MARKHAM STOUFFVILLE HOSPITAL CORPORATION	**Conflict of Interest for Research**
Location: Administration Manual\Research	Version: 1
Document Owner: Director Medical Administration and Family Medicine	Original Approval Date: 8/13/2018 3:30:21 PM
Electronic Approval: Director Medical Administration and Family Medicine	Approved Date: 8/14/2018 7:13:14 AM
Review Frequency: 2 Years	Next Review Date: 2/1/2020

PURPOSE AND SCOPE:
The purpose of this policy is to describe the potential Conflicts of Interest (COI) for Research Ethics Board (REB) members, researchers and research staff engaged in human participant research at Markham Stouffville Hospital (MSH), and the requirements and procedures for disclosure and managing COI.

This policy applies to REBs, researchers and research staff that review or engage in human participant research in compliance with applicable regulations and guidelines.

POLICY STATEMENT(S):
Researchers and research staff should identify and manage COI to maintain the public confidence and trust and to maintain the independence and integrity of the research process. If a COI cannot be avoided, procedures should be in place to manage and/or to mitigate the conflict.

This policy is not intended to prohibit researcher relationships with companies; however, the REB should ensure that participant protection, the integrity of the ethics review, and the conduct of the research are not jeopardized by an unidentified and unmanaged COI.

REBs should identify and manage COI to maintain the public confidence and trust and to maintain the independence and integrity of the ethics review. If a COI cannot be avoided, procedures should be in place to mitigate the conflict.

The REB must be perceived to be fair and impartial, immune from pressure either by the sponsor, affiliated organizations or the researchers whose research is being reviewed, or by other professional and/or nonprofessional sources.

The standard that guides decisions about determining COI is whether an independent observer could reasonably question whether the individual’s actions or decisions are based on factors other than the rights, welfare and safety of the participants.

PROCEDURE:

1. **REB Committee Disclosure of Conflicts of Interest**

a. At the outset of each REB meeting, members are reminded of their obligation to orally disclose/declare any real, potential or perceived COI. All declared COI will be recorded in the REB meeting minutes
b. If a COI is declared and determined as such, the REB member may be asked to provide information about the research, but must be recused for the deliberation and decision
c. If recused, the REB member should abstain from voting on/approving the minutes of that meeting
d. The REB Chair or designee will assess projects undergoing the delegated review process to determine potential COI
e. REB members involved in the delegated review process are expected to disclose any conflicting interests
f. If a COI is identified, the project is assigned to another REB member
g. In the event that the REB Chair declares a COI, the Vice-Chair or alternate REB member will assume the REB Chair's responsibilities for the specific project(s)
h. All Office of Research staff are expected to disclose any conflicts that arise and any Office of Research staff whose job status or compensation is impacted by research that is reviewed by the REB must recuse themselves when such research is reviewed
i. Any disclosure of a COI by Office of Research staff should be referred to the REB Chair or designee for the development of a management plan
j. If Office of Research staff is unclear as to whether a COI exists, they must contact the REB Chair or designee to seek clarification. The REB Chair or designee will determine whether the circumstances should be defined as a COI

2. Researcher Disclosure of Conflicts of Interest

a. Researchers submitting research applications to the REB are required to declare any COI
b. The researcher is additionally required to provide information on the clinical trial budget, as applicable, when submitting a research application
c. Such disclosures shall be in writing and sufficiently detailed to allow accurate and objective evaluation of conflict
d. The researcher shall disclose any conflicts to the REB at the following times:
    - With the initial REB application
    - At each continuing review of the project
    - Whenever a COI arises, such as changes in responsibilities or financial circumstances
e. The researcher shall cooperate with the REB and with other officials involved in the review of the pertinent facts and circumstances regarding any COI disclosed, and shall comply with all the requirements of the REB and MSH COI policies to eliminate and/or to manage the conflict
f. The researcher shall ensure that all requirements from any COI reviews are appropriately incorporated into the corresponding informed consent documents and research, as applicable.

3. **REB Review of Researcher Conflict of Interest**
    a. The REB will review each application for disclosure of COI
    b. If the researcher indicates on the REB application that a conflict exists, the REB will determine whether the disclosed COI is likely to affect or appear to affect the design, conduct, or reporting of the research
    c. The REB review shall focus on those aspects of the COI that may reasonably affect human participant protection and the steps taken should be context-based and commensurate with the risks
    d. In determining the appropriate action, the REB may take into consideration information presented by the researcher such as:
        - The nature of the research
        - The magnitude of the interest or the degree to which the conflict is related to the research
        - The extent to which the interest could affect the research
        - Whether a specific individual is unique in his/her clinical or scientific qualifications to conduct the research
        - The degree of risk to the human participants involved in the research that is inherent in the research, and/or
        - The management plan for the COI already developed by the researcher
    e. The REB may approve the research and may require a management plan, which may include changes at the researcher's or sponsor's expense, to eliminate or to mitigate the conflict.
    f. The REB has the final authority to determine whether a COI has been eliminated or managed appropriately
    g. Any COI management plan will be documented in the final project files. Any discussions at the REB meeting regarding the COI and the management plan will be documented in the REB meeting minutes
    h. After review by the REB and input by the appropriate MSH Administration, if applicable, the REB may reject research that involves a COI that cannot be appropriately managed.

DEFINITION(S):

Conflict of Interest (COI): Real, potential or perceived COI arise when an individual in a position of trust has competing professional or personal interests. Such competing interests may influence his or her professional judgment, objectivity and independence and can potentially influence the outcome of a decision, for personal benefit. A COI may exist even if no unethical or improper act results from the conflict.

REFERENCE(S):

1. CAREB-ACCER N2 Canadian REB SOPs – Version II (https://www.careb-accer.org/n2careb-accer-reb-sops)
2. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans. www.pre.ethics.gc.ca

3. International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use: Guideline for Good Clinical Practice. www.ich.org
4. The Personal Health Information Protection Act. www.ipc.on.ca

RELATED DOCUMENTS:

1. Research Ethics Board Declaration of Conflict of Interest Form for Researchers

RESPONSIBILITY:

Required Endorsements	Sponsor	Approval Authority
	Manager, Office of Research	Research Ethics Board (REB)

DOCUMENT HISTORY:

Type	Individual/Committee	Date	Outcome
Draft	Research Ethics Board	13/08/2018	New Document; Approved

APPENDICES:

Not Applicable.