

POLICY AND PROCEDURE – RE-14

Subject:
RE14 Conflicts of Interest in Research

Effective Date:
February 2005

Applies to:
All Houston Methodist Entities

Date Revised/Reviewed:
May 2018

Originating Area:
Houston Methodist Research Institute:
Office of Research Protections

Target Review Date:
May 2020

I. GENERAL STATEMENT

This Policy is intended to provide a reasonable expectation that the design, conduct, reporting, and publication of Research will not be biased by Financial Conflicts of Interest (COI). Methodist's goal is to promote the identification, reporting, and, if required, elimination or management of such conflicts in the context of Research.

This Policy applies to all persons within Methodist who perform Research, including, but not limited to medical and non-medical staff and other members of Methodist, regardless of title, who are responsible for the design, conduct or reporting of research at Methodist (hereinafter "Covered Individual").

Appendix A is part of this Policy and contains additional requirements for Covered Individuals engaged in research sponsored by the U.S. Public Health Service ("PHS"), which includes the National Institutes of Health ("NIH").

II. DEFINITIONS

- A. **Business**: Means any corporation, firm or other legal entity organized for profit or charitable purposes, excluding Methodist.
- B. **Financial Conflict of Interest**: When the HMRI Business Practices Committee reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct or reporting of Research.
- C. **Methodist**: Abbreviation of the Houston Methodist encompassing all of its subsidiaries, affiliates, and joint venture systems operated by Houston Methodist.
- D. **HMRI BPC**: The HMRI Business Practices Committee.
- E. **Immediate Family Members**: Includes the following:
- Spouse (husband or wife)
 - Dependent Children/Step Children
- F. **Research**: Means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge. The scope of Research as used in this Policy, covers **both current and anticipated**, basic and applied Research, product development,

behavioral and social sciences Research, and any Research performed with or without human subjects (as defined in 45 CFR 46 & 21 CFR 56) or animals¹.

- G. Covered Individual: All persons within Methodist who perform Research, including but not limited to medical and non-medical staff, as well as any member of Methodist, regardless of title, who is responsible for the design, conduct or reporting of research at Methodist. This includes but is not limited to, the Principal Investigator and members of the research team listed on a HMRI application and “Key Personnel” listed on a grant proposal.
- H. PHS Awarding Component: Means the organizational unit of the PHS that funds the research.
- I. Institutional Responsibilities: Include professional responsibilities on behalf of Methodist, including, but not limited to, research, research consultation, professional practice, institutional committee membership, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.
- J. Significant Financial Interest: A financial interest consisting of one or more of the following known interests of the Covered Individual or the Covered Individual’s Immediate Family Member that reasonably appears to be related to the Covered Individual’s Institutional Responsibilities:
 - 1. Any remuneration received from a Business in the twelve-month period immediately prior to the disclosure or expected from a Business in the twelve-month period immediately following the disclosure. 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);
 - 2. Any equity interest in a Business. For purposes of this definition, 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; or
 - 3. Any intellectual property rights (e.g., patents, copyrights), royalties from such rights, and agreements to share in royalties related to such rights.

The term Significant Financial Interest does not include: (i) income from investment vehicles, such as mutual funds and retirement accounts, as long as the Covered Individual or Immediate Family Member does not directly control the investment decisions made in these vehicles;(ii) income from seminars, lectures and teaching engagements sponsored by 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; or (iii) income from service on advisory committees or review panels for 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.

¹The term “Research” also includes educational activities funded or proposed for funding by the National Science Foundation (NSF).

III. PROCEDURE

A. Disclosure

1. Initial Disclosure

Covered Individuals have principal responsibility for avoiding Financial Conflicts of Interest. Covered Individuals are required to make full, written disclosure of their and their Immediate Family Members' Significant Financial Interests and other requested information to the HMRI BPC. Covered Individuals must make disclosures prior to submission of each PHS funded grant application, and prior to submission of any non-PHS funded grant application if required by the external funding entity. In addition, Covered Individuals must make disclosures prior to engaging in a new Research protocol if a disclosure was not made as part of a grant application submission. Disclosures should provide sufficient detail to permit an accurate and objective evaluation and must be submitted through MORTI (HMRI electronic submission system).

