



Policy /Procedure Document	
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<b>Policy Number:</b>	Investigator Conflict of Interest
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<b>Policy Owner:</b>	Alicia Dombkowski
<b>Required Approvals:</b>	President of Memorial Hospital
	Vice President of Operations
	Hospital Leadership Committee

<b>TITLE:</b>	<b>Investigator Conflict of Interest</b>
<b>SCOPE:</b>	Institutional Review Board (IRB)
<b>PURPOSE:</b>	This policy promotes 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 Investigator financial conflicts of interest.
<b>POLICY/PROCEDURE:</b>	

**Investigator Financial Conflict of Interest**

1. The Investigator Conflict of Interest policy will be made available to the general public on the Memorial Hospital website.
2. Each investigator will be informed of the Investigator Conflict of Interest policy prior to initiating a research study with the IRB.
3. Each investigator is required to disclose any significant financial interests (and those of the Investigator's spouse and dependent children) prior to initiating research at Memorial Hospital, annually, and within thirty days of discovering or acquiring (e.g. through purchase, marriage or inheritance) a new significant financial interest.
4. Each investigator is required to complete training regarding conflict of interest prior to engaging in research and at least every four years and immediately when any of the following circumstances apply:
  - a. The investigator conflict of interest policy is revised in any manner that affects the requirements of Investigators;
  - b. An investigator is new to the institution; or
  - c. An investigator is not in compliance with the conflict of interest policy.
5. The IRB chair will solicit and review disclosure of significant financial interest from each Investigator who is planning to participate in or is participating in research at Memorial Hospital.
  - a. If a significant financial interest exists the IRB chair in conjunction with the President of Memorial Hospital and Corporate Compliance Officer will determine if the significant financial interest could directly and significantly affect the design, conduct or reporting of the research.
  - b. If a financial conflict of interest is determined, a management plan will be developed and implemented and if necessary, a retrospective review and mitigation report will be filled.
6. All documentation of disclosure of significant financial interests and financial conflicts of interest will be maintained for at least three years from the closure of the research study.
7. Memorial Hospital agrees to make information available, promptly upon request to HHS relating to any investigator disclosure of financial interest and the institution's review of, and response to, such disclosure, whether or not the disclosure resulted in the determination of a financial conflict of interest.

**Management and reporting of financial conflicts of interest.**

1. If an investigator financial conflict of interest exists, a management plan will be implemented that specifies the actions that have been, and shall be, taken to manage such financial conflict of interest.

Examples of conditions or restrictions that might be imposed to manage a financial conflict of interest include but are not limited to:

- a. Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
  - b. For research projects involving human subject research, disclosure of financial conflicts of interest directly to participants;
  - c. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of research against bias resulting from the financial conflict of interest;
  - d. Modifications of the research plan;
  - e. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
  - f. Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
  - g. Severance of relationships that create financial conflicts.
2. Whenever, in the course of an ongoing research project, an investigator who is new to participating in the research project discloses a significant financial interest or an existing investigator discloses a new significant financial interest, the designated officials shall within sixty days: review the disclosure of the significant financial interest, determine whether a financial conflict of interest exists; and if so, implement, on at least in interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest. Depending on the nature of the significant financial interest, a determination that additional interim measures are necessary with regard to the investigator's participation in the research project between the date of disclosure and the completion of the review.
3. Whenever a significant financial interest is determined that was not disclosed timely by an investigator or, for whatever reason, was not previously reviewed during an ongoing research project, the designated official(s) shall, within sixty days: review the significant financial interest; determine whether it is related to research; determine whether a financial conflict of interest exists; and, if so:
- a. Implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest going forward;
    - i. In addition, whenever a financial conflict of interest is not identified or managed in a timely manner including failure by the investigator to disclose a significant financial interest that is determined to constitute a financial conflict of interest; failure to review or manage such a financial conflict of interest; or failure by the investigator to comply with a financial conflict of interest management plan, within 120 days of the determination of noncompliance, a retrospective review of the investigator's activities and the research project will be conducted to determine whether the research, or a portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.
    - ii. The retrospective review will be documented; such documentation shall include, but not necessarily be limited to, all of the following key elements:
      1. Project number;
      2. Project title;
      3. Principal Investigator;
      4. Name of the Investigator with the FCOI;
      5. Name of the entity with which the Investigator has a financial conflict of interest;
      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.
    - iii. Based on the results of the retrospective review, if appropriate, the FCOI report will be updated specifying the actions that will be taken to manage the financial conflict of interest going forward. If bias is found, a mitigation report will be submitted. 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 the plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, a FCOI report will be completed annually. Depending on the nature of the financial conflict of interest, additional interim measures may be determined which are necessary with regard to the investigator's participation in the research project between the date that the financial conflict of interest or the investigator's noncompliance is determined and the completion of the retrospective review.

4. Whenever a management plan is implemented, it shall monitor investigator compliance with the management plan on an ongoing basis until the completion of the research project.
5. Prior to the initiation of a research project, public accessibility, via a publicly accessible Web site or written response to any requestor within five business days of a request, of information concerning any significant financial interest will be disclosed if it meets the following three criteria:
  - a. The significant financial interest was disclosed and is still held by the senior/key personnel as defined;
  - b. It was determined that the significant financial interest is related to the research; and
  - c. It was determined that the significant financial interest is a financial conflict of interest.
6. The information made available via a publicly accessible Web site or written response to any requestor within five business days of a request, shall include, at a minimum, the following: the investigator's name; the investigator's title and role with respect to the research project; 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.
7. The information posted on the web site shall be updated at least annually. In addition, the web site shall be updated within sixty days of the receipt or identification of information concerning any additional significant financial interest of the senior/key personnel for the research project that was not previously disclosed, or upon the disclosure of a significant financial interest of senior/key personnel new to the research project, if determined that the significant financial interest is related to the research and is a financial conflict of interest. The Web site shall note that the information provided is current as of the date listed and is subject to updates, on at least an annual basis and within 60 days of the identification of a new financial conflict of interest. If responding to a written request, the written response will include 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 the identification of a new financial conflict of interest, which should be requested subsequently by the requestor.
8. Information concerning the significant financial interests shall remain available, for responses to written requests or for posting via the publicly accessible web site for at least three years from the date that the information was most recently updated.

**DEFINITIONS:**

**Disclosure of significant financial interests:** an Investigator's disclosure of significant financial interests to an Institution.

**Financial conflict of interest (FCOI):** a significant financial interest that could directly and significantly affect the design, conduct, or reporting of research.

**FCOI report:** an Institution's report of a financial conflict of interest.

**Financial interest:** anything of monetary value, whether or not the value is readily ascertainable.

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

**Investigator:** the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research

**Manage:** taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design,

conduct, and reporting of research will be free from bias.

**PHS:** 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).

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

**Research:** a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug). As used in this subpart, 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, 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:**

(1) 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:

(i) 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;

(ii) 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

(iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

(2) Investigators also 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 institutional 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. The Institution's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the Institution's FCOI policy, the institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the research.

(3) The term *significant financial interest* does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; 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; 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 medical center, or a research institute that is affiliated with an Institution of higher education; or 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.

**REFERENCES:**

FDA 42 CFR 50

Document Revision History:			
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07/14/2015	07/14/2015	Alicia Dombkowski	Original Document

**SIGNATURES OF APPROVAL:**

Date Signed	Signature	Name	Title
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