

“Investigator” – Any person regardless of title or position who is responsible for the design, conduct, or reporting of research

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 withh ed .15 Td [(anh)-1(u(B)-6(,)11(e)-17-7(an)e)1(pot

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.

President and CEO

Designated Institutional Official (DIO)

VP Audit and Compliance

Effective 4/1/02

Reviewed/Revised 2/3/2012