2. Updated Disclosures

Disclosures must be updated annually by Covered Individuals, with the exception of investigators of internally funded exempt human subject research. Such updated disclosures shall include Significant Financial Interests not previously disclosed and updates to previously disclosed Significant Financial Interests. In addition, Covered Individuals are required to report new Significant Financial Interests within 30 days of discovering or acquiring the interest. Updates should be submitted according to the same procedure as initial disclosures, described in Section 4.a. above.

B. Review of Disclosures

Upon receipt of a disclosure of a Significant Financial Interest greater than or equal to \$5,000.00, the HMRI BPC will determine (a) whether the Significant Financial Interest is related to the Research, and, if so related, (b) whether the Significant Financial Interest is a Financial Conflict of Interest. A Covered Individual's Significant Financial Interest is related to the Research when the HMRI BPC reasonably determines that the Significant Financial Interest could be affected by the Research or is in an entity whose financial interest could be affected by the Research. Initial review and determination of related Significant Financial Interest is delegated to the HMRI Office of Research Protection. A Financial Conflict of Interest exists when the HMRI BPC reasonably determines that the Significant Financial Interest could directly and significantly affect the design, conduct or reporting of the Research.

C. Management of Actual or Apparent Conflicts of Interest

If a Financial Conflict of Interest is identified pursuant to Section 5, prior to the expenditure of award funds or engaging in any Research, the HMRI BPC will develop a proposed management plan specifying the actions that will be taken to manage, reduce or eliminate the Financial Conflict of Interest. The HMRI BPC will provide the proposed management plan to the Covered Individual for input, and then the HMRI BPC will develop and approve a final management plan. If the Covered Individual is not the Principal Investigator, the HMRI BPC may consult with the Principal Investigator on the management plan.

Examples of conditions or restrictions that might be imposed to manage a Financial Conflict of Interest include, but are not limited to:

1. Public disclosure of the Financial Conflict of Interest (e.g., when presenting or publishing the research);
2. For Research projects involving human subjects, 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 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 Conflict of Interest (e.g., sale of an equity interest);
7. Severance of the relationships that create actual or potential Financial Conflict of Interest; or
8. Notification of other individuals involved in the Research.

Determination of the existence of a Financial Conflict of Interest and the means adopted by the HMRI BPC for eliminating or managing the conflict will be communicated in writing to the affected Covered Individual and other appropriate personnel. When applicable, the HMRI Director of the Office of Grants and Contracts will also be notified of pertinent facts needed for grant or contract administration and regulatory compliance.

The HMRI BPC may monitor the Covered Individual's compliance with any management plan implemented pursuant to this section on an ongoing basis until completion of the Research project. The HMRI BPC may delegate this obligation to the HMRI Office of Research Protections.

D. Reports to Sponsors

Prior to grant submission, and prior to expenditure of funds, Grants and Contracts will verify that applicable personnel have submitted a Conflict of Interest disclosure as required by the Sponsor. Grants and Contracts will communicate requirements with the Director, Office of Research Protections (ORP) who will assure review and applicable management of disclosures as applicable to the specific research and Sponsor. The reporting process will generally follow the process described for PHS funded research in Appendix A.

Methodist will make reports to appropriate external sponsors to the extent required by and in accordance with its funding agreement with the sponsor and applicable law and regulation². Reports to PHS will be made in accordance with Appendix A.

E. Record Retention

Records relating to all Covered Individuals' disclosures of Significant Financial Interests related to the Research and Methodist's review of, and response to, such disclosures will be maintained for at least three years from the termination or completion of the Research or for such longer periods as prescribed in any grant or contract, or applicable regulations. Upon authorized request of a sponsoring agency, disclosure documents and related records pertaining to the specific sponsored project will be made available to appropriate officials.

F. Sanctions

All persons subject to this Policy are expected to comply fully and promptly with applicable requirements. Failure to make required disclosures or making incomplete, erroneous or misleading disclosures, failure to comply with prescribed management plans, and other violations of this Policy will be reported to the HMRI BPC and to the President and CEO of HMRI as appropriate.

Possible sanctions to be imposed on the individual may include, but are not limited to: (a) formal admonition; (b) ineligibility to engage in Research; or (c) dismissal.

²For NSF funded research and educational activities, Methodist will keep NSF's Office of General Counsel appropriately informed if Methodist finds that it is unable to satisfactorily manage a conflict of interest.

