

	<p>Administrative Policy & Procedure</p> <p>Title: Financial Conflict of Interest in Research</p> <p>Section: Human Resources</p>	<p>Policy Number: HR 1061</p> <p>Origination Date: 8/2012</p> <p>Effective Date: 8/2012</p> <p>Page 1 of 9</p>
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Policy Statement

It shall be the joint policy of Memorial Health, Inc. and Memorial Health University Medical Center, Inc. (together, "Memorial Health") to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research will be free from bias resulting from financial conflict of interest.

Definition of Terms

Compensation shall mean anything of monetary value including, but not limited to salary, consulting fees, honoraria, or other payments for services, of any type, including speaking, teaching, and educational engagements, as well as gifts to Investigators.

Equity Interest shall mean stocks, stock options, or other ownership interests.

Financial Conflict of Interest means any Significant Financial Interest requiring disclosures that is reasonably determined by Memorial Health to constitute a real or perceived conflict of interest that could directly and significantly affect the design, conduct or reporting of the Research and that requires management, reduction, or elimination.

Institutional Official means the person appointed by Memorial Health or his/her designee(s), to solicit and review statements from investigators of Significant Financial Interests Requiring Disclosure. [See, Section 42 CFR 50.604 (b) and 45 CFR Section 94.4 (b)]. Memorial Health has appointed the Vice President of Ethics as its Institutional Official.

Investigator shall mean the Project Director, Principal Investigator, or any other members of the research team identified as senior/key personnel on the grant or contract application, progress report, or any other report. In addition individuals identified by the Principal Investigator Project Director

who are responsible for and have substantial independent decision making with respect to the design, conduct or reporting of the research, such as collaborators or consultants named on the grant. [See 42 CFR Section 50.603 & 45 CFR Section 94.3].

Institutional Responsibilities shall mean the Investigator's professional responsibilities on behalf of Memorial Health, such as those activities related to their clinical, administrative, research, teaching or professional duties at Memorial Health.

Research means any systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge, including

behavioral and social-sciences research. The term encompasses basic and

applied Research as well as product testing and development. The term includes, but is not limited to, any activity for which Research funding is available from a Public Health Service ("PHS") component that awards funds

under grants, cooperative agreements or otherwise. For PHS-funded

activities, this 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, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project or research resources award.

Significant Financial Interest means interests held individually by the

Investigator, his/her spouse or same-sex domestic partner, and dependent

children. These must be added together and the aggregate value used to determine limits is set forth below:

- 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 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 twelve months preceding the disclosure, when aggregated exceeds \$5,000, or when the Investigator (or the Investigator's spouse, same-sex domestic partner, or dependent children) holds any equity interest (e.g., stock, stock option or other ownership interest); or
- c) Intellectual property rights and interests (e.g., patents, copyrights) upon receipt of income related to such rights and interests.
- d) Holding any management position (e.g., director, officer, trustee,

management employee) in a non-Memorial Health entity.

The following items are NOT considered to be a Significant Financial Interest:

- a) Salary or other payments from Memorial Health to the Investigator if the Investigator is currently employed or otherwise appointed by Memorial Health, including intellectual property rights assigned to Memorial 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) Gifts to Memorial Health provided the Investigator does not have signing authority for the Memorial Health account.
- d) Income from seminars, lectures, or teaching engagements sponsored and paid for by governmental entities, 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; or
- e) Income from service on advisory committees or review panels for governmental entities, 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.

Significant Financial Interest Requiring Disclosure means, for Non-PHS

projects, an Investigator's Significant Financial Interest (a) that would reasonably appear to be affected by the Research on which the Investigator is working; or (b) that is held in an entity whose financial interests would reasonably appear to be affected by the Investigator's Research.

Any Significant Financial Interest Requiring Disclosure must be reported to the Institutional Office or his/her designee. PHS Investigators must disclose all Significant Financial Interests related to their Institutional Responsibilities – teaching, research, clinical or administrative duties. Additionally, they must disclose any reimbursed or sponsored travel (i.e., the travel was paid for on their behalf, but not reimbursed to them by Memorial Health), related to their administrative, clinical, or teaching duties at Memorial Health. It does not include travel that is reimbursed or sponsored by the following:

- federal, state, or local government agency,
- an institution of higher education,
- academic teaching hospital,
- medical center, or
- research institute that is affiliated with an institution of higher education.

