

**HUNTINGTON MEMORIAL HOSPITAL
ADMINISTRATIVE POLICY & PROCEDURE
CLINICAL RESEARCH DEPARTMENT**

SUBJECT: Conflict of Interest Disclosure, Consideration, Management, and Reporting	POLICY NO: 1002	PAGE 1 of 3
AUTHORIZED APPROVAL:	EFFECTIVE DATE 8/23/2012	SUPERCEDES/REPLACES 6/01/2012

PURPOSE

This policy describes how Huntington Memorial Hospital (“HMH”) manages conflicts of interest as well as perceived conflicts of interest related to clinical research.

POLICY

It is the responsibility of HMH to require that the financial and other personal interests of research investigators do not directly and significantly affect the protection of human subjects or the design, conduct, review or reporting of research at HMH.

Each investigator’s relevant interests are disclosed prior to consideration of the first research project submitted by an investigator, as well as annually thereafter, and whenever a new interest is acquired that might involve a conflict, or upon any change to a previously disclosed interest that creates or could create a conflict.

DEFINITIONS

See Policy No. 1001, “Clinical Research Definitions,” for definitions of terms used in this policy.

PROCEDURE

- I. Disclosure of Investigators’ Interests
 - A. The potential effect(s) of a financial relationship between a Principal Investigator, Co-Investigator, Sub-Investigator or other person involved in conducting research at HMH and the sponsor of a research project, or any other company that will furnish goods or services for the proposed research project, or a competitor of the sponsor, on the conduct of the research or the rights and welfare of research subjects must be considered.
 - B. HMH shall comply with and shall require HMH’s contracted Institutional Review Board (“IRB”) (the “Contracted IRB”) to comply and assist HMH to comply with applicable research Conflict of Interest laws, including requirements for disclosure of relevant financial and non-financial interests in compliance with United States Food and Drug Administration (“FDA”), Office of Human Research Protections (“OHRP”) and Public Health Service (“PHS”) regulations (collectively, the “COI Regulations”). These interests include financial interests in assets or liabilities; grants, honoraria, retainers or equipment; intellectual property rights or proprietary interests; options or other compensation arrangements; employment or executive relationships; and enrollment bonuses or finder’s fees. Investigators conducting or seeking to conduct research at HMH must make Conflict of Interest disclosures in

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accordance with applicable COI Regulations. Detailed information regarding these disclosures and the related regulatory requirements can be found on the website of HMH's Contracted IRB at www.quorumreview.com [or insert more specific link].

- C. If a new interest or a change to a previously disclosed interest arises at any time during which a research project is under review by the Contracted IRB, the investigator is responsible for disclosing the change to the Contracted IRB.

II. Training

Investigators conducting research at HMH will complete training concerning conflicts of interest in accordance with applicable HMH and Contracted IRB requirements and COI Regulations prior to engaging in research at HMH.

III. Institutional Conflicts of Interest

The Institutional Official and the Clinical Research Committee are responsible for determining and disclosing any institutional financial interests of HMH to the Contracted IRB prior to the consideration of any research that is subject to IRB review and may be affected by such interests.

IV. Management, Posting and Reporting of Conflicts

The HMH Institutional Official will be informed by the Contracted IRB and/or by the affected investigators regarding any actual conflicts of interest relating to research conducted at HMH, and will work with the Contracted IRB to ensure that such conflicts are managed, posted and reported in accordance with applicable requirements.

V. Enforcement

HMH, through its Institutional Official, Compliance Officer, and the Contracted IRB shall promote, monitor and enforce compliance with applicable conflict of interest disclosure, management and reporting requirements. Enforcement will include disciplinary action as and when warranted, which will include appropriate processes, reporting and other documentation

VI. Records

Records shall be maintained of all investigator disclosures of financial and other interests, and the review of and any actions taken in response to such disclosures, regardless of whether or not a disclosure resulted in a determination of a conflict of interest. Such records shall be kept in accordance with applicable COI regulations.

VII. Confidentiality

To the extent permitted by law, disclosure forms, conflict management plans and related information will be kept confidential. However, HMH and/or the Contracted IRB will make such information available when and as required by law, e.g., to the FDA, OHRP,

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PHS, or other agency funding or overseeing research, in which event the affected investigator will be informed of the disclosure. Actual conflicts of interest are subject to public disclosure in accordance with the COI Regulations.