

Title: RESEARCH CONFLICT OF INTEREST POLICY

Scope:

This policy applies to all persons at MultiCare Health System who meet the definition of Investigator and applies to MultiCare research activities, funded or if unfunded, where the work involves human subjects. The provisions of this policy apply only to Investigators applying for or conducting research funded by the Public Health Service. Investigators who conduct studies regulated by the Food and Drug Administration or who conduct research funded by other federal agencies are subject to specific agency regulations relating to financial conflicts of interest in research. Affected Investigators are advised to review such regulations prior to submission of a research proposal or application.

Policy Statement:

Integrity, objectivity, and absence of self-dealing are essential at all levels and in all aspects of MultiCare Health System activities, including research. MultiCare and its employees are committed to conducting themselves and their activities in accordance with the highest standards of integrity and ethics. MultiCare recognizes that actual or potential conflicts of interest may occur in the normal conduct of research and other activities. Thus, it is essential that Investigators disclose their and their family members' financial interests related to research for review by the Institute for Research & Innovation. After disclosure the Institute can make an informed judgment about a particular activity and require appropriate oversight, limitations, or prohibitions in accordance with this policy.

In compliance with state and Federal law, this regulation sets forth policies, principles, and procedures to ensure that the personal financial interests of MultiCare employees do not compromise:

- A. The objectivity with which research is designed, conducted, and reported;
- B. The welfare of research participants; or
- C. The objectivity with which intellectual property is developed.

Procedure:

I. Research Conflict of Interest Committee (RCOIC)

A. Membership:

- 1. The RCOIC is appointed by the President and reports to the Vice President for Quality (VPQ). The President shall designate the chair and appoint members.
- 2. The RCOIC shall be composed of a minimum of five (5) members appointed by the President and selected from recommendations submitted separately by the VPQ.
- 3. A majority of the membership shall consist of MHS employees without research appointments. The remaining appointments shall be comprised of employees with research appointments or research staff.

4. The RCOIC members shall have staggered three (3)-year appointments.

B. Responsibilities:

1. The RCOIC provides assistance on matters involving conflicts of interest and disclosures of significant financial interests in research as defined by this regulation. The RCOIC makes recommendations on courses of action designed to manage, reduce, or eliminate the conflict.
2. The RCOIC shall maintain minutes of meetings and, on request, shall prepare reports for the VPQ.
3. The VPQ shall appoint the Medical Director of the Institute for Research and Innovation and his/her designee the role of Conflict of Interest Officer (COIO).

II. Conflicts of Interest:

- A. A potential or actual conflict of interest exists when a significant financial interest (as defined herein) of an Investigator, a family member of the Investigator or an associated entity, would reasonably appear to be affected by the research activities of the Investigator or the development of intellectual property.
- B. An Investigator may not engage in research activities in which a potential or actual conflict of interest exists in fact or develop intellectual property for which actual or potential conflict exists, unless authorized in writing by the VPQ and conducted in full accord with conditions and restrictions imposed by the VPQ.

III. Disclosure of Financial Interests:

A. Prior to submission/initiation of research:

1. Prior to the Investigator's submission of a grant application or MultiCare's execution of a cooperative agreement or sponsored research contract, or prior to initiation of any human subjects research, whether funded or not, each Investigator is required to submit a disclosure form describing any financial interest held by the Investigator, the Investigator's spouse, or any dependent child of the Investigator that the Investigator determines to be reasonably related to the Investigator's institutional responsibilities. The disclosure form will be submitted to MultiCare's Conflict of Interest Officer, who will then review any financial interest disclosed as provided below.
2. When an Investigator not covered above reasonably concludes or reasonably should conclude that his/her research presents or appears to present a financial conflict of interest, the Investigator must disclose that fact to MultiCare's Conflict of Interest Officer.
3. In those cases where MultiCare has determined that a financial conflict of interest exists, no research funds may be expended and no research may begin until the Investigator has agreed in writing to any management plan required by MultiCare for this research.

B. Annual Update to Disclosure:

1. Each Investigator who submits a financial interest disclosure form is required to update that disclosure annually during the period of the award

or, for non-sponsored research, annually during the conduct of the project.

