



The Brooklyn Hospital Center

*Keeping Brooklyn healthy.*

## **THE BROOKLYN HOSPITAL CENTER POLICY AND PROCEDURE MANUAL**

### **SUBJECT:**

Research Financial Conflicts Of Interest, Policy # C-195

### **RESPONSIBILITY:**

Designated Institutional Official

### **POLICY:**

The purpose of this policy is to assure that all financial conflicts of interest that directly affect research are managed, reduced, or eliminated in accordance with standards for objectivity in research of the U.S. Public Health Service.

### **DEFINITIONS:**

“Financial conflict of interest” – A significant financial interest in an entity other than TBHC that could directly and significantly affect the design, conduct, or reporting of research at TBHC

“Institutional Responsibilities” – An Investigator’s professional responsibilities on behalf of TBHC, including research, research consultation, teaching, professional practice, services on Hospital committees, or service on the Institutional Review Board

“Significant financial interest” – A financial interest in or relationship with an entity other than TBHC by an Investigator or his/her Family Member consisting of one or more of the following if it reasonably appears to be related to the Investigator’s Institutional Responsibilities:

- Annual remuneration exceeding \$5,000, including salary, consulting fees, honoraria, or paid authorships
- Stock ownership or other equity interest except through a mutual fund, retirement account, or other similar instrument where the investment decisions are not under the direct control of the Investigator or his Family Members
- Intellectual property rights and interests, upon receipt of income
- Any reimbursed or sponsored travel regardless of value

“Investigator” – Any person regardless of title or position who is responsible for the design, conduct, or reporting of research at TBHC, including collaborators or consultants.

“Family Members” – Investigator’s spouse and dependent children

## **PROCEDURES:**

### **Investigators**

Each Investigator engaged in research at TBHC will be informed of this policy, and of his or her responsibilities regarding disclosure of significant financial interests. Each Investigator will be required to complete training regarding this policy prior to engaging in research and at least every four years. The Designated Institutional Official (DIO) will ensure that Investigators are appropriately trained on this policy.

If TBHC carries out PHS-funded research through a subcontractor or a consortium, the DIO will ensure that sub-recipient Investigators comply with this policy and with related HHS regulations.

As part of the research protocol submission process, all Investigators will submit a Research Conflict of Interest disclosure form disclosing any significant financial interest as defined in this policy. Disclosures of reimbursed or sponsored travel will include the purpose of the trip, the identity of the sponsor or organizer, the destination, and the duration of the trip. Investigators will also submit updated disclosures of significant financial interests on an annual basis during the course of a research protocol.

If in the course of an ongoing research project an Investigator develops a new significant financial interest, he or she will submit an updated Research Conflict of Interest disclosure form within 30 days of acquiring the interest. The DIO or his/her designee will, within 60 days, review the disclosure in accordance with the procedures outlined below.

The DIO or his/her designee will review all disclosures and determine whether a financial conflict of interest exists, that is, whether the significant financial interest could directly and significantly affect the design, conduct, or reporting of research. If the DIO determines that a financial conflict of interest exists, he or she will develop and implement a management plan specifying the actions that shall be taken to manage the conflict. This may include public disclosure of the conflict when publishing or presenting the research; disclosure directly to research subjects; appointment of an independent monitor to protect the design, conduct and reporting of the research against bias; modification of the research plan; change of personnel or disqualification of personnel from participation in all or part of the research; or elimination of the financial interest. The DIO will monitor the Investigator’s compliance with the management plan until the completion of the research project.

If a significant financial interest of an Investigator is identified that was not disclosed or was not reviewed by the Hospital at the time of the protocol submission, the DIO or

his/her designee will within 60 days review the relationships as outlined above. In addition, within 120 days the IRB will perform a retrospective review of the Investigator's activities to determine whether any research was biased in design, conduct, or reporting. The review will be documented, including the project number; project title, Principal Investigator, name of the Investigator with the financial conflict of interest; name of the entity involved in the conflict; reason for the review; methodology used for the review; findings and conclusion. If bias is found, the Hospital will notify the Public Health Service or other funding entity promptly and submit a mitigation report which will include the elements documented in the review as above; a description of the impact of the bias on the research; the Hospital's plan of action to mitigate the effect of the bias; extent of harm done; and any additional measures taken.

Any Investigator who fails to comply with this policy, or who submits inaccurate disclosure reports, will be subject to disciplinary action by the Hospital, up to and including termination of employment or termination of privileges in accordance with medical staff by-laws.

Information concerning all Investigators' conflicts of interest will be posted on the TBHC public website. The information posted will include the Investigator's name, title, and role in the research, the name of the entity in which the significant financial interest is held, and the nature and approximate dollar value of the interest. This information shall be updated at least annually, or within 60 days of any additional information regarding the Investigator, until the completion of the research project.

This policy will be made available to the public on the TBHC website. If the policy is amended, the website will be updated within 30 days of the policy being signed.

The IRB Coordinator will maintain records of all disclosures of financial interests of Investigators, and records of the response to the disclosure, for at least three years.

### **IRB Members**

All IRB members will complete an annual Conflict of Interest questionnaire in accordance with the Hospital's Conflict of Interest policy (#C-111). If an apparent conflict is identified, the VP Audit and Compliance will inform the DIO and the Chairman of the IRB, who will determine how the potential conflict should be managed. At a minimum, the IRB member must abstain from discussing, voting on, or monitoring any research project related to the company with which he or she has a financial interest. It is the responsibility of the IRB member to inform the IRB Coordinator and the VP Audit and Compliance throughout the year of any new information that may create a potential conflict.

No member of the IRB may participate in the initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

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President and CEO

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Designated Institutional Official (DIO)

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VP Audit and Compliance

Effective 4/1/02  
Reviewed/Revised 2/3/2012