Procedure

1. General Applicability

This policy applies to all team members at Memorial Health. The procedures for Public Health Services (PHS) Investigators shall apply to PHS funded grants or cooperative agreements with an issue date of the Notice of Award that is subsequent to August 24, 2012 and to solicitations issued and contracts awarded subsequent to August 24, 2012. This policy shall not apply to research funded solely by PHS SBIR/STTR Program Phase 1 awards subsequent to August 24, 2012; however, human subject research funded by PHS SBIR/STTR will be subject to this policy.

2. Applicability to Subrecipients

For Research sponsored by the US Public Health Services that involves subcontractors, subgrantees or subawardees (collectively subrecipients") at other institutions, Memorial Health requires a written agreement from the Subrecipients that determines if Memorial Health's policy or that of the Subrecipient shall apply to the subrecipient's Investigators. Memorial Health

must report to the PHS funding agency any Subrecipient's Financial Conflict of Interest prior to the execution of the subcontract or within 60 days of identification of a new Financial Conflict of Interest by the Subrecipient or Memorial Health that arises during the term of the subcontract

- a. If the subrecipient's policy is used, they must conform to the requirements of all applicable regulations, including, but not limited to those set forth at 45 CFR Part 94 and 42 CFR Part 50, Subpart F and will be responsible for ensuring that the Subrecipient Institution and its Investigators comply with the federal regulations. Subrecipients must report to Memorial Health as the awardee Institution any identified Financial Conflict of Interest within 10 business days of the management plan agreement with the Subrecipient's Investigator but no later than 45 days after identification of the Financial Conflict of Interest by the Subrecipient. The details of the Financial Conflict of Interest will be reported to the funding agency as required under applicable regulations or policies.
- b. If Memorial Health's policy is used, the Subrecipient must ensure that its Investigators submit the Investigators Financial Conflict of Interest Document to Memorial Health at the time of application by Memorial health or at the time the institution signs documentation for an on-going award grant or contract.

3. Reporting Requirements and Process

- a. The definitions in this Policy describe Significant Financial Interests and Significant Financial Interests Requiring Disclosure. Individuals may have difficulty deciding if an interest falls within these categories. Accordingly, individuals should always err on the side of reporting any Significant Financial Interest that they think may affect, or be affected by, Research on which they are working.

Once any Significant Financial Interest is reported, Memorial Health will (a) confirm that the Significant Financial Interest is a Significant Financial Interest Requiring Disclosure; and if so, (b) determine whether the interest constitutes a Financial Conflict of Interest that must be managed, reduced or eliminated. Individuals should not make the decision about whether a Significant Financial Interest Related to Research is a Financial Conflict of Interest; this determination is made through the review process.

- b. The Institutional Official is the person designated by Memorial Health to oversee the solicitation and review of financial reporting statements from any Investigators who will be participating in Research. For the purpose of this policy, the Institutional Official is the Vice President of Ethics.

4. Methods of Report

All Investigators are required to report Significant Financial Interests Related to Research BOTH on an annual basis, and at anytime that a new Significant Financial Interest Related to Research occurs. Each investigator who holds a Significant Financial Interest Related to Research must report the existence and nature of the interest prior to submitting a formal proposal to any proposed sponsor of the Research, or prior to conducting the Research, if the Research is internally funded. At the time of routing a grant or contract proposal for sponsored Research, Investigators are responsible for accurately completing the Memorial Health, Inc. Proposal Routing Form. If any member of Memorial Health intends to conduct research using Memorial Health resources in an area in which he/she holds a Significant Financial Interest Related to Research, they must notify the Office of Sponsored Programs, and any perceived or actual conflicts of interest must be managed, reduced, or eliminated prior to initiating the Research. Investigators are required to update reports in real time to reflect changes in or additions to Significant Financial Interest Related to Research. In cases where Investigators are not aware of the existence of a Significant Financial Interest Related to Research at the time of a proposal for Research funding, or if the significant Financial Interest develops after submission of a proposal, then Investigators shall report the interest to the Office of Sponsored Programs with three (3) business days of learning of the interest.

5. Conflict of Interest Management, Reduction, or Elimination of Interest

The Vice President of Academic Affairs, in consultation with the Senior Vice President & Chief Medical Officer, and the Vice President for Finance, shall review and recommend plans for the management, reduction or elimination of the interest. They will review any reports made regarding Significant Financial Interests Related to Research brought to their attention by Investigators, Institutional Official or the Office of Sponsored Programs. They will request and review any additional materials needed to evaluate the relationship of the interest of Research, recommend whether the Significant Financial Interest related to Research constitutes a Financial Conflict of

Interest and develop a plan to manage, reduce or eliminate any Financial Conflict of Interest.

