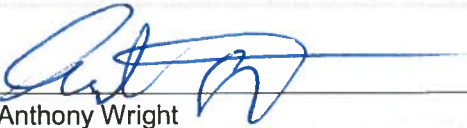
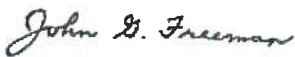
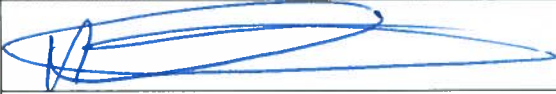


Section 100:	General Administration
Title:	Conflicts of Interest (COI): Researchers
SOP Code:	105.001B
Effective Date:	2016FEB08

Site Approvals

Signature of Responsible Individual:		
Ethics Compliance Advisor		Date: 2016FEB08
	Name: Anthony Wright	
Approval Authority:		
Chair, GREB		Date: 2016FEB08
	Name: Dr. John Freeman	
Approval Authority:		
Director, Research Ethics Compliance		Date: 2016FEB08
	Name: Dr. Andrew Winterborn	

1.0 PURPOSE

This SOP describes potential Conflicts of Interest (COI) for researchers and research staff engaged in human participant research, and the requirements and procedures for disclosure and management of such COI.

2.0 SCOPE

The scope of this SOP is restricted to the review of the ethical conduct of research involving humans that falls under GREB's oversight. GREB primarily has research ethics oversight over Humanities, Social Sciences, Science, Engineering, and administrative research conducted under the auspice of Queen's University. The scope

of GREB's oversight is limited to those activities defined in the TCPS2 (2014) as "research" involving "human participants."

3.0 RESPONSIBILITIES

All GREB members, GREB 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 GREB.

GREB is responsible for determining whether or not 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

Conflict of Interest (COI) is defined as: the incompatibility of two or more duties, responsibilities, or interests (personal or professional) of an individual or institution as they relate to the ethical conduct of research, such that one cannot be fulfilled without compromising another (TCPS2, 2014).

A COI (real, potential, or perceived) may arise when individuals are placed in a situation where their professional, personal, or financial interests conflict with their responsibilities to GREB. The most common type of COI occurs when individuals are directly involved in a research project that has been submitted for GREB review or have a friend/colleague involved in the research. COI may also be an issue if individuals have a financial interest in the research project or a relationship with a funder or sponsor. Such competing interests may influence their professional judgment, objectivity, and

independence and can potentially influence the outcome of a GREB decision for personal benefit. A COI may exist even if no unethical or improper act results from the conflict. More information is available in Chapter 7 of TCPS2.

Researchers and research staff should identify and manage COI to maintain the public confidence and trust, and 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, GREB 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.

GREB must be perceived to be fair and impartial, immune from pressure by the sponsor, Queen's University, the researchers whose research is being reviewed, or other professional and/or non-professional sources. GREB 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.

The standard that guides decisions about determining COI is whether or not an independent observer could reasonably question that 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 GREB are required to declare any COI including those of any researcher or sub/co-researcher(s), research staff, and their immediate families;
- 5.1.2 Researchers are additionally required to provide information on the 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 Researchers shall disclose any conflicts to GREB at the following times:

- a) With the initial GREB 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 Researchers shall cooperate with GREB and other university official(s) involved in the review of the pertinent facts and circumstances regarding any COI disclosed, and shall comply with all the requirements of GREB and with any other Queen's policies. Policies to eliminate and/or to manage the conflict may include, but are not limited to, the QUFA-Queen's Collective Agreement (August 21, 2015 - April 30, 2019; Appendix 1), Queen's University Conflict of Interest and Conflict of Commitment Policy (Faculty; Appendix 2), Human Resources Conflict of Interest and Conflict of Commitment Policy (Appendix 3), and the Monieson Centre - Policy on Authorship and Co-authorship December 2010 (Appendix 4);

5.1.6 Researchers shall ensure that all requirements from any COI reviews are appropriately incorporated into the corresponding informed consent documents and research, as applicable.

5.2 GREB Review of Researcher Conflict of Interest

5.2.1 GREB will review each application for disclosure of COI;

5.2.2 If a researcher indicates on the GREB application that a conflict exists, GREB will determine whether or not the disclosed COI is likely to affect or appear to affect the design, conduct, or reporting of the research;

5.2.3 GREB review shall focus on those aspects of the COI that may reasonably affect human participant protection; the steps taken should be context-based and commensurate with the risks as per Chapter 7 of TCPS2;

5.2.4 In determining the appropriate action, GREB may take into consideration information presented by the researcher such as:

- a) The nature of the research,

- b) The magnitude of the interest or the degree to which the conflict is related to the research,
- c) The extent to which the interest could affect the research,
- d) Whether or not a specific individual is unique in clinical or scientific qualifications to conduct the research,
- e) The degree of risk to the human participants involved in the research that is inherent in the research, and/or
- f) The management plan for the COI already developed by the researcher;

5.2.5 GREB may grant ethical clearance for the research; however, it may require that the researcher submit a plan to GREB 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:

- a) Divestiture or termination of relevant economic interests,
- b) Mandated researcher recusal from research,
- c) Modification or limitation of the participation of the researcher in all or in a portion of the research,
- d) In cases involving equity, imposition of a bar on insider trading or requirement that securities be transferred to an independent financial manager or blind trust, or limitations on the timing of sales or distributions,
- e) Monitoring of research (i.e., independent review of data and other retrospective review for bias, objectivity, comprehensiveness of reporting [versus withholding data]),
- f) Monitoring of the consent process, and/or
- g) Disclosure of the conflict to organizational committees, research participants, and journals;

5.4.6 GREB has the final authority to determine whether or not a COI has been eliminated or managed appropriately;

- 5.4.7 Any COI management plan will be documented in the research ethic file. Any discussions at the GREB meeting regarding the COI and the management plan will be documented in the GREB meeting minutes;
- 5.4.8 After review by GREB and input by appropriate Queen's University official(s), if applicable, GREB may reject research that involves a COI that cannot be appropriately managed.

6.0 REFERENCES

See References.

7.0 APPENDICES

1. Collective Agreement (Faculty, Librarians and Archivists) Between Queen's University Faculty Association (QUFA) and Queen's University at Kingston (August 21, 2015 - April 30, 2019):
<http://www.queensu.ca/facultyrelations/sites/webpublish.queensu.ca/files/files/CA%202015-19%20with%20changes%20marked%20and%20compensation%20added.pdf>
2. Queen's University Conflict of Interest and Conflict of Commitment Policy (Faculty):
<http://www.queensu.ca/secretariat/policies/senateandtrustees/conflict.html>
3. Human Resources Conflict of Interest and Conflict of Commitment Policy:
<http://www.queensu.ca/humanresources/policies/workplaceissues/conflictofinterest.html>
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

8.0 REVISION HISTORY

SOP Title	Version	Updates
Conflict of Interest: Researcher	v.105.001B 2016FEB08	Original: This SOP was developed based on information from the TCPS2 (2014) and Queen's University previous documents or policies (using the format of CAREB/N2).

