

MEMORIAL HOSPITAL OF RHODE ISLAND

Policy on Financial Conflicts of Interest Concerning Research Funded by the U.S. Public Health Service

It is the policy of Memorial Hospital of Rhode Island (“MHRI” or “Hospital”) to comply with all applicable laws and regulations, including the regulations set forth at 42 CFR Part 50 Subpart F and at 45 CFR Part 94 issued by the Public Health Service (“PHS”) of the U.S. Department of Health and Human Services (“DHHS”), concerning the disclosure, management and reporting of financial conflicts of interest with respect to PHS-funded research.

DEFINITIONS

Investigator: This term means the project director and/or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct or reporting of research funded by the PHS, or proposed for such funding. The term “Investigator” may include, for example, collaborators or consultants.

Senior/Key Personnel: This term means the Investigators and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted by MHRI to the PHS with respect to research funded by the PHS, or proposed for such funding.

Covered Person: This term means an individual who fulfills this policy’s definition of *Investigator* or *Senior/Key Personnel* and is used in this policy to denote the individuals who must disclose Significant Conflicts of Interest and otherwise comply with the requirements of this policy.

Subrecipient: This term means and refers to any individual or entity engaged by MHRI, such as a sub-contractor, or with which MHRI collaborates in the design, conduct or reporting of research funded by the PHS, or proposed for such funding.

Financial Interest: means anything of monetary value, whether or not the value is readily ascertainable.

Significant Financial Interest: 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 PHS-funded 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.”

Related Significant Financial Interest: means a Significant Financial Interest that (a) reasonably could be affected by the research project(s) for which the Covered Person having the interest is among the project's Senior/Key Personnel or serves as an Investigator or PD/PI; or (b) is an entity whose financial interest could be affected by the research.

Financial Conflict of Interest: means a Related Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of a research project.

REQUIREMENTS

1. Training

Before engaging in research funded by the PHS, all Covered Persons must complete a program of training that is deemed satisfactory under this Policy. Covered Persons must renew their training no less frequently than every four years.

The following programs of training satisfy this policy:

- a. The tutorial on conflicts of interest offered by the National Institutes of Health, which is accessible at <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm> .
- b. The conflicts of interest module(s) offered by the Collaborative Institutional Training Initiative (“CITI”).
- c. Annually the investigator will certify that they have read and understand the policy and are in compliance with internal reporting requirements.

Each Covered Person is to submit to the Grant Accounting Office documentation evidencing his or her successful completion of one of these modes of training. Additional training will be required within 60 days if MHRI revises its conflict of interest policy in a way that affects the requirements applicable to investigators, when an investigator is new to MHRI, or when an investigator fails to comply with this policy or an imposed FCOI management plan.

2. Disclosure

All Covered Persons must disclose significant financial conflicts using a form designated for that purpose by MHRI. Such disclosures are to be made as follows:

- a) To the Grant Accounting Office when applying for research funding from PHS;
- b) To the Grant Accounting Office at least annually during the award period; and

- c) To the Grant Accounting Office within 30 days of acquiring or discovering a new significant financial interest.

3. Administrative Processes for Submission and Receipt of Disclosures.

- a) **Preliminary Processing by Grant Accounting.** The Grant Accounting Office will review all disclosures it receives pursuant to this policy, and will forward to the Corporate Compliance Officer a copy of each such disclosure in which a Covered Person indicates that he or she has a potential Significant Financial Interest.
- b) **Processing by Corporate Compliance Officer (“CCO”).** With respect to each disclosure received by the CCO indicating the existence of a potential Significant Financial Interest, the CCO shall:
 - i. with respect research projects involving human subjects, refer the disclosure to the IRB, which shall review the disclosure in accordance with Section 4, below;
 - ii. with respect to research projects involving animals, refer the disclosure to the IACUC/Animal Care Committee, which shall review the disclosure in accordance with Section 4; and
 - iii. With respect to research that involves neither human subjects nor animals, review the disclosure in accordance with Section 4, below.

4. Review of Disclosures of Significant Financial Interests.

Prior to MHRI’s expenditure of any funds received from a PHS component in sponsorship of a research project, the committee (in the case of the IRB or IACUC) or individual (in the case of the CCO) charged with reviewing disclosures of Significant Financial Interests shall determine whether the Significant Financial Interest is a Related Significant Financial Interest and, if so, whether the Significant Financial Interest constitutes a Financial Conflict of Interest.

The committee or person conducting this review may, but is not required to, involve the Covered Person in the determination of whether a Significant Financial Interest is a Related Significant Financial Interest.

Determinations of the existence of Financial Conflicts of Interest are to be reported to the Grant Accounting Office.

5. Management of Financial Conflicts of Interest.

When it is determined that a Financial Conflict of Interest exists the committee or individual making such determination may formulate and implement a management plan that will specify the conditions and/or restrictions that will be taken to manage such Financial Conflict of Interest, which may include, but would not be limited to, the following:

- a) Public disclosure of such Financial Conflict of Interest (e.g., when presenting or publishing the research);
- b) For research involving human subjects, disclosure of such Financial Conflict of Interest directly to participants; and/or
- c) Modification of the research plan.