IV. COUNCILS OR COMMITTEES REVIEWING OR APPROVING PROCEDURE

HMRI Business Practices Committee

V. AUTHORITATIVE REFERENCES

None.

VI. NAME OF APPROVING EXECUTIVE: Mauro Ferrari, Ph.D.
TITLE: President and Chief Executive Officer, HMRI

Signed Original on File

Signature of Approving Executive

Date Signed

Revision History

| Revision | Date | Changed by | Revision Summary |
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APPENDIX A: Additional Provisions Applicable to U.S. Public Health Service (“PHS”) Sponsored Research¹

Research funded by or proposed for funding by the U.S. Public Health Service (PHS), including the National Institutes of Health, is subject to certain requirements imposed by PHS regulations, as amended from time to time (see <http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>). Such research is also subject to the Policy and this Appendix A. To the extent of any conflict between a provision of the Policy and a provision of this Appendix A, the provision of this Appendix A shall govern.

1. Disclosure Obligations

In addition to the obligation to disclose Significant Financial Interests as set forth in Section 4 of the Policy, Covered Individuals who are listed as the PI, Project Director, or other Key Personnel, engaged in PHS funded research also must disclose the occurrence of any reimbursed or sponsored travel, for themselves and their immediate family, related to their Institutional Responsibilities, regardless of the relationship to PHS funding, unless the travel is reimbursed or sponsored by Methodist, 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. The disclosure must include, at a minimum, the purpose of the trip, the identity of the sponsor/organization, the destination, and the duration. Sponsored travel means travel that is paid on behalf of the Covered Individual and not reimbursed to the Covered Individual (so that the exact monetary amount may not be readily determined).

2. Review of Conflicts of Interest

If during the course of an ongoing PHS-funded project (i) a Significant Financial Interest is disclosed by a new Covered Individual, (ii) an existing Covered Individual discloses a Significant Financial Interest not previously reported, or (iii) it comes to the attention of Methodist officials that a Significant Financial Interest related to the PHS-funded research was not disclosed in a timely manner by a Covered Individual, the Significant Financial Interest shall be reviewed pursuant to Section 5 of the Policy within 60 days and a decision shall be made as to whether the Significant Financial Interest constitutes a Financial Conflict of Interest. If the HMRI BPC determines that a Financial Conflict of Interest exists, the HMRI BPC shall implement, on at least an interim basis, a management plan, as set forth in Section 6 of the Policy, that shall specify the actions that have been, or will be taken, to manage the Financial Conflict of Interest.

3. Retrospective Review

Whenever a Financial Conflict of Interest involving PHS-funded research is not identified in a timely manner, including failure by the Covered Individual to disclose a Significant Financial Interest that is determined by the HMRI BPC to constitute a Financial Conflict of Interest, failure by the HMRI BPC to review or by Methodist to manage such a Financial Conflict of Interest, or failure by the Covered Individual to comply with a management plan, the HMRI BPC or its designee shall, within 120 days of his/her determination of noncompliance, complete a retrospective review of the Covered Individual's activity and the PHS-funded research to determine whether any PHS-funded research, or portion thereof, conducted during the time period of noncompliance was biased in design, conduct, or reporting of such research.

The HMRI BPC or its designee will document the retrospective review. Such documentation shall include the following elements: (i) Project/Contract number and title; (ii) principal investigator/project director; (iii) name of the Covered Individual with the Financial Conflict of Interest; (iv) name of entity in which the Covered Individual has a Significant Financial Interest that gives rise to the Financial

Conflict of Interest; (v) reason for the retrospective review; (vi) detailed methodology used for the retrospective review; (vii) findings of the review; and (viii) conclusions of the review.

4. Conflict of Interest Reports to PHS

Prior to Methodist's expenditure of any funds under a PHS-funded research project, Methodist will provide the PHS Awarding Component with a Financial Conflict of Interest Report ("Report") regarding any Significant Financial Interests, including Significant Financial Interests of subrecipient investigators, related to the PHS-funded research that Methodist finds to be a Financial Conflict of Interest and, to the extent required by regulation, will ensure that Methodist has implemented a management plan as set forth in Section 6 of the Policy. In addition, during the course of a PHS-funded research project, Methodist will provide the PHS Awarding Component with a Report within 60 days of identifying any Significant Financial Interest that Methodist identifies as conflicting which was not included in its initial Report.