2. Annual updates must be submitted by March 30th of each calendar year.
3. It is the responsibility of the Principal Investigator or project director of a research project to ensure that each Investigator working on/who will work on the project submits a timely annual update to a previously-submitted disclosure form.
4. The annual update will be submitted to MultiCare's Conflict of Interest Officer, who will then review any updated financial interest disclosed as provided below.

C. Updating or Submitting a New Disclosure in an Ongoing Project:

1. When changes occur related to a financial interest in an ongoing research project, the Investigator is required to update the disclosure describing that interest. This may occur, for example, where the Investigator acquires a new financial interest or has changes to a previously-disclosed financial interest. A disclosure is also required when a new Investigator is added to an existing project. Such disclosures must be submitted to the Conflict of Interest Officer within 30 days of the event requiring the disclosure. The Conflict of Interest Officer will then review any such interest disclosed as provided below.
2. Disclosure Forms are available at www.multicare.org/home/research-forms

IV. Review by Conflict of Interest Officer (COIO):

- A. **Determination of Significant Financial Interest:** Prior to the Investigator's expenditure of any funds, or prior to the **initiation** of the research in the case of research with no external funding, the Conflict of Interest Officer will review the disclosed financial interest to determine whether it constitutes a significant financial interest.
- B. **Determination of Financial Conflict of Interest:** Upon concluding that the disclosed financial interest constitutes a significant financial interest, the Conflict of Interest Officer will review the disclosed significant financial interest to determine whether a financial conflict of interest exists and thus whether further review and management is required.
- C. In this review, the Conflict of Interest Officer will notify the relevant careline administrator and/or departmental director of the existence of the financial conflict of interest. This notification will alert the administrator or department director to the existence of the financial conflict of interest in the event s/he does not support the conduct of the research project in the departmental facilities with departmental resources.
- D. If the Investigator and department administrator or director determines that no significant conflict of interest exists, the COIO may either agree with that determination, disagree and require a management plan to be submitted to the Research Conflict of Interest Committee.

V. Review by Research Conflict of Interest Committee :

- A. Where the Conflict of Interest Officer has determined that a significant

financial conflict of interest exists, the RCOIC will develop and recommend for implementation to the Vice President for Quality a management plan that specifies the actions that have been and/or will be taken to manage the financial conflict of interest.

- B. In so doing, the RCOIC will consider the nature of the research, the nature and size of the interest, the degree to which the conflict is related to the research, the extent to which the interest could be affected by the research, and any management strategies that would mitigate or eliminate the conflict.
- C. Management strategies may include, but are not limited to:
 - 1. Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
 - 2. For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
 - 3. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias, or the appearance of bias, resulting from the financial conflict of interest;
 - 4. Modification of the research plan;
 - 5. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
 - 6. Reduction or elimination of the financial interest (e.g., sale of an equity interest); and
 - 7. Severance of relationships that create actual or potential financial conflicts.
- D. No member of the RCOIC who holds a significant financial interest in a project may participate in the review of interest or the development of a management plan for that project.
- E. RCOIC meetings are closed to the public.
- F. Specific Provisions Applicable to Human Subjects Research:
 - 1. As a general policy, MultiCare will not allow an Investigator with a financial conflict of interest to conduct a clinical research project whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment. In such cases, disclosure or standard conflict management strategies may be inadequate and adequate monitoring plans may be difficult or impossible to implement. This prohibition applies not only to the Principal Investigator of a clinical research project, but also to any Investigator involved in the design, conduct, or reporting of the research. A Principal Investigator would thus be prohibited not only from serving in that role, but in any Investigator role on the study.
 - 2. MultiCare may waive this prohibition only where the Investigator provides a compelling justification for its waiver. In considering an Investigator request for waiver, the RCOIC at a minimum will require the Investigator to address the following points:
 - a. The nature of the research project (including whether it is early-stage

or closer to commercial application);

- b. The size and nature of the Investigator's financial interest;
- c. The degree to which the financial interest is related to the research;
- d. The extent to which the interest is or may be affected by the research;
- e. The degree of risk to participants in the research;
- f. The Investigator's proposed role in the research, including protocol design, selection of participants, administration of informed consent, performance of protocol-mandated clinical procedures, evaluation of the effectiveness of the drug, device, or treatment, and evaluation of adverse effects; and
- g. The existence of unique RCOIC circumstances that would require the research to be performed at this institution as opposed to another (such as the unique qualifications of the Investigator and/or unique resources/capabilities of MultiCare).

