from service on advisory committees or review panels for a United States federal, state or local government agency, a United States institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States institution of higher education.

POLICY:

It is the policy of Rogers Behavioral Health and the Rogers Research Center (collectively referred to hereafter as "Rogers") that research be conducted in an unbiased, consistent, and objective manner, and separate from personal interests or obligations. Key Study Personnel must disclose their own and their immediate family members' potential conflicting and competing interests annually, and any changes at the time of study submission, to the Rogers Institutional Review Board (IRB).

WHAT MUST BE DISCLOSED?

Significant Financial Interests

Key Study Personnel are required to disclose any Significant Financial Interests that reasonably appear to be related to the Key Study Personnel's Institutional Responsibilities.

Foreign Components:

For NIH-funded studies, the NIH requires recipients to determine whether activities it supports include a foreign component. While the NIH has not directly defined "significant," it has provided examples of activities occurring outside the United States that it believes represent a "significant scientific element or segment of a project". These include:

- Collaborations with investigators at a foreign site anticipated to result in co-authorship
- Use of facilities or instrumentation at a foreign site
- Receipt of financial support or resources from a foreign entity

If a Rogers grant recipient determines that a portion of the project will be conducted outside of the U.S., the individual then will need to determine if the activities are considered significant. If both criteria are met, then there is a foreign component and it should be disclosed to the NIH for review and approval.

NIH defines a foreign institution as an organization located in a country other than the United States and its territories that is subject to the laws of that country, regardless of the citizenship of the proposed Project Director/PI.

PROCEDURES:

Training

All Key Study Personnel and Research Center staff must complete COI training annually.

PHS-supported Key Study Personnel must complete FCOI training prior to engaging in research related to any PHS-funded grant annually, and immediately when any of the following circumstances apply:

- a) Rogers revises its FCOI policies or procedures in any manner that affects the requirements of Key Study Personnel;
- b) Any Key Study Personnel is new to Rogers or upon becoming a Key Study Personnel; or,
- c) Rogers finds that Key Study Personnel is not in compliance with the FCOI policy or management plan.

Disclosing Conflicts of Interest

Key Study Personnel must complete a Research Conflict of Interest Disclosure Form no less than annually.

1. Disclosure shall be updated as soon as reasonably possible but in no event past 30 days of discovering or acquiring a new Significant Financial Interest.
2. Investigators and Key Study Personnel shall disclose FCOIs upon IRB submission of a project involving a third-party sponsor.
3. If there is any doubt about the existence of an actual or apparent conflict of interest, Key Study Personnel should err on the side of disclosure.
4. Disclosure shall be submitted no later than the time of application for PHS-funded research.
5. Financial disclosures are required for all Key Study Personnel, regardless of the individual's employment status with Rogers or the project sponsor or funding source.
6. Principal Investigators are responsible for informing any co-investigators, Key Study Personnel, subrecipients/subawardees, or students involved in the design, conducting, or reporting of the externally sponsored research project that they are required to complete a disclosure form.
7. Key Study Personnel who participate in a privately sponsored clinical study shall not concurrently receive any compensation from the sponsor, including honoraria and consulting fees, during the study. In addition, they shall not have any investment in, or serve in a decision-making capacity (such as service on the Board of Directors or management committee) or be an officer or employee of the company sponsoring the research study.

Review of Disclosures

FCOI disclosures will be reviewed by the Vice President of Research, Chief Compliance Officer, and General Counsel, as applicable. Compliance and/or Legal is responsible for determining whether an apparent or actual conflict of interest exists and thus whether further review and management is required. The Vice President of Research may involve other Rogers officials in the review process if deemed necessary.

For PHS-funded research projects, review, determination, and implementation of any management plans (including interim plans), as necessary, for identified Significant Financial Interests will occur consistent with 42 CFR Part 50 Subpart F, as follows:

- a) Within sixty (60) days of disclosure from current or new Key Study Personnel;
- b) Within sixty (60) days of identification if not previously disclosed by Key Study Personnel in a timely manner in accordance with this policy;
- c) Within sixty (60) days of identification if previously disclosed to Rogers but not evaluated by Rogers in a timely manner in accordance with this policy.