The Report will contain all elements required by regulation, which may include: (i) Project/Contract number; (ii) principal investigator/project director; (iii) name of the Covered Individual with the Financial Conflict of Interest; (iv) name of entity in which the Covered Individual has a Significant Financial Interest that gives rise to the Financial Conflict of Interest; (v) nature of the financial interest; (vi) value of the financial interest, within dollar ranges, or if the value cannot be readily determined through reference to public prices or other reasonable measures, a statement to that effect; (vii) a description of how the financial interest relates to the PHS-funded research and the basis for Methodist's determination that the financial interest conflicts with such research; and (viii) a description of the key elements of the management plan, including (a) the role and principal duties of the conflicted Covered Individual in the research project, (b) conditions of the management plan, (c) how the management plan is designed to safeguard objectivity in the research project, (d) confirmation of the Covered Individual's agreement to the management plan, (e) how the management plan will be monitored to ensure Covered Individual compliance, and (f) other information as needed.

If a retrospective review is performed as provided for in Section 3 of this Appendix A, previously submitted Reports affected by the review will be updated to specify the actions taken to manage the Financial Conflict of Interest going forward. If the retrospective review finds that the PHS-funded research was biased, Methodist will promptly notify the PHS Awarding Component and submit a mitigation report, which shall include: (i) the key elements documented in the retrospective review; (ii) a description of the impact of the bias on the research project; and (iii) Methodist's plan of action or actions taken to eliminate or mitigate the effect of the bias.

Methodist will submit updated Reports annually to PHS, addressing the status of previously identified Financial Conflicts of Interest and any changes to management plans, including whether the Financial Conflict of Interest is still being managed or, if it no longer exists, an explanation as to why it no longer exists. Reports will be submitted for the duration of the PHS-funded project period.

5. Subawardees and Collaborators

If Methodist carries out PHS-funded research through a subrecipient (e.g., subgrantees, contractors, or collaborators), Methodist will include in its written agreement with the subrecipient a statement as to whether this Policy or that of the subrecipient applies to the subrecipient's investigators.

If the subrecipient's conflicts of interest policy applies to subrecipient investigators, the subrecipient shall certify as part of the agreement that its policy complies with the PHS regulations. If the subrecipient cannot make such a certification, this Policy, including this Appendix A, will apply to subrecipient investigators.

If the subrecipient's conflict of interest policy applies, Methodist will include in the subrecipient agreement time periods for the subrecipient to report all identified Financial Conflicts of Interests to Methodist. Such time periods must provide Methodist with sufficient time to review the reports and make timely reports to PHS, as necessary.

If subrecipient investigators are subject to this Policy, the subrecipient agreement will specify time periods for the subrecipient investigators to submit investigator disclosures of Significant Financial Interests to Methodist so that Methodist has sufficient time to review the disclosures and comply timely with its review, management, and reporting obligations under the Policy and this Appendix A.

6. Public Disclosure of Information

Methodist shall make this Policy available via a publicly accessible website. In addition, Methodist shall provide a written response to a requestor within five business days of the receipt of the HMRI Office of Research Protections of a request for information concerning a Significant Financial Interest held by a Covered Individual if Methodist has determined that the Significant Financial Interest constitutes a Financial Conflict of Interest in PHS-funded research.

If the Department of Health and Human Services 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 a Covered Individual with a Financial Conflict of Interest that was not managed or reported by Methodist as required by this Policy, Methodist will require that the Covered Individual disclose the Financial Conflict of Interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

7. Notification to PHS

Methodist will promptly notify the PHS Awarding Component if failure of a Covered Individual to comply with this Policy or a management plan provided for hereunder has biased the design, conduct or reporting of PHS-funded research.

8. Training

Prior to engaging in PHS-funded research, Covered Individuals will be required to complete training regarding the requirements set forth in this Policy. Training shall be completed every four (4) years, and immediately when any of the following circumstances apply: (i) Methodist revises this Policy in a manner that affects the requirements for Covered Individuals with regard to the Financial Interests of themselves or their Immediate Family Members; (ii) a Covered Individual is new to Methodist; or (iii) Methodist finds that a Covered Individual is not in compliance with this Policy or any management plan implemented hereunder.

¹The term “research” as used in this Appendix A includes any activity for which research funding is available from a PHS Awarding Component, including a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.