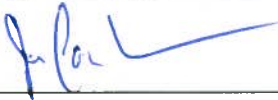




Section 100:	General Administration
Title:	Conflict of Interest: Researcher
SOP Code:	105.001B
Effective Date:	2015MAY25

Site Approvals

Signature of Responsible Individual:		
Ethics Compliance Advisor		2015MAY22 Date
	Name: Jennifer Couture	
Approval Authority:		
Chair, HSREB		May 22, 2015 Date
	Name: Dr. Albert Clark	
Approval Authority:		
Director, Research Ethics Compliance		May 22, 2015 Date
	Name: Dr. Andrew Winterborn	

1.0 PURPOSE

This SOP describes potential COI for Researchers and research staff engaged in human participant research, and the requirements and procedures for disclosure and managing COI.

2.0 SCOPE

This SOP pertains to the HSREB that reviews human participant research in compliance with applicable regulations, guidelines and current and emerging best practices.

3.0 RESPONSIBILITIES

All HSREB members, HSREB Office Personnel and Researchers are responsible for ensuring that the requirements of this SOP are met.

Researchers are responsible for disclosing any real, potential or perceived COI to the HSREB.

The HSREB is responsible for determining whether the disclosed COI is likely to affect or appear to affect the design, conduct, or reporting of the research.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURES

A COI (real, potential or perceived) may arise when an individual is placed in a situation where his or her professional, personal or financial interests conflict with their responsibilities to the HSREB. The most common type of COI occurs when an individual is directly involved in a research project that has been submitted for HSREB review, in which they are directly involved or have a friend/colleague involved in the research. COI may also be an issue if an individual has a financial interest in the research project or a relationship with a funder or sponsor. Such competing interests may influence his or her professional judgment, objectivity and independence and can potentially influence the outcome of a HSREB decision, for personal benefit. A COI may exist even if no unethical or improper act results from the conflict.

For the purposes of this Policy, immediate family member means a spouse, partner, parent, child or sibling, as defined by the Queen's University Conflict of Interest and Conflict of Commitment Policy (Faculty) (Appendix 1).

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 SOP is not intended to prohibit Researcher relationships with companies; however, the HSREB 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.

The HSREB should identify and manage COI to maintain the confidence and trust of the public, the institution, researchers and colleagues, 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 HSREB must be perceived to be fair and impartial, immune from pressure either by the sponsor, Queen's University and Affiliated Teaching Hospitals 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.

5.1 Researcher Disclosure of Conflicts of Interest

- 5.1.1 Researchers submitting research applications to the HSREB are required to declare any COI including those of his/her sub/co-Researcher(s), research staff, and their immediate families;
- 5.1.2 The Researcher is additionally required to provide information on the clinical trial budget, as applicable, when submitting a research application;
- 5.1.3 Such disclosures shall be in writing and sufficiently detailed to allow accurate and objective evaluation of conflict;
- 5.1.4 The Researcher shall disclose any conflicts to the HSREB at the following times:
 - a) With the initial HSREB application,
 - b) At each renewal review of the project,
 - c) Whenever a COI arises, such as changes in responsibilities or financial circumstances;
- 5.1.5 The Researcher shall cooperate with the HSREB and with other University or Affiliated Teaching Hospital Official(s) involved in the review of the pertinent facts and circumstances regarding any COI disclosed, and shall comply with all the requirements of the HSREB and with any Queen's University and Affiliated Teaching Hospitals COI policies. This may include, but is not limited to the Queen's University Conflict of Interest and Conflict of Commitment Policy (Faculty) (Appendix 1), Human Resources Conflict of Interest and Conflict of Commitment Policy (Appendix 2), Faculty of Health Sciences Conflict of Interest in Interactions with Industry Policy, Queen's University (Draft 2014SEP) (Appendix 3), The Monieson Centre - Policy on Authorship and Co-authorship December 2010 (Appendix 4), The Southeastern Ontario Academic Medical Organization (SEAMO) Conflict of Commitment Policy (Appendix 5), Hotel Dieu Hospital Health Ethics Guide and Values booklet (Appendix 6), KGH Conflict of Interest Provisions for Directors and Members (2014FEB) (Appendix 7), to eliminate and/or to manage the conflict;
- 5.1.6 The Researcher shall ensure that all requirements from any COI reviews are appropriately incorporated into the corresponding informed consent documents and research, as applicable.

