

Policy & Procedure

Title:	Research and Industry Conflict	Date of Origin:	08/12	Policy #	R66		
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Affiliate(s):	<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p><input checked="" type="checkbox"/> Hospital:</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Clifton Springs <input checked="" type="checkbox"/> NWCH <input checked="" type="checkbox"/> RGH <input checked="" type="checkbox"/> UMMC <input checked="" type="checkbox"/> Unity <input checked="" type="checkbox"/> Unity Specialty Hospital <p><input checked="" type="checkbox"/> Hospital Subcategories:</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Inpatient Services <input checked="" type="checkbox"/> Outpatient Services <input type="checkbox"/> ElderOne (ext. clinics) <input checked="" type="checkbox"/> PCASI <input checked="" type="checkbox"/> SMS <input checked="" type="checkbox"/> Behavioral Health <p><input type="checkbox"/> Lifetime (Homecare and Hospice)</p> <p><input type="checkbox"/> Lifetime Pharmacy</p> <p><input type="checkbox"/> Homecare Plus</p> </div> <div style="width: 45%;"> <p><input checked="" type="checkbox"/> Long Term Care</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Clifton Springs Nursing Home <input checked="" type="checkbox"/> DeMay Living Center <input checked="" type="checkbox"/> Edna Tina Wilson Living Center <input checked="" type="checkbox"/> Hill Haven <input checked="" type="checkbox"/> Park Ridge Living Center <input checked="" type="checkbox"/> Unity Living Center <p><input checked="" type="checkbox"/> ACM Laboratory</p> <p><input checked="" type="checkbox"/> Ambulatory Surgery Centers</p> <p><input checked="" type="checkbox"/> Elder One – PACE</p> <p><input checked="" type="checkbox"/> NonArticle 28 Practices (WNY)</p> <p><input checked="" type="checkbox"/> PRCD, Inc.</p> <p><input checked="" type="checkbox"/> RMHC</p> </div> </div>
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For purposes of this policy, “Rochester Regional Health” shall collectively refer to the affiliates identified in the header of the policy except those outside the U.S.

Policy Statement:	<p style="text-align: center;">Purpose</p> <p>The purpose of this policy is to promote objectivity in research at Rochester Regional Health to ensure there is no reasonable expectation that the design, conduct or reporting of Sponsored Research funded, including research funded through Public Health Service (“PHS”) grants, cooperative agreements, will be biased by any conflicting financial interest of an Investigator or team members who conduct or are in the position to influence research activities at Rochester Regional Health. Individuals participating in research and other Sponsored Research must disclose all financial interests that reasonably appear to be related to the individual’s responsibilities at Rochester Regional Health and to the specific project. Rochester Regional Health’s Office of Sponsored Programs/Research will review and evaluate disclosures of potential conflicts of interest and determine whether such conflicts can be managed or must be eliminated in order to permit the individual to engage in the research project.</p>
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This policy also serves to educate individuals about situations that generate conflicts of interest when individuals have financial relationships with Industry. Covered Individuals must disclose any financial relationships with Industry, both domestic and foreign, on an annual basis as described in this policy. Further, as set forth in the Rochester Regional Health Code of Conduct, all Rochester Regional Health personnel, including individuals with a duty to complete an annual disclosure form under this policy, should be aware of the types of conflicts that could arise due to relationships with Industry (e.g. under the Physician Sunshine Act/CMS Open Payments; participating in Industry-sponsored events; or when receiving gifts or other items of value from Industry representatives) and should avoid such conflicts or the appearance of a conflict in conducting their day-to-day responsibilities for Rochester Regional Health. Any questions about management of a potential conflict may be addressed to the Corporate Compliance Department at conflictofinterest@rochesterregional.org; in addition, any questions about potential financial conflicts of interest related to Sponsor Research may be addressed to the Director of the Office of Sponsored Programs/Research at: gayle.ellledge@rochesterregional.org.

Applicability

This policy is applicable to all Medical and Dental Staff Members, Adjunct Staff/Allied Health Professionals, Senior/Key Personnel, Directors, and all team members who conduct or are in the position to influence research activities at Rochester Regional Health, including any Investigators and personnel conducting or planning to conduct PHS-supported research (referred to herein as “Covered Individuals”).

Definitions

Conflict of Interest. A conflict of interest (or “COI”) arises when there is a divergence between an individual’s (and/or an individual’s Immediate Family member’s) private interests and his/her professional obligations to Rochester Regional Health, such that an independent observer might reasonably question whether the individual’s professional actions or decisions are determined by considerations of personal gain or advantage, financial or otherwise. Individuals participating Sponsored Research must disclose all domestic and foreign financial interests that reasonably appear to be related to the individual’s Institutional Responsibilities at Rochester Regional Health and to their research.