- 3. If the Committee finds a compelling justification for waiver of the prohibition in a particular case, a stringent management plan, including a plan for rigorous oversight of the study, will be implemented to ensure the safety of study participants and the integrity of the research

VI. Monitoring: The Investigator's management plan will be monitored on an ongoing basis until the completion of the research project.

VII. Sub recipients:

- A. If MultiCare carries out the PHS-funded research through a subrecipient, MultiCare will incorporate as part of a written agreement with the subrecipient terms that establish whether MultiCare's or the subrecipient's policy on conflict of interest in research will apply to the subrecipient Investigators.
- B. If the sub recipient's policy will apply, the subrecipient will certify as part of the agreement that its policy complies with the PHS regulations on Objectivity in Research. Additionally, the agreement shall specify time period(s) for the subrecipient to report all identified financial conflicts of interest to MultiCare to enable MultiCare to provide timely reports to PHS.
- C. Alternatively, if MultiCare's policy on conflict of interest will apply, the agreement shall specify time period(s) for the subrecipient to submit all subrecipient Investigator disclosures of significant financial interests to MultiCare. Such time periods shall be sufficient to enable MultiCare to comply with timely review, management, and reporting obligations under the PHS regulations.

VIII. Undisclosed Significant Financial Conflict of Interest: In the event MultiCare identifies a significant financial interest that was not disclosed in a timely manner by an Investigator or, for whatever reason, was not previously reviewed by MultiCare during an ongoing research project, and where the COIO has determined that the undisclosed significant financial interest constitutes a financial conflict of interest related to a PHS-funded research project, the RCOIC will review the financial conflict of interest and MultiCare

will implement a management plan for the project within 60 days of identification of that interest. In addition, the RCOIC will, within 120 days of its determination of noncompliance, complete a retrospective review of the Investigator's research activities associated with the project to determine whether the research conducted during the period of the noncompliance was biased in the design, conduct, or reporting of such research.

IX. Mitigation Plan: If the RCOIC determines in the conduct of its retrospective review of PHS-funded research that the research or any part of it was biased, the RCOIC will recommend a mitigation plan to the Vice President for Quality to address any such issues. MultiCare will notify the PHS Awarding Component of its determination and subsequently follow up with the mitigation report for the project.

X. Public Access of Disclosed Significant Financial Interest:

- A. MultiCare will make available to the public upon request information concerning any significant financial interest disclosed to MultiCare that meets the following three criteria:
1. The disclosed significant financial interest is still held by the senior/key personnel of the active PHS project;
 2. MultiCare determines that the significant financial interest is related to the PHS-funded research; and
 3. MultiCare determines that the significant financial interest is a financial Conflict of Interest.
- B. The information request must be made to the Conflict of Interest Officer who will respond within five (5) business days of receipt of the request. Disclosed information will be provided to the extent required by applicable PHS regulations and state law.

XI. Ongoing Research:

- A. When in the course of an ongoing research project an Investigator new to the project discloses a significant financial interest or an existing Investigator discloses a new or changed significant financial interest, and where the COIO has determined that the disclosed significant financial interest constitutes a financial conflict of interest subject to management under this policy, the RCOIC will review the disclosure and MultiCare will implement a management plan for the project within 60 days of the submission of the disclosure to MultiCare.
- B. Depending on the nature of the financial conflict of interest, MultiCare may determine that additional interim measures are necessary with regard to the Investigator's participation in the research project between the date of disclosure and the implementation of MultiCare's management plan. Particular consideration will be given to any additional interim measures that MultiCare's Institutional Review Board views as necessary for the protection of human participants in any ongoing research.