In addition, the committee or individual may recommend to the Hospital’s chief executive officer or governing body that one or more of the following actions be taken:

- a) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- b) Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the Research against bias resulting from such Financial Conflict of Interest; or

- c) Conditioning the Covered Person's involvement in the research on his or her reducing or eliminating his or her Related Financial Conflict of Interest through, for example, the sale of an investment interest or the discontinuation of the arrangement or relationship that gave rise to the conflict.

6. Reporting Financial Conflicts of Interest to PHS/NIH.

The Grant Accounting Office will send to relevant PHS components the initial, annual and revised FCOI reports for the Hospital and, when applicable, its sub-recipients in conformance with PHS regulation. As required, reports will be sent prior to the expenditure of funds, within 60 days of identification of an investigator who is newly participating in a project, and at least annually to provide the status of the FCOI and any changes to the management plan, if applicable, until the project is completed.

The Grant Accounting Office will promptly notify the relevant PHS component if an investigator fails to comply with this policy or if a management plan appears to have biased the design, conduct or reporting of the NIH-funded research. The CCO or appropriate research review committee will institute corrective action for noncompliance with the Hospital's policy or the management plan.

7. Noncompliance.

(a) Significant Financial Interest. Whenever a Significant Financial Interest is identified that was not timely disclosed by a Covered Person or was not previously reviewed or managed in accordance with this policy, the relevant research review committee or CCO, as appropriate, shall within sixty days of such identification review the Significant Financial Interest in accordance with section 4 above, and, if a Financial Conflict of Interest is found to exist, shall formulate and implement a management plan in accordance with Section 6 above and shall perform the review process delineated in sub-section (b) below.

(b) Financial Conflict of Interest. Whenever a Financial Conflict of Interest is identified that was not disclosed, reviewed or managed in a timely manner, the relevant research review committee or the CCO, whichever is appropriate, shall within 120 days of the determination of non-compliance, complete a retrospective review of the PHS-funded research and of the activities of the Covered Person(s) with the Financial Conflict of Interest to determine whether all or any portion of any PHS-funded research conducted during the time period of the noncompliance was biased in the design, conduct or reporting of such research. MHRI shall comply with the documentation, reporting, notification and mitigation requirements set forth in PHS regulation at 42 CFR 50.605(a)(3)(iii).

(c) The Hospital will take specific action in any case in which the DHHS determines that the Hospital failed to manage or report an investigator FCOI in PHS-funded clinical research project that evaluates the safety or effectiveness of a drug, medical device or treatment. The relevant research review committee or the CCO, whichever is applicable, will require the Covered Person to disclose the FCOI in each public presentation of the results of the research, and will request an addendum to previously published presentations.

(d) Covered Persons who fail to disclose Significant Financial Interests or who otherwise fail to comply with this Policy or with any management plan related to such Covered Person will be reported to the Hospital's Corporate Compliance Committee and, if the Covered Person is a member of the Hospital's medical staff, to the appropriate hospital medical staff department chairperson. Such Covered Person shall be subject to appropriate disciplinary measures in accordance with hospital and/or medical staff policy.

8. Subrecipients.

In instances in which MHRI conducts PHS funded research through or in collaboration with one or more Subrecipients, MHRI will take reasonable steps to ensure that each Subrecipient complies with PHS regulations by:

- (a) Incorporating as part of a written agreement with the Subrecipient the terms that establish whether Subrecipient and its Investigators will comply with this policy or with the financial conflicts of interest policy of the Subrecipient. If the written agreement requires the Subrecipient and its investigators to comply

with the Subrecipient's policy, then the Subrecipient must certify in the agreement that its policy complies with PHS regulations; and

- (b) Specifying within such written agreement the time period(s) within which the Subrecipient shall report to MHRI all identified financial conflicts of interest (if the Subrecipient's policy applies) or all Significant Financial Interests (if MHRI's policy applies).

9. Public Accessibility.

Information about identified financial conflicts of interest will be available from the CCO only upon request. The information required under PHS regulations will be provided within five business days. The information will include the minimum elements as provided by the regulation. It will be updated annually and within 60 days of a newly identified FCOI. The information will remain available for three years from the date that it was most recently updated.

This Policy for shall be available on the Hospital's public web site.

10. Record Maintenance.

The Grant Accounting Office is responsible for maintaining (i) the written disclosures submitted by Covered Persons under this policy; and (ii) reports submitted to PHS/NIH as required in Section 6 above.

The CCO, IRB and IACUC are responsible for maintaining documentation concerning reviews and other activities required under Sections 4, 5 and 7 above.

All documentation maintained under this Section shall be retained for at least three years from the date the final expenditures report is submitted to the relevant PHS component or where applicable, from other dates specified in 45 C.F.R. 74.53(b) and 92.42(b).