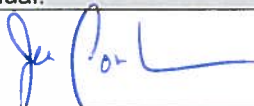




<b>Section 100:</b>	<b>General Administration</b>
<b>Title:</b>	<b>Conflict of Interest: Queen's University</b>
<b>SOP Code:</b>	<b>105.001C</b>
<b>Effective Date:</b>	<b>2015MAY25</b>

### Site Approvals

Signature of Responsible Individual:		
Ethics Compliance Advisor		2015MAY22
	Name: Jennifer Couture	Date
Approval Authority:		
Chair, HSREB		May 22, 2015
	Name: Dr. Albert Clark	Date
Approval Authority:		
Director, Research Ethics Compliance		May 23, 2015
	Name: Dr. Andrew Winterborn	Date

## 1.0 PURPOSE

This SOP describes potential COI in the relationship between Queen's University and Affiliated Teaching Hospitals in establishing the HSREB and the HSREB itself, and the requirements and procedures for disclosure and for managing potential COI within this relationship.

## 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 and HSREB Office Personnel are responsible for ensuring that the requirements of this SOP are met.

## 4.0 DEFINITIONS

See Glossary of Terms.

## 5.0 PROCEDURES

Queen's University's, Affiliated Teaching Hospitals, and other applicable COI policies (referenced in SOP 105B Conflicts of Interest Researchers) and the HSREB COI SOPs 105A Conflicts of Interest HSREB Members and Office Personnel and 105B Conflicts of Interest Researchers should address the roles, responsibilities and process for identifying, eliminating, minimizing or otherwise managing COI relevant to research, including disclosure to the HSREB. Management of COI includes, but is not limited to, prevention, evaluation, disclosure and the application of appropriate remedies as defined by Queen's University.

The HSREB must be fair and impartial, immune from pressure by the sponsor, Queen's University and Affiliated Teaching Hospitals and the Researchers whose research is submitted for review. In the interest of public trust and the integrity of the ethics review, the HSREB must act independently from Queen's University and Affiliated Teaching Hospitals, and avoid or manage real or apparent COI. Queen's University and Affiliated Teaching Hospitals must respect the autonomy of the HSREB and ensure that the HSREB has the appropriate financial and administrative independence to fulfill its primary duties.

The standard that should guide decisions about determining conflicting interests is whether an independent observer could reasonably question whether the HSREB actions or decisions could be based on factors other than the rights, welfare, and safety of the research participants.

### 5.1 Disclosure of COI

- 5.1.1 All Queen's University employees should be familiar with the Queen's University's, Affiliated Teaching Hospitals, and other applicable COI policies (referenced in SOP 105B Conflicts of Interest Researchers) and the HSREB COI SOPs 105A Conflicts of Interest HSREB Members and Office Personnel and 105B Conflicts of Interest Researchers;
- 5.1.2 Prior to engaging in any of the professional activities outlined in the COI policies and SOPs, employees should seek the approval of the Director of Research Ethics Compliance to ensure that no conflict exists in doing so;
- 5.1.3 HSREB members shall be apprised of Queen's University's organizational structure with emphasis placed on the independent nature of the relationship between the HSREB and Queen's University, as outlined in SOP 101 Authority and Purpose. The actions of the HSREB members relating to their responsibilities to protect human research participants shall not be measured or evaluated in terms of organizational or financial goals;

- 5.1.4 HSREB meetings are closed to employees of Queen's University and Affiliated Teaching Hospital(s) unless they are HSREB members, HSREB Office Personnel, permitted as observers, or invited by the HSREB to provide information, and only after signed confidentiality agreements are in place;
- 5.1.5 Queen's University and Affiliated Teaching Hospitals Senior Administrators shall not serve as HSREB members nor observe HSREB meetings when their presence may influence HSREB deliberations. The mere presence of non-voting institutional Senior Administrator(s) at HSREB meetings may be a source of real, potential or perceived COI, and may undermine the independence of the HSREB by unduly influencing deliberations and decisions;
- 5.1.6 Queen's University and HSREB policies and procedures will be made publically available to all members of the research enterprise, including participants, researchers, administrators and sponsors, on the Queen's University Research Ethics website.

## **5.2 Management of COI**

- 5.2.1 The HSREB Chair or designee must be notified if a Queen's University and/or Affiliated Teaching Hospital(s) COI, relating to the HSREB, is declared or discovered;
- 5.2.2 The HSREB Chair or designee must be notified immediately if any Queen's University and/or Affiliated Teaching Hospital(s) employee attempts to, or appears to attempt to, influence the research ethics review process or to obtain preferential treatment;
- 5.2.3 The HSREB Chair or designee and/or Director of Research Ethics will review the available information to determine if a conflict exists, and to determine those aspects of the COI that might reasonably affect human participant protection;
- 5.2.4 The HSREB Chair or designee may require a plan to manage the COI, which may include actions to eliminate or to mitigate the conflict. Required actions may include, but are not limited to:
  - Divestiture or termination of relevant economic interest,
  - Recusal of HSREB Office Personnel whose job status or compensation is impacted by research that is reviewed by the HSREB,
  - If Queen's University and/or Affiliated Teaching Hospital(s) staff members are involved, inform the appropriate responsible Queen's University and Affiliated Teaching Hospital management personnel to develop and implement a plan for remediation,
  - If the HSREB Chair or designee is unable to satisfactorily manage the COI, or if there are unresolved concerns about

any undue influence on the HSREB, the HSREB Chair or designee will bring this to the Director of Research Ethics Compliance, and/or Affiliated Teaching Hospital Official(s) for determination of the appropriate course of action;

- 5.2.5 In the event that the HSREB Chair or designee cannot bring the matter to the appropriate Queen's University and/or Affiliated Teaching Hospital Official(s) because of an emergent situation or competing COI with Queen's University and/or Affiliated Teaching Hospital(s), the HSREB Chair or designee may escalate the issue to the board authority.

## 6.0 REFERENCES

See References.

## 7.0 APPENDICES

None.

## 8.0 REVISION HISTORY

SOP Title	Version	Updates
Conflict of Interest: Queen's University	v.105.001C 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.