Covered Individual means all Medical and Dental Staff Members, Adjunct Staff/Allied Health Professionals, Senior/Key Personnel, Directors, and all team members who conduct or are in the position to influence research activities at Rochester Regional Health, including any Investigators and personnel conducting or planning to conduct PHS-supported research.

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DHHS means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

Disclosure of significant financial interests means a Covered Individual’s disclosure of significant financial interests to Rochester Regional Health.

Financial conflict of interest (FCOI) means a Significant Financial Interest that could directly and significantly affect the design, conduct or reporting of Sponsored Research.

FCOI report means Rochester Regional Health’s report of a FCOI to a PHS Awarding Component or other research sponsor.

Financial interest means anything of monetary value, whether or not the value is readily ascertainable, of a Covered Individual or his/her Immediate Family member. Financial interests may include outside positions as a manager, member of a board, employment position, consultant; ownership interests; intellectual property rights; travel reimbursement; royalty income; or gifts, whether monetary or in-kind.

Immediate Family means the person’s spouse, domestic partner, dependent children, or other family members residing in the person’s household.

Industry means any domestic or foreign organization that is not a federal, state or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education. Examples of industry include biomedical, pharmaceutical and medical device companies and companies that make other products or provide services used in the treatment of patients or the provision of medical care.

Institution means Rochester Regional Health (Rochester Regional Health), or its Affiliates, including Clifton Springs Nursing Home, DeMay Living Center, Edna Tina Wilson Living Center, Hill Haven, Park Ridge Living Center, Unity Living Center.

Institutional responsibilities mean a Covered Individual’s professional responsibilities on behalf of the Institution, which may include: research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Investigator means the project director (“PD”) or principal investigator (“PI”) and any other person, regardless of title or position (e.g. collaborators and consultants), who is responsible for the design, conduct or reporting of Sponsored Research,

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including research funded by the PHS, or proposed for such funding. For purposes of the requirements of this policy relating to financial interests, "Investigator" includes the Investigator's Immediate Family.

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

PD/PI means a project director or principal investigator of Sponsored Research project; the PD/PI is included in the definitions of senior/key personnel and Investigator.

PHS means the Public Health Service, an operating division 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).

PHS Awarding Component means the organizational unit of the PHS that funds the research that is subject to this policy.

Public Health Service Act or PHS Act means the statute codified at 42 U.S.C. 201 et seq.

Research means a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research and product development. As used in this policy, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, or other Sponsored Research.

Senior/Key Personnel means the PD/PI and any other person identified as senior/key personnel by Rochester Regional Health in the grant application, progress report or any other report submitted in relation to Sponsored Research, including collaborators and consultants.

Significant Financial Interest (SFI) means:

1. A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's Immediate Family members) that reasonably appears to be related to the Investigator's Rochester Regional Health responsibilities:
 - a. With regard to any publicly traded entity, a SFI exists if the value of any remuneration received from the entity in the twelve (12) months preceding

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	<p>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 any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measure of fair market value;</p> <p>b. With regard to any non-publicly traded entity, a SFI exists if the value of any remuneration received from the entity in the twelve (12) months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator’s spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.</p> <p>2. Investigators must disclose the occurrence of any 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 their Rochester Regional Health responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or 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. This disclosure will include, at a minimum:</p> <ol style="list-style-type: none"> a. Purpose of the trip; b. Identity of the sponsor/organization; c. Destination; and d. Duration. <p>3. The term SFI does not include the following types of financial interests:</p> <ol style="list-style-type: none"> a. Salary, royalties or other remuneration paid by Rochester Regional Health to the Investigator if the Investigator is currently employed or otherwise appointed by Rochester Regional Health, including intellectual property rights assigned to Rochester Regional Health and agreements to share in royalties related to such rights; b. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; c. 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
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- medical center, or a research institute that is affiliated with an institution of higher education; or
- d. 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.

Sponsored Research means research conducted with funding or material support from any government agency, foundation, non-profit or for-profit entity, including Industry-supported or PHS-funded research.

Procedure:

Annual COI Disclosure Questionnaire

Each Covered Individual is required to annually disclose between January 1 and March 1 of each year, or within 60 days of a new appointment or hire, all domestic and foreign financial interests that reasonably appear to be related to his/her Rochester Regional Health responsibilities and to the Sponsored Research project.