In addition, whenever a FCOI is not identified or managed in a timely manner, including failure by the Key Study Personnel to disclose a Significant Financial Interest that is determined by Rogers to constitute a FCOI (see (b) above); failure by Rogers to review or manage such a FCOI (see (c) above); or failure by Key Study Personnel to comply with a FCOI management plan, Rogers shall, within 120 days of a determination of noncompliance, complete a retrospective review of the Key Study Personnel activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research. The retrospective review shall be documented and contain the following information at a minimum:

1. Project number;
2. Project title;
3. Project Director or Project Investigator contact information;
4. Name of the Key Study Personnel with the FCOI;
5. Name of the entity with which the Key Study Personnel has a FCOI;
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, Rogers shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward. If bias is found, Rogers will notify the PHS awarding organization promptly and submit a mitigation report. The mitigation report will include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and the plan of action or actions taken by Rogers 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, Rogers will submit FCOI reports annually. Depending on the nature of the FCOI, Rogers may determine that additional interim measures are necessary regarding the Key Study Personnel's participation in the PHS-funded research project between the date that the FCOI or the Key Study Personnel's noncompliance is determined and the completion of Rogers retrospective review.

FCOI Management Plans

If it is determined that an actual or apparent FCOI exists, Key Study Personnel may be required to comply with a management plan to ensure the reduction, management, or elimination of the conflict.

The Vice President of Research will determine how the conflict should be managed, reduced, or eliminated. If the conflict cannot be eliminated, a management plan must be created. The Vice President of Research may involve other Rogers officials in the management process if deemed necessary. In situations where the conflicted party objects to the resolution

of the Vice President of Research and wishes to appeal the decision, the Chief Compliance Officer, General Counsel, and Chief Executive Officer shall be consulted and review the matter to make a final determination.

Conditions or restrictions that might be imposed by Rogers to manage, reduce, or eliminate actual or potential conflicts of interest include but are not limited to:

- Public disclosure of relevant significant financial interests (e.g., when presenting or publishing the research).
- For research projects involving human subjects research, disclosure of FCOIs directly to participants.
- Monitoring of research by independent reviewers.
- Modification of the research plan.
- Disqualification from participation in the portion of the activity that would be affected by the significant financial interests.
- Divestiture of significant financial interests.
- Severance of the relationships that create actual or potential conflicts.
- If the Key Study Personnel disagrees with the management plan, an appeal request may be submitted to the Chief Compliance Officer. The Compliance Department will then gather facts from both the Key Study Personnel and Vice President of Research, confer with General Counsel, and provide such information and a recommendation to the Chief Executive Officer, who will make the final determination.
- The Key Study Personnel must accept the management plan in writing before beginning work on the project. Copies of the signed management plan will also be provided to the Key Study Personnel's department head.

For PHS-funded research, the management plan will be in compliance with 42 CFR Part 50 Subpart F. 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 Key Study Personnel with a FCOI that was not managed or reported by Rogers as required by 42 CFR Part 50 Subpart F, Rogers shall require the Key Study Personnel involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

Management plans are monitored on an ongoing basis in accordance with 42 CFR § 50.605(4) by the Vice President of Research until the completion of the PHS-funded research project.

Confidentiality

Limited information describing Key Study Personnel's conflict of interest disclosure may be provided to the IRB, as required, for purposes of review, approval, or study oversight. Any recipient of such information shall be fully authorized to receive this information and obligated to maintain confidentiality, except as required for the performance of Rogers duties or as otherwise required by law.

Disclosure forms, management plans, and other records will be maintained electronically with firewall and password protection. Records will be maintained for at least three years from the date of submission of the final expenditures report or other time periods as required by law.