XII. Implementation by Vice President for Quality: The Vice President for Quality will review the recommendation of the RCOIC and determine the final management plan to be implemented for the research. This determination will be provided to the Investigator, who must accept the requirements of the management plan in writing before beginning work on the project. Copies of

the signed management plan will also be provided to the Investigator's careline administrator or departmental director and in the case of research involving human participants, to the Institutional Review Board.

XIII. Appeal: Any Investigator may appeal the decision of the Vice President for Quality regarding management of a financial conflict of interest in writing to the President of MultiCare and thereafter to MultiCare Health System Board of Directors.

XIV. Noncompliance:

A. Failure to file a complete and truthful disclosure as required by this policy or to comply with the conditions or restrictions imposed in the resolution, management, or elimination of financial conflicts of interest constitutes a violation of MultiCare policy and may violate state and/or federal law. In such cases, the Investigator will be subject to appropriate sanctions consistent with MultiCare policies relating to staff or other applicable disciplinary policies. In addition, MultiCare may suspend an ongoing research project, halt the expenditure of funds, or suspend technology transfer activity to prevent continued violation of this policy. In any case in which the Investigator does not comply with any applicable conditions or restrictions imposed pursuant to this policy, MultiCare will withdraw any affected applications for funding if the project cannot otherwise be completed without the services of the Investigator.

B. In the event MultiCare discovers that a failure to comply with this policy has biased the design, conduct, or reporting of the research in accordance with the process previously outlined, MultiCare will promptly notify the sponsor of the research as required by applicable law and describe the corrective action(s) taken or to be taken.

XV. Training: Prior to engaging in any research project, all Investigators must complete training on the Investigator obligations under this policy. This training must be repeated at least every four years and must be completed immediately if this policy is revised so as to affect the Investigator's obligations, if an Investigator is new to MultiCare, or if MultiCare finds an Investigator to have violated this policy or any applicable management plan.

XVI. Reporting: MultiCare will provide initial and ongoing reports of its management of financial conflicts of interest to external sponsors of MultiCare research as required by law and in accordance with this policy.

XVII. Records: Records relating to all Investigator disclosures of significant financial interests and MultiCare's review and management of such disclosures, will be maintained by MultiCare in the case of externally-funded research for three years from the date of submission of the final expenditures report (in the case of grants and cooperative agreements) or three years from the final payment (in the case of research contracts), or as otherwise required by law. Such records in the case of research with no external funding will be maintained for three years from the close of the study.

XVIII. Miscellaneous:

A. Disclosure statements, other documentation used in the review of such statements, and records of institutional action taken pursuant to this policy shall be maintained in the MultiCare Institute for Research & Innovation for a period of three (3) years following completion of the research project that

generated the disclosure statements, documentation, or institutional actions, for a period of time needed for resolution of government action involving such records, or for a period of time fixed by the VPO, whichever is longer. To the extent permitted by law, such records shall be maintained confidentially.

- B. The Institute shall make the information described in the preceding paragraph available as prescribed by the sponsoring agency's policy or, upon request, to external funding agencies, along with requested information as to how a relevant potential or actual conflict of interest was managed, reduced, or eliminated to protect the objectivity of the research. If a potential or actual conflict of interest is identified after a grant or contract has been awarded, the Institute shall inform the awarding agency of that conflict within sixty (60) days of its discovery (or as otherwise required by law) along with actions taken to manage, reduce, or eliminate the actual or potential conflict of interest.
- C. If the Institute ever determines that it is unable to manage satisfactorily a potential or actual conflict of interest that threatens the objectivity of particular research activity, the Institute shall promptly inform the relevant external funding agencies of that fact as required by the agency policy.
- D. In making applications for external funding of research activities, Investigators will be required to certify that they have read and understand this regulation.

XIX. Definitions: The following definitions apply to this regulation, unless a different definition is used by an applicable federal agency. In that case, the definition used in the federal agency's regulations will apply.

Disclosure means an Investigator's disclosure of financial interests to MultiCare related to his or her institutional responsibilities.

Entity means any non-MHS organization, whether public or private. Examples include the following: a company, partnership, professional association, voluntary health organizations, etc.

