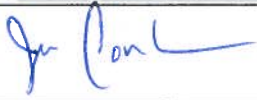




<b>Section 800:</b>	<b>Responsibilities of Investigators</b>
<b>Title:</b>	<b>Researcher Qualifications and Responsibilities</b>
<b>SOP Code:</b>	<b>801.001</b>
<b>Effective Date:</b>	<b>2015MAY25</b>

### 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 22, 2015
	Name: Dr. Andrew Winterborn	Date

## 1.0 PURPOSE

This SOP describes the qualifications and responsibilities of the Researcher who engages in research involving human participants.

## 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 Researchers, 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

Research involving human participants must be conducted by individuals appropriately qualified by education, training, and experience to assume responsibility for the proper conduct of the research and for the protection of human research participants. The HSREB must have assurance that the qualifications of new Researchers, for the conduct of research, are appropriate.

Researchers are required to conduct the research in compliance with applicable regulations and guidelines, and to comply with all Queen's University, HSREB, Affiliated Teaching Hospital(s) and other applicable policies (see SOP 105B Conflict of Interest: Researchers Appendices).

## **5.1 Researcher Qualifications**

- 5.1.1 The Researcher must make available to the HSREB his/her current CV and medical license number (if applicable) and his/her relevant training and experience, in sufficient detail for the HSREB to make an objective judgment regarding the Researcher's qualifications, if necessary;
- 5.1.2 If applicable, the Researcher must be a physician with a specialty qualification in their field and with current professional qualifications entitling them to provide health care under the applicable laws;
- 5.1.3 The Researcher must have completed appropriate training regarding the requirements of conducting and overseeing research;
- 5.1.4 If applicable, all specified Queen's University and Affiliated Teaching Hospital Official(s) must approve the application to the HSREB;
- 5.1.5 Any concerns raised in the HSREB review of the Researcher's qualifications will be communicated to the Researcher and must be satisfied prior to HSREB ethical clearance of the application.

## **5.2 Researcher Responsibilities**

- 5.2.1 The Researcher is responsible for complying with the decisions and responsibilities set out by the HSREB. In addition, it is the Researcher's responsibility to comply with all applicable policies (See Appendices) and regulations and ensure that (if applicable):
  - He/she and his/her staff members are appropriately qualified by education, training and experience to assume responsibility for the proper conduct of the research and for protection of human research participants;
  - He/she must consider the type of research and phase (if applicable) during research design and all ethical issues associated with it;
  - He/she has adequate resources to properly conduct the research and conducts the research following written SOPs,

- All real, potential, or perceived conflicts of interest are declared to the HSREB at the time of the initial application, and as they arise,
- The HSREB review and ethical clearance is obtained before engaging in research involving human participants,
- All necessary documentation is signed by the responsible Researcher, as applicable,
- Must safeguard all information entrusted to them and not misuse or wrongfully disclose it, as well as maintain all promises of confidentiality,
- Informed consent, when required, is obtained from participants in accordance with applicable regulations prior to their enrollment into the research, and using the most current informed consent document(s) ethically cleared by the HSREB (as applicable),
- He/she must provide full disclosure to prospective participants and/or applicable third parties, of all necessary information for making an informed decision to participate in the research project,
- He/she should be inclusive in selecting participants such that participants should not be excluded on the basis of attributes such as culture, language, religion, race, disability, sexual orientation, ethnicity, linguistic proficiency, gender (including reproductive capacity), age (including children and elderly), those that may lack the capacity to consent and vulnerable populations in the context of research, unless there is a valid reason for the exclusion,
- He/she personally conducts or supervises the described investigation(s),
- He/she should maintain a list of appropriately qualified persons to whom they have delegated significant trial-related duties,
- The research is conducted in compliance with the ethically cleared research and applicable reporting criteria are reported to the HSREB, including deviations, serious, unexpected adverse events and privacy breaches,
- Any changes in the ethically cleared research are not initiated without HSREB review and ethical clearance, except where necessary to eliminate an immediate hazard(s) to the participant(s),
- Premature termination or suspension of the research is reported to the HSREB,

- Accurate and complete records are maintained according to applicable regulatory requirements,
- Written summaries of the research status are submitted to the HSREB at least annually, or more frequently if required by the HSREB, and an application for renewal of ethics clearance is submitted to the HSREB prior to the expiration of HSREB ethical clearance,
- Any other unexpected finding or new research knowledge that could affect the risk/benefit ratio of the research is reported to the HSREB,
- The HSREB is notified if there is a change in Researcher,
- The HSREB is notified immediately if his/her medical or dental license or hospital privileges are suspended, restricted or revoked (if applicable) or should his/her qualifications otherwise no longer be appropriate,
- The HSREB is notified when the research is complete;

Note: (if applicable) the obligations of a Researcher holding a Clinical Trial Application (CTA) with Health Canada (i.e., sponsor-Researcher) include both those of a sponsor and those of a Researcher.

- 5.2.2 The HSREB Affiliated Teaching Hospital(s) are responsible for maintaining current CVs and medical licenses (if appropriate) for each of its Researchers. Queen's University and/or Affiliated Teaching Hospital(s) are responsible for immediately advising the HSREB should it become aware of any information that would indicate that the qualifications of the Researcher may no longer be appropriate;
- 5.2.3 The researcher should permit monitoring and auditing by the sponsor, and inspection by the appropriate regulatory authorities.

## **6.0 REFERENCES**

See References.

## **7.0 APPENDICES**

1. See SOP 105B Conflict of Interest: Researcher Appendices

## **8.0 REVISION HISTORY**

<b>SOP Title</b>	<b>Version</b>	<b>Updates</b>
Researcher Qualifications and Responsibilities	v.801.001 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.