Non-Compliance

Individuals are expected to comply fully and promptly with the policy, including the requirements of disclosure. Individuals who deliberately or repeatedly fail to disclose fully and truthfully conflict of interest situations or fail to comply with any stipulated plan for managing the disclosed conflict will be subject to the applicable disciplinary processes, which could include suspension of research privileges or funding or termination from employment. Further, violations of full and prompt disclosure may result in the loss of funding and sanctions regarding future funding from federal agencies. Violators may also be subject to criminal sanctions or civil liability under federal or state law. Before any corrective action or violation reporting, is implemented both Human Resources and Corporate Legal Counsel shall be consulted for guidance and direction.

In the event Rogers discovers that a failure to comply with this policy has biased the design, conducting or reporting of the research in accordance with the processes outlined above, the Vice President of Research or designee will notify the Chief

Compliance Officer, General Counsel, and the sponsor or PHS awarding organization of the research as required by applicable law or under contractual obligations and describe the corrective action(s) taken or to be taken in writing as soon as reasonably possible, but not longer than five (5) business days following such discovery.

Reporting

Rogers will provide initial and ongoing reports of its management of FCOI to external sponsors of Rogers research as required by law and in accordance with this policy. Further, the Rogers Research Center shall provide an annual accounting of its FCOIs to the Chief Compliance Officer and General Counsel to ensure consistency with the larger System-wide Conflict of Interest Disclosure Form completion.

For PHS-funded research, initial and ongoing FCOIs (including management plans) will be reported to the PHS awarding organization, consistent with 42 CFR 50.605:

- Prior to expenditure of any funds by Rogers under PHS-funded research.
- Within 60 days of identification of Key Study Personnel who are newly participating in the project.
- Within 60 days of new, or newly identified, FCOIs for existing Key Study Personnel.
- At least annually (at the same time as when Rogers is required to submit the annual progress report, multi-year progress report, if applicable, or at time of extension) to provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project.
- Following a retrospective review to update a previously submitted report, if appropriate.

Records

The Rogers Research Center is responsible for the retention of management plans and other records for at least three years from the date of submission of the final expenditures report, from dates specified in accordance with 45 CFR 75.361 for federal awards, as applicable, or as otherwise required by law.

Public Accessibility (PHS-Funded Research)

For research funded by PHS, Rogers will maintain an up to date, written, enforced policy on FCOIs that complies with 42 CFR 50, and will make such policy available via its publicly accessible website.

Prior to expenditure of any funds under a PHS-funded research project, Rogers shall provide written response to any requestor within five (5) business days of a request, for information concerning any Significant Financial Interest disclosed to Rogers that meets the following three criteria:

1. The Significant Financial Interest was disclosed and is still held by the project director, project investigator and any other person identified as senior or Key Study Personnel by Rogers in the grant application, progress report, or any other report submitted to the PHS by Rogers;
2. Rogers determines that the Significant Financial Interest is related to the PHS-funded research; and
3. Rogers determines that the Significant Financial Interest is a FCOI.

If such request meets the criteria above for PHS-funded research, Rogers shall make the following information available:

- The name, title and role with respect to the research project, of the project director or PI and any other Key Study Personnel;
- The name of the entity in which the Significant Financial Interest is held;
- The nature of the Significant Financial Interest; and,
- The approximate dollar value of the Significant Financial Interest (dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or 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.

When Rogers responds to written requests for the purposes of this subsection, Rogers will note in its written response that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60 days of Rogers identification of a new FCOI, which should be requested subsequently by the

requestor.

Information concerning the Significant Financial Interests of an individual subject to this section shall remain available, for responses to written requests or for posting via Rogers publicly accessible Web site for at least three years from the date that the information was most recently updated.

Subcontractor/Subrecipients of PHS-Funded Research

Management of FCOIs for subcontractors and subrecipients of PHS-funded research will be in accordance with Rogers Grants Administration Policies and Procedures Manual.
