Holland Bloorview Kids Rehabilitation Hospital Research Ethics Board (REB) Standard Operating Procedures

Holland Blcorview
Kids Rehabilitation Hospital

| | GENERAL ADMINISTRATION | | |
|--------------------------|--|------------------|-----------------|
| POLICY: REB-106 | DISCLOSURE AND DOCUMENTATION OF CONFLICTS OF INTEREST | | |
| This policy pertains to: | REB staff and members of the Holland Bloorview Research Ethics Board (REB) | | |
| Responsibility for | Chair, Holland Bloorview REB (or designate) | | |
| executing this policy: | | | |
| Approval authority: | Research. Teaching & Learning Advisory Committee (RTLAC) of the Holland | | |
| | Bloorview Board of Trustees | | |
| Effective date: | September 30, 2014 | Supersedes | V3: August 2013 |
| | | documents dated: | _ |
| Approved: | Chair of the REB | | |
| | Research, Teaching & Learning Advisory Committee | | |
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1. PURPOSE REFERENCES

The purpose of this SOP is to address the risk of possible conflict of interest (COI) for REB members, REB Chair, and REB Office staff and extends to consultants who are not REB members but may be asked to review a project because of their expertise.

2. POLICY STATEMENT

In the environment of research, openness and honesty are indicators of integrity and responsibility, characteristics that promote quality research and can only strengthen the research process. Therefore, conflicts should be eliminated when possible. The REB must have procedures in place to declare and manage conflicts of interest situations that could influence its mandate, operations, and/or jurisdiction. A record of management and disclosure will be produced for reference for legal and inspection purposes.

CAN/CGSB-191.1-2013 – (4.2.2.6)

A conflict of interest may arise when activities or situations place an REB member in a real, potential or perceived conflict between the duties or responsibilities related to research, and personal, institutional or other interests. These interests include, but are not limited to, business, commercial or financial interests pertaining to the individual, their family members, friends, or their former, current or prospective professional associates. REB members shall be knowledgeable about the conflicts of interest which may arise in ethics reviews and about the relevant policies and procedures of the REB and Holland Bloorview/Bloorview Research Institute. A conflict of interest does not necessarily imply wrongdoing, as a conflict of interest depends upon the circumstances, and not on the character of the REB member.

Tri-agency Framework: Responsible Conduct of Research, Article 2.1 and TCPS2, Chapter 7

CAN/CGSB-191.1-2013 – (4.3.2.8)

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3. SPECIFIC POLICIES

3.1. COI for REB Members

REB members are in conflict of interest when

- a. their own research projects are under review by their REB;
- b. they are co investigators of a research project under review by their REB;
- c. they are in a supervisory relationship with a studentwhose application is under REB review;
- d. they have an interpersonal or financial relationship with the researchers;
- e. they have personal or financial interest in a company, labour union or non-for-profit organization that may be the sponsor of the research project;
- f. they may be substantially affected by the research.

When reviewing research proposals, REB members shall disclose real, potential or perceived conflicts of interest to the REB in writing. When necessary, the REB may decide that those member(s) must withdraw from REB deliberations and decisions and this is recorded in the meeting minutes that outline the assessment and impact of the COI.

If an REB is reviewing research in which a member of the REB has a personal or financial interest (e.g., as a researcher or as an entrepreneur) the REB member must disclose the nature of the conflict of interest and absent themselves from any REB deliberations and decision making regarding that research project. In the event that a member's conflict of interest and necessary withdrawal from the meeting will threaten the maintenance of quorum, the REB must ensure that a substitute member be in attendance to maintain quorum.

3.2. Disclosure and Documentation of COI

No regular or alternate REB member may participate in the initial or continuing review of any research project or protocol, in which the member has a conflict of interest (COI), except to provide information as requested.

It is the responsibility of each voting member of the REB to disclose any COI in a study submitted to the REB. The REB member shall be excluded when the REB discusses its decisions, reaches a consensus or votes on an application, except as requested to provide information.

CAN/CGSB-191.1-2013 – (4.3.2.8 (a))

CAN/CGSB-191.1-2013 – (4.4.4.4.9)

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TCPS2, Chapter 7 and specifically Article 7.3

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The procedures for recusal of REB members, including the Chair, from deliberating/voting on any protocols for which there is a potential or actual conflict of interest are detailed in REB minutes.

When in doubt as to whether a conflict of interest exists, the REB member shall disclose the situation to the Chair of the REB (or designate). The REB Chair, in consultation with other REB members, has the authority to determine when a COI exists as defined by this policy. The REB member must abide by the REB Chair's decision regarding any actions required to mitigate his or her real or perceived conflict of interest.

3.3. Employees

Holland Bloorview staff whose job status or compensation is impacted by research that is reviewed by the REB must excuse themselves from any meeting at which such a protocol is reviewed. Any case of disclosure of a COI by staff shall be referred to the REB Chair for development of a management plan. In the case of the Chair having a conflict of interest, the matter will be referred to the REB Vice-Chair or designate for development of a management plan.

3.4. Researchers

Matters pertaining to possible conflicts of interest by researchers are referred to the Bloorview Research Institute Policies and Procedures Regarding Conflict of Interest and the Tri-agency Framework: Responsible Conduct of Research.

Researchers must disclose on the TAHSN application form the existence of any potential, actual or perceived COI.

3.5. Education and training in COI

REB members and REB Office staff are required to participate in education and training activities related to conflict of interest issues as required by Holland Bloorview.

Revision History

V3/August 2013: Changed 'REB Manager' to 'REB office staff' to accommodate growth and job title changes within the REB administrative office.

V4/July 2014: CAN/CGSB-191.1-2013 references incorporated to reflect compliance. Changed Research Advisory Committee to Research, Teaching & Learning Advisory Committee. Revised section 2.: clarified that the REB must have procedures in place to declare and manage COI. Clarified that REB members must be knowledgeable about types and potential for COI and applicable policies. Revised section 3.2: clarified that REB members with COI will be excluded from discussions and deliberations. Clarified the REB chair's role and authority in managing COI.

CAN/CGSB-191.1-2013 – (4.3.2.8 (b))

Tri-agency Framework: Responsible Conduct of Research (http://www.rcr.ethics.gc.ca /eng/policypolitique/framework-cadre/) Bloorview Research Institute Policy and Procedure: Conflict of Interest BRI-00086 CAN/CGSB-191.1-2013 – (4.4.3.2 (I))

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