Plans for management of conflict of interest shall focus on developing steps by which the objectivity of the Research can be ensured. Components of the plan may include, but not be limited to:

- Public disclosure of any investigator's interest in a Research sponsor or in an entity whose service or product is the subject of any Research results being reported or in the competitor of such entity; or
- Monitoring of any Research project by independent reviewers; or
- Modification of any Research or plan; or
- Disqualification of any Investigator from participating in all or a portion of any Research; or
- Divestiture by an Investigator of any financial interest in any Research sponsor or entity whose products or services are the subject of the Research or the competitor of such entity.
- Severance of any relationship between an Investigator and a Research sponsor or entity (or competitor thereof) whose service or product is the subject of the Research that may create actual or potential conflicts of interests.

6. Research with Human Subjects

Special precautions must be taken to avoid perceived or actual bias with respect to Research involving Human Subjects that encompasses the evaluation of strategies or products that may affect or be affected by the financial interests of Memorial Health or Memorial Health Investigators. A Memorial Health Investigator shall not ordinarily participate in any Research involving human subjects that encompasses evaluation of such a strategy or product if he/she has a Significant Financial Interest that could directly affect the design, conduct or reporting of the Research unless he/she presents a compelling justification for a waiver of this policy based on his/her unique qualifications as an Investigator. The degree of risk to human subjects and the compelling justification will be reviewed by the Vice President of Academic Affairs, Senior Vice President & Chief Medical Officer, and the Institutional Official. If compelling circumstances justify a waiver of this policy, the Research will be subject to stringent management measures to ensure the safety of the human participants and the integrity of the Research. The IRB must review and approve any management plan for human subject Research. The IRB may require additional safeguards to protect human subject participants.

In accordance with 42 CFR Section 50.606(c), in any case in which the Department of Health and Human Services determines that a Public Health Service-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 conflicting interest that was not reported or managed as required by this Policy or the applicable regulations, then Memorial Health shall, at minimum, require the Investigator involved to disclose the conflicting interest in each public presentation of the results of the Research. An Investigator who has failed to report a Significant Financial Interest related to clinical Research will be subject to sanctions.

7. Reporting and Expenditures of Funds

No expenditure of sponsor funding for Research shall occur with respect to any Research project for which a Financial Conflict of Interest exists unless and until the Financial Conflict of Interest is reported to the sponsor, and has been managed, reduced or eliminated pursuant to a plan also reported to the sponsor [42 CFR Part 50 Subpart F]. For any Financial Conflict of Interest that is identified after the funding for the Research is awarded, Memorial Health will report to the sponsor, as required by sponsor's regulations or policies, the Financial Conflict of Interest and the plan for its management, reduction or elimination within 60 days of the interest's identification.

8. Compliance with this Policy and Relevant Law

The Investigator is ultimately responsible for ensuring that he/she makes any necessary disclosures and reports required by this Policy and follows any prescribed plan for the management, reduction, or elimination of an identified Financial Conflict of Interest. Failure to do so shall be deemed a violation of Memorial Health Policy.

9. Reporting Conflicts of Interest; Maintenance of Records

The outcome of reviews will be communicated to the Institutional Review Board (IRB) for all Research involving human subjects and to the Institutional Animal Care and Use Committee (IACUC) for all Research involving animal subjects. The IRB and IACUC may require additional measures to protect the safety and welfare of Research subjects under their purview.

For Research involving external sponsorship, the Office of Sponsored Programs will notify those sponsors that require notification of the disclosure and action, in accordance with the sponsor's applicable regulations or policies has occurred. The Office of Sponsored Programs shall be responsible for maintaining records, identifiable to each project, all transactional reports of Significant Financial Interests, and all actions taken as a result of the Conflict of Interest review to manage any actual or potential Financial Conflicts of Interest for the longer of at least three (3) years from: (a) the date of submission of the final expenditures report, for federally funded grants; (b) from the date of termination or completion of the award; or (c) from the date of the resolution of any action by any governmental agency involving the records; or (d) as applicable, from any other date specified in 45 CFR Section 74.53(b) and 92.42(b) for different situations, as appropriate.

Approved by:

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Senior Vice President & Chief Medical Officer

Original Implementation Date:	8/2012
Originating Department:	Office of Sponsored Programs
Next Review Date:	8/2015
Past Revised Date:	

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Past Reviewed Date:
Former Policy Number(s):
Attachment(s):