

BRYN MAWR HOSPITAL

LANKENAU MEDICAL CENTER

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LANKENAU INSTITUTE FOR MEDICAL RESEARCH

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**ADMINISTRATIVE POLICY AND PROCEDURE MANUAL**  
**MAIN LINE HOSPITALS INSTITUTIONAL REVIEW BOARD**

Part 1

Policy No. II-B

**Subject: CONFLICTS OF INTEREST: Researchers and Research Staff**

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**I. Policy**

Main Line Hospitals Institutional Review Board (MLH IRB) promotes objectivity in research by ensuring researchers' and research staff's financial conflicts of interest or even the appearance of conflicts of interest are managed, minimized or eliminated when appropriate. The MLH IRB ensures an existing financial conflict of interest does not adversely affect the protection of participants or the integrity of the research.

**Scope**

The policy applies to all researchers and research staff conducting research under the jurisdiction of the MLH IRB regardless of the source of funding. In addition to the requirements outlined in this policy, human subjects research that is sponsored by the Department of Health and Human Services (DHHS) must comply with the Lankenau Institute for Medical Research Financial Conflict of Interest Policy for Public Health Services funded research. Refer to the *Main Line Health Administrative Policy: Conflict of Interest and Confidentiality* for institutional conflicts of interest.

**Definitions**

1. **Researchers and Research Staff**: Includes those individuals involved in the design, conduct or reporting of human subjects research and their *immediate family*<sup>1</sup>. This includes but is not limited to, the Principal Investigators, Co-investigators, study coordinators, staff, nurses and any others involved in the conduct of a research study.
2. **Financial Conflict of Interest (FCOI)**: Means any Significant Financial Interests that could directly and significantly affect the design, conduct, or reporting of research.
3. **Financial Interest**: Means anything of monetary value, whether or not the value is readily ascertainable.
4. **Financial Interests which must be disclosed**: Means any personal, professional, financial or ownership interest or other beneficial interest in the research, sponsor, product or service being tested or held by the researchers or researcher staff including immediate family and may include any of the following interests:

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<sup>1</sup> "Immediate family member" means: spouse and dependent children

- a. Ownership or interest of any value including but not limited to stocks and options (exclusive of interests in a publicly traded, diversified mutual fund).
  - b. Compensation of any value including but not limited to salary, honoraria, paid authorship, consultant fees, royalties, equity or other income.
  - c. Proprietary interest of any value including but not limited to, patents, trademarks, copyrights, licensing agreements or other intellectual property rights and interests.
  - d. Per subject or other recruitment bonuses paid in addition to the negotiated research budget.
  - e. A financial interest or compensation of any value which will be affected by the outcome of the research.
  - f. Serves or has ever served as a board member, executive, employee, consultant, advisor or speaker.
  - g. Any other interest or potential interest that may conflict with your duties in the research and may affect a subject's voluntary and informed choice to participate in the research.
5. **Significant Financial Interest (SFI) means:** A financial interest consisting of one or more of the following that reasonably appears to be related to a specific research study:
- a. With regard to any publicly traded entity, a SFI 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 for the preceding 12 months and immediate family members, exceeds \$10,000. 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 process or other reasonable measures of fair market value.
  - b. With regard to any non-publicly traded entity, a SFI exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated for the preceding 12 months and immediate family members exceeds \$10,000.
  - c. With regard to any non-publicly traded entity, a SFI exists when any equity interest (e.g., stock, stock option, or other ownership interest) is held or;
  - d. Intellectual property rights and interests (e.g. patents, copyrights), upon receipt of income related to such rights and interests.

## **II. Procedure**

- A. Disclosure:** Conflict of Interest (COI) Disclosure Forms are submitted to the Office of Research Affairs when:
- a. Researcher and research staff at the time of submission of a new human subjects research protocol are required to complete a Conflict of Interest Disclosure Form.
  - b. Researcher and research staff with an active human subjects research protocol are required to complete a Conflict of Interest Disclosure Form at least annually at time of Continuing Review submission.
  - c. Researcher and research staff with an active human subjects research protocol must update new significant financial interests within 30 days of changes in financial circumstances (i.e. acquisition or discovery) by providing an updated Conflict of Interest Disclosure Form.
- B. Training:** Researchers and research staff will receive training related to financial conflict of interest at least every four years on-line through the Collaborative Institutional Training Initiative (CITI). Training will be required immediately when:
- a. Financial conflict of interest policies are revised in a manner that changes researcher requirements.

- b. A researcher is new to the organization.
- c. A researcher is non-compliant with financial conflict of interest policies and procedures.

### **Evaluation and Management of Financial Conflicts of Interest**

The Office of Research Affairs will review each COI Disclosure Form received and identify any researcher or research staff who makes a disclosure on the COI Disclosure Form. The Chair of the MLH IRB and Director, Regulatory Affairs or will evaluate those forms which contain a disclosure and will develop a management plan when necessary. If the Chair of the MLH IRB or the Director of Regulatory Affairs declares a conflict, COI Disclosure Form will be referred to the Main Line Hospitals Designated Institutional Official for evaluation.

When an *SFI* appears to be an *FCOI* or any other interest and has the potential to adversely affect the protection of subjects in terms of the criteria for IRB approval or will adversely affect the integrity of the research, it will be referred to the Main Line Health Research COI Committee for further evaluation and development of a management plan.

When an *FCOI* has the potential to adversely affect the protection of participants in terms of the criteria for IRB approval or will adversely affect the integrity of the research a management plan is required. Management strategies may include removing the affected persons from directly engaging in aspects of the trial that could be influenced inappropriately by the *FCOI* including obtaining informed consent, monitoring of study, design of the study, oversight responsibilities, partial or complete divestment. In addition, a determination shall be made whether the research study may be reviewed by the MLH IRB and whether the study may be conducted at Main Line Health. Disclosures alone can not be used to manage *FCOIs* that might affect the protection of participants. *FCOIs* are evaluated and management plans are developed prior to IRB review.

### **Role of the Main Line Hospitals IRB**

Management plans are provided to the Office of Research Affairs and presented to the MLH IRB at the time of review. The MLH IRB has the final authority to determine whether the research may be approved.

The MLH IRB and the Office of Research Affairs are responsible for implementing and monitoring the management plan. Researchers and research staff will be required to submit an annual report describing compliance with their Management Plan. Annual reports will be reviewed by the MLH IRB Chair and Director, Regulatory Affairs. Deviations from the Management Plan will be handled under the policy on *Noncompliance, Part 1, Policy XXV*.

### **Record Keeping**

Conflict of Interest Disclosure Forms, Management Plans related to human subjects research, and related documents will be maintained in the Office of Research Affairs. Records will be maintained for a minimum of three years after completion of the research (refer to the MLH Records Management (Retention and Destruction) Policy No. I.96).

### **Regulatory References**

FDA Regulations: 21 CFR 54 Financial Disclosure by Clinical Investigators

### **Revision Date**

04/09/14