In addition, in certain cases a Covered Individual may be required to complete a disclosure form prior to the submission of a proposal.

Identification of Rochester Regional Health Covered Individuals who are subject to the requirements of this Policy

The Office of Sponsored Programs/Research will identify Covered Individuals with a duty to complete an annual COI Disclosure Questionnaire under this Policy. Any Rochester Regional Health Investigator who is subject to this Policy will be identified during the time of the proposal review and sign-off by the Director of the Office of Sponsored Programs/Research, who is the Rochester Regional Health designated official.

Management of Potential Conflicts

The Office of Sponsored Programs/Research will review the annual disclosure questionnaires for all potential conflicts and any financial interest disclosures. The Office of Sponsored Programs/Research will determine whether any potential conflict must be managed, including whether to eliminate, reduce, or manage any conflict. As necessary, the Director of the Office of Sponsored Programs/Research will work with Corporate Compliance to manage potential or actual conflicts. A final decision rendered on any conflicts will be forwarded in writing to the individual and, as appropriate, to relevant individuals (i.e., chairperson of individual's department or nursing administration). The written decision will include an explanation of the reasons for the decision.

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Notification – 42 CFR 50.604(b)

Those Rochester Regional Health Investigators who are currently involved in PHS sponsored research activities or expect to submit PHS-funded research proposals as identified by the Director of the Office of Sponsored Programs/Research will be informed of this policy, their reporting responsibilities, and of the applicable federal regulation by the Office of Sponsored Programs/Research via e-mail and/or phone notification.

Training - 42 CFR 50.604(b)

Each PHS-supported Rochester Regional Health Investigator will be informed of the requirement to complete FCOI training by the Office of Sponsored Programs/Research via e-mail and/or phone notification:

for initiating research related to any PHS-funded grant or cooperative agreement; least every four (4) years; and

promptly, if:

Rochester Regional Health revises its FCOI policy that affects the requirements of Investigators;

An Investigator is new to Rochester Regional Health; or

An Investigator is not in compliance with the policy or management plan.

Training will be provided by the CITI Program under Rochester Regional Health’s current subscription.

The Office of Sponsored Programs/Research will verify that all Investigators have completed the required FCOI training prior to the submission of any PHS-funded research proposal.

Disclosure, Review and Monitoring – 42 CFR 50.603, 42 CFR 50.604(1)-(3), 42 CFR 50.604(d), 42 CFR 50.604(f), 42 CFR 50.605(a)(1), 42 CFR 50.6-5(a)(2), 42 CFR 50.605(a)(3) and (i)-(iii), 42 CFR 50.604(g), 42 CFR 50.605(a)(4)

The Office of Sponsored Programs/Research will identify Rochester Regional Health Investigators who currently receive PHS support and/or those who expect to submit a PHS proposal or to be involved in a PHS proposal that will be submitted by in the future. This identification occurs when a proposal is submitted to the Office of Sponsored Programs/Research for review. An individual involved in research and/or on the budget for the project will be required to complete an annual Conflict of Interest Disclosure Form. The Conflict of Interest Disclosure Form is the mechanism by which any SFIs related to the Rochester Regional Health Investigators institutional responsibilities are disclosed.

The Rochester Regional Health Proposal Sign-off Form that is completed for each proposal requires all Rochester Regional Health Investigators to certify by signature

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that they have completed a Conflict of Interest Disclosure Form for any PHS-funded research proposal. The Office of Sponsored Programs/Research will verify that the Conflict of Interest Disclosure Form for all individuals meeting the definition of Investigator who are involved in the proposed PHS-funded research project has been completed and is up-to-date prior to submission of the proposal.

At the time that a Notice of Award is received for any PHS-funded research project and prior to any expenditure of funds, the Office of Sponsored Programs/Research / Research Accounting and Reporting will verify that the Conflict of Interest Disclosure Form for all individuals meeting the definition of Investigator who are involved in the awarded PHS-funded research project has been completed and is up-to-date.

PHS-supported Rochester Regional Health Investigators are required to disclose SFIs annually during the period of the award and within 30 days of discovering or acquiring a new SFI.