5.2 HSREB Review of Researcher Conflict of Interest

- 5.2.1 The HSREB will review each application for disclosure of COI;
- 5.2.2 If the Researcher indicates on the HSREB application that a conflict exists, the HSREB will determine whether the disclosed COI is likely to affect or appear to affect the design, conduct, or reporting of the research;

- 5.2.3 The HSREB 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;
- 5.2.4 In determining the appropriate action, the HSREB 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;
- 5.3 The HSREB may grant ethical clearance for the research, however they may require that the researcher submit a plan to the HSREB to manage the COI, which may include changes at the Researcher's or sponsor's expense, to eliminate or to mitigate the conflict. Required actions may include, but are not limited to:
- Divestiture or termination of relevant economic interests,
 - Mandating Researcher recusal from research,
 - Modifying or limiting the participation of the Researcher in all or in a portion of the research,
 - In cases involving equity, by imposing a bar on insider trading or requiring the transfer of securities to an independent financial manager or blind trust, or limited the timing of sales or distributions,
 - Monitoring research (i.e., independent review of data and other retrospective review for bias, objectivity, comprehensiveness of reporting (versus withholding data)),
 - Independent clinical review of appropriateness of clinical care given to research participants, if applicable,
 - Monitoring the consent process, and/or
 - Disclosure of the conflict to organizational committees, research participants, journals, and the data safety monitoring boards,
 - The HSREB has the final authority to determine whether a COI has been eliminated or managed appropriately;
- 5.3.1 Any COI management plan will be documented in the research ethic file. Any discussions at the HSREB meeting regarding the COI

and the management plan will be documented in the HSREB meeting minutes;

- 5.3.2 After review by the HSREB and input by the appropriate Queen's University and/or Affiliated Teaching Hospital Official(s), if applicable, the HSREB may reject research that involves a COI that cannot be appropriately managed.

6.0 REFERENCES

See References.

7.0 APPENDICES

1. Queen's University Conflict of Interest and Conflict of Commitment Policy (Faculty):
<http://www.queensu.ca/secretariat/policies/senateandtrustees/conflict.html>
2. Human Resources Conflict of Interest and Conflict of Commitment Policy:
<http://www.queensu.ca/humanresources/policies/workplaceissues/conflictointerest.html>
3. Faculty of Health Sciences Conflict of Interest in Interactions with Industry Policy, Queen's University (Draft 2014SEP)
http://meds.queensu.ca/somac/assets/oct2014final_draft_fhs_coi_sept_24_2014.pdf
4. The Monieson Centre - Policy on Authorship and Co-authorship December 2010:
http://business.queensu.ca/ConversionDocs/Monieson/Policy_on_Authorship_and_Co-authorship_December_2010.pdf
5. The Southeastern Ontario Academic Medical Organization (SEAMO) Conflict of Commitment Policy:
http://www.seamo.ca/assets/Conflict_of_Commitment_Policy_-_final_24_June_2014.pdf
6. Hotel Dieu Hospital Health Ethics Guide and Values booklet (Hard copy)
7. KGH Conflict of Interest Provisions for Directors and Members (2014FEB) (Hard copy)

8.0 REVISION HISTORY

SOP Title	Version	Updates
Conflict of Interest: Researcher	v.105.001B 2015MAY25	Original: Adoption of standardized SOPs developed by CAREB/N2 with an effective date of 2014SEP15. Minor modifications were made to the CAREB/N2 SOPs to reflect institutional policies.