Family Member means spouse or dependent child.

Financial Conflict of Interest means a significant financial interest that is related to the proposed MultiCare research (i.e. the interest reasonably appears to be affected by the research) and that could directly and significantly affect the design, conduct, or reporting of research.

Financial Interest means anything of monetary value, whether or not the value is readily ascertainable in any one of the following categories: compensation, equity (stock, stock options or other ownership interest) in a public or private company; royalty/licensing income; a position in a non-MultiCare entity giving rise to a fiduciary duty such as director, officer, partner, trustee, employee or any position of management; or, for researchers with funding from the Public Health Service, any reimbursed or sponsored travel.

Human Subjects Research means research conducted with a living individual about whom an Investigator obtains 1) data through intervention or interaction with the individual, or 2) identifiable private information.

Investigator means the Principal Investigator, a Co-Principal Investigator, Sub-Investigator and any other person at MultiCare who is responsible for the

design, conduct, or reporting of research. Also includes subgrantees, contractors, collaborators, or consultants of the Institute for Research & Innovation.

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 the research will be free from bias.

Research or "Research Activity" means a systematic investigation designed to develop or contribute to generalizable knowledge. The term encompasses basic and applied research such as bench work, clinical trials or other work and product development, and other forms of creative activity. The term includes any such research or creative activity conducted at MultiCare, by MultiCare personnel under the auspices of MultiCare, or conducted in situations in which MultiCare positions or titles are utilized in resultant publications, presentations, or other forms of intellectual property, irrespective of whether such research is funded by contract, gift, cooperative agreement, or general funds of the System. The term also includes collaborative work with a manufacturer, a distributor, or a sponsor of the research and includes any tangible or intangible inventions, discoveries, patents, or ideas necessary for development, utilization or processes associated with the activity.

Significant Financial Interest means a financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

1. With regard to any publically 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 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.
2. 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 the Investigator's spouse or dependent children) holds any equity interest (e.g. stock, stock option, or other ownership interest); or
3. Intellectual property rights and interests (e.g. patents, copyrights) , upon receipt of income related to such rights and interests.
4. Investigators are required to disclose all travel reimbursements that are either reimbursed or sponsored travel (i.e. paid for on behalf of the investigator and not reimbursed directly to the Investigator so that the exact monetary value may not be readily available) related to their Institutional responsibilities.

The term does not include any of the following:

	<ol style="list-style-type: none"> 1. Salary or other remuneration from MultiCare; 2. Income from seminars, lectures, teaching engagements, or service on advisory panels sponsored by government entities or institutions of higher education; 3. Income (e.g., salary, fees, or other continuing payments) in an amount of \$5,000 or less per annum from any one business enterprise or entity when aggregated for the Investigator and members of the Investigator's family; and 4. Financial interests in any one business enterprise or entity if the value of those interests does not exceed \$5,000 in value as determined through public prices or other reasonable measures of fair market value, and does not represent more than a five percent (5%) ownership interest when aggregated for the Investigator and members of the Investigator's family. 5. Sponsored or reimbursed travel provided by a Federal, state, or local government agency, an Institution of higher education as defined at 20 USC 1001(a), an academic teaching hospital, a medical center, or a research institute affiliated with an Institution of higher education.
	<p>Related Policies: MHS Policy: <i>"Corporate Compliance – Standards for Business Conduct, Distribution and Training at MHS"</i></p>
	<p>Related Forms: FCOI Disclosure Form FCOI Disclosure Attachment Form</p>
	<p>References: Responsibility of Applicants for Promoting Objectivity in Research for which PHS funding is Sought - 42 CFR Part 50 Subpart F</p>
	<p>Points of Contact: Medical Director, Institute for Research & Innovation – 403.7251 Manager, Institute for Research & Innovation – 403.5272</p>
<p>Approval By: MHS Medical Staff Operations MGSH Medical Executive Committee Quality Steering Council</p>	<p>Date of Approval:</p>
<p>Original Date: Revision Dates: Reviewed with no Changes Dates:</p>	<p>8/12 none none</p>
<p>Distribution: MHS Intranet</p>	