The Director of the Office of Sponsored Programs/Research, the Rochester Regional Health Designated Official will, prior to the submission of a PHS proposal, and if such PHS proposal is awarded, prior to the expenditure of any PHS funds:

- a. Solicit and review all disclosures of SFIs for any Rochester Regional Health Investigator (and those of the Investigator’s spouse and dependent children) who receives PHS support or plans to submit a PHS proposal or be involved in a PHS proposal to be submitted by another institution;
- b. Determine, in conjunction with the Rochester Regional Health Investigator and/or Conflict of Interest Committee members, whether a Rochester Regional Health Investigator’s disclosed SFI is related to any PHS-funded research and whether the SFI is an FCOI based on the regulation; and
- c. Develop and implement, in conjunction with the Rochester Regional Health Investigator and/or Conflict of Interest Committee members, a management plan, as needed, to manage all identified FCOIs.

This above-referenced process will also be conducted within sixty (60) days by the Director of the Office of Sponsored Programs/Research when:

- a. A new Investigator becomes involved in a PHS-funded research project. The Principal Investigator, or his/her designee, of a PHS-funded research project must promptly notify the Office of Sponsored Programs/Research / Sponsored Accounting and Reporting when there is a new Investigator participating on the project;
- b. An existing Investigator discloses a new SFI; and
- c. Rochester Regional Health identifies an SFI that was not disclosed timely by an Investigator or not previously reviewed by Rochester Regional Health.

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Investigator compliance with a management plan implemented for a FCOI will be monitored regularly by the Director of the Office of Sponsored Programs/Research until the associated PHS-supported research project is completed

4. Reporting to the PHS Awarding Component – 42 CFR 50.604(h), 42 CFR 50.605(b), 42 CFR 50.605(a)(3)(iii), 42 CFR 50.606(a)

The Rochester Regional Health Office of Sponsored Programs/Research will provide the PHS Awarding Component a FCOI report regarding any Investigator’s SFI identified to be conflicting and provide assurance that a management plan has been developed and implemented in accordance with the regulation. However, if any identified, FCOI has been eliminated prior to the expenditure of PHS-awarded funds; the Office of Sponsored Programs/Research will not submit a FCOI report to the PHS Awarding Component. A FCOI report will be provided:

- a. Initially, prior to the expenditure of funds;
- b. Subsequently, within sixty (60) days of identification of a FCOI for an Investigator who is new to the PHS-funded research project;
- c. Subsequently, within sixty (60) days of identification of a new, or newly identified, FCOI for any existing Investigators;
- d. At least annually (at the same time as when the annual progress report, multi-year progress report, if applicable, or at the time of an extension) to provide the status of any FCOI and any changes to the management plan, if applicable, until the completion of the PHS-awarded research project; and
- e. Following a retrospective review to update a previously submitted FCOI report, if indicated.

A FCOI report provided to the PHS Awarding Component will include:

- a. Project number;
- b. Program Director (PD)/Principal Investigator(PI) or Contact PD/PI if a multiple PD/PI model is used;
- c. Name of the Investigator with the FCOI;
- d. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- e. Value of the 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 readily be determined through reference to public prices or other reasonable measures of fair market value;
- f. A description of how the financial interest relates to the PHS-funded research and the basis for Rochester Regional Health’s determination that the financial interest conflicts with such research; and

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- g. A description of the key elements of Rochester Regional Health’s management plan, including:
- i. Role and principal duties of the conflicted Investigator in the research project;
 - ii. Conditions of the management plan;
 - iii. How the management plan is designed to safeguard objectivity in the research project;
 - iv. Confirmation of the Investigator’s agreement to the management plan;
 - v. How the management plan will be monitored to ensure Investigator compliance; and
 - vi. Other information as needed.

The Rochester Regional Health Office of Sponsored Programs/Research will notify the PHS-Awarding Component promptly:

- a. If bias is found with the design, conduct or reporting of PHS-funded research and will include the requirement to submit a Mitigation Report in accordance with the regulation; and
- b. If an Investigator fails to comply with the Rochester Regional Health’s FCOI policy or a FCOI management plan and this appears to have biased the design, conduct or reporting of the PHS-funded research and will include the requirement to take corrective action as determined by Rochester Regional Health and the PHS Awarding Component.

Maintenance of Records – 42 CFR 50.604(i)

All FCOI-related records that meet or exceed the requirements of the regulation will be maintained by the Rochester Regional Health Office of Sponsored Programs/Research for each PHS-supported research project:

- a. For at least three (3) years from the date the final financial report was submitted to a PHS Awarding Component; and
- b. From other dates specified in 45 CFR 74.53(b) and 92.42(b), as applicable.

Enforcement Mechanisms, Remedies and Noncompliance – 42 CFR 50.604(j), 42 CFR 50.605(a)(3), 42 CFR 50.606(c)

Rochester Regional Health will institute appropriate enforcement mechanisms, employee sanctions and administrative actions to ensure Investigator compliance with the regulation.

Whenever a FCOI is not identified or managed in a timely manner including: failure by the Investigator to disclose a SFI that is determined by Rochester Regional Health to constitute a FCOI; failure by RRH to review or manage such a FCOI; or failure by the Investigator to comply with a FCOI management plan, Rochester Regional Health shall, within one hundred twenty (120) days of Rochester Regional Health’s

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determination of noncompliance, complete a retrospective review of the Investigator’s 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 will be documented and include, at a minimum, the following key elements:

- a. Project number;
- b. Project title;
- c. PD/PI or contact PD/PI if a multiple PD/PI model is used;
- d. Name of the Investigator with the FCOI;
- e. Name of the entity with which the Investigator has a FCOI;
- f. Reason(s) for the retrospective review;
- g. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed); Finding of the review; and
- h. Conclusions of the review.

Based on the results of the retrospective review, if appropriate, Rochester Regional Health will update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward. If bias is found, Rochester Regional Health will notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report must 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 Rochester Regional Health’s plan of action taken to eliminate or mitigate the effect of the bias. Thereafter, Rochester Regional Health will submit FCOI reports, annually. Depending on the nature of the FCOI, Rochester Regional Health may determine that additional interim measures are necessary with regard to the Investigator’s participation in the PHS-funded research project between the date that the FCOI or Investigator’s noncompliance is determined and the completion of Rochester Regional Health’s retrospective review.

When DHHS 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 Rochester Regional Health as required by the regulation, Rochester Regional Health shall require the Investigator involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

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Subrecipients – 42 CFR 50.604(c) and NIH Grants Policy Statement 15.2.1, 42 CFR 50.604(c)(1), 42 CFR 50.604(c)(ii), 42 CFR 50.604(c)(iii)

All subrecipients that are included in a PHS proposal submitted by Rochester Regional Health are required to provide information to the Rochester Regional Health Designated Official about whether they will follow the FCOI policy of Rochester Regional Health which complies with the regulation or their own FCOI policy should the PHS proposal be funded. The subrecipient will be required to certify that their FCOI policy does comply with the regulation if they intend to follow their own FCOI policy.

At the time Rochester Regional Health issues a subaward under a PHS-supported award to a subrecipient, the subrecipient will be required to re-certify that its FCOI policy does comply with the regulation. If the subrecipient is unable to make this certification then the subrecipient is required to follow the Rochester Regional Health FCOI policy that complies with the regulation. This requirement will be incorporated into the written subaward agreement with the subrecipient. As part of the written subaward agreement, the subrecipient who follows their own FCOI policy will be required to report identified FCOIs for its Investigators in a time frame that allows Rochester Regional Health to report identified FCOIs to the PHS Awarding Component as required by the regulation. Alternatively, for the subrecipient who does not have their own FCOI policy, the written subaward agreement will require that the subrecipient allow Rochester Regional Health to solicit and review any subrecipient Investigator disclosures in order to enable Rochester Regional Health to identify, manage and report identified FCOIs to the PHS Awarding Component within the applicable specified time-period.

Public Accessibility – 42 CFR 50.604(a), 42 CFR 50.605(a)(5)(i)-(iv)


- a. Rochester Regional Health’s FCOI Policy will be publicly accessible on Rochester Regional Health’s website;
- b. Any member of the public can contact the Director of the Rochester Regional Health Office of Sponsored Programs/Research for information concerning any SFI disclosed to Rochester Regional Health that meets the following three criteria: The SFI was disclosed and is still held by the senior/key personnel;
 - i. Rochester Regional Health determines that the SFI is related to the PHS-funded research; and
 - ii. Rochester Regional Health determines that the SFI is a FCOI.
- c. This information will be made available directly to the requesting individual within 5 business days of receiving a written request and will include the following:
 - i. Investigator’s name;
 - ii. Investigator’s title and role with respect to the research project;
 - iii. Name of the entity in which the SFI is held;

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	<ul style="list-style-type: none"> iv. Nature of the SFI; and v. Approximate dollar value of the SFI expressed in dollar ranges identified in the regulation 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. <p>d. The information will remain available for three (3) years from the date that the information was last update</p>
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References:	<p>See 42 CFR Part 50 Subpart F for PHS-sponsored research</p> <p>See 21 CFR Part 54 for FDA clinical studies</p>
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<i>Approvals</i>	<u>Signature</u>	<u>Name</u>	<u>Title</u>	<u>Date</u>
		Robert Mayo, MD	EVP, Chief Medical Officer	8/1/2020