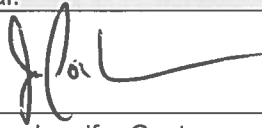
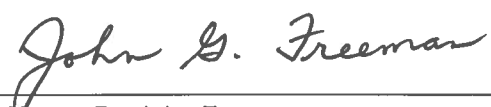
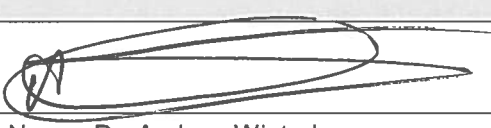


Section 800:	Responsibilities of Researchers
Title:	Researcher Qualifications and Responsibilities
SOP Code:	801.002
Effective Date:	2017FEB15

Site Approvals

Signature of Responsible Individual:		
Ethics Compliance Advisor		Date: 2017Feb15
	Name: Jennifer Couture	
Approval Authority:		
Chair, GREB		Date: 2017 Feb. 15
	Name: Dr. John Freeman	
Approval Authority:		
Director, Research Ethics Compliance		Date: 2017Feb15
	Name: Dr. Andrew Winterborn	

1.0 PURPOSE

This SOP describes the qualifications and responsibilities of researchers who engage in research involving human participants.

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 researchers, GREB members, and GREB 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. GREB must have assurance that the qualifications of new researchers are appropriate for the conduct of research.

Researchers are required to conduct research in compliance with applicable regulations and guidelines, and to comply with all Queen's University, GREB, and other applicable policies (see [SOP 105B, Conflict of Interest: Researchers' Appendices](#)).

5.1 Researcher Qualifications

- 5.1.1 The Researcher must have completed appropriate training regarding the requirements of conducting and overseeing research;
- 5.1.2 All non-faculty researchers at Queen's University (undergraduate and graduate students, post-doctoral fellows and staff), must complete the Course on Research Ethics (CORE) tutorial and attach a copy of the completed certificate to the ethics application. The CORE tutorial is available on the Panel of Research Ethics website: <http://tcps2core.ca/welcome/>;
- 5.1.3 If you are a student in the Principal Investigator's role you must attach a letter/e-mail from a Queen's faculty supervisor stating that they have reviewed and approved the ethics application. Post-doctoral fellows are exempt from this requirement. All research supervisors must be a faculty member at Queen's who is a member

of the School of Graduate Studies. For a list of eligible faculty supervisors, refer to the School of Graduate Studies website <http://www.queensu.ca/calendars/sgsr/Staff.html/>. Contact the School of Graduate Studies or the Office of Research Ethics if your faculty supervisor is not listed on the School of Graduate Studies website;

- 5.1.4 Any concerns raised by GREB with respect to researchers' qualifications will be communicated to the researchers and must be satisfied prior to processing the ethics application;

5.2 Researcher Responsibilities

5.2.1 The Researcher is responsible for complying with the decisions and responsibilities set out by GREB. In addition, Researchers are responsible for complying with all applicable policies (see Appendices) and regulations to ensure that (if applicable) they:

- 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,
- ensure their 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,
- consider the type of research during research design and all ethical issues associated with it,
- have adequate resources to properly conduct the research and conduct the research following written SOPs,
- declare all real, potential, or perceived conflicts of interest to GREB at the time of the initial application, and as such conflicts arise,

- obtain GREB Ethical Clearance before engaging in research involving human participants,
- sign all necessary documentation, as applicable,
- safeguard all information entrusted to them and not misuse or wrongfully disclose it, as well as maintain all promises of confidentiality,
- obtain, when required, informed consent from participants in accordance with applicable regulations prior to participants' enrollment into the research, using the most current Consent Form ethically cleared by the GREB (as applicable),
- 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,
- are 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), limited capacity to consent, and other similar attributes in the context of research, unless there is a valid reason for the exclusion,
- personally conduct or supervise the described investigation(s),
- maintain a list of appropriately qualified persons to whom they have delegated significant study-related duties,
- comply with the ethically-cleared research and applicable reporting criteria to GREB, including deviations, adverse events and privacy breaches,

- do not initiate any changes in the ethically-cleared research are not initiated without GREB Review and Ethical Clearance, except where necessary to eliminate an immediate hazard to the participants,
 - report premature termination or suspension of the research to GREB,
 - maintain accurate and complete records according to applicable regulatory requirements,
 - submit written summaries of the research status to GREB at least annually, or more frequently if required by GREB,
 - submit an application for renewal of ethics clearance to GREB prior to the expiration of GREB Ethical Clearance;
 - report to GREB any other unexpected finding or new research knowledge that could affect the risk/benefit ratio of the research,
 - notify GREB if there is a change in researchers,
 - notify immediately if their medical or hospital privileges are suspended, restricted, or revoked (if applicable) or should their qualifications otherwise no longer be appropriate,
 - notify GREB when the research is complete;
- 5.2.2 Queen's University is responsible for immediately advising GREB should it become aware of any information that would indicate that the qualifications of researchers may no longer be appropriate;
- 5.2.3 Researchers 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

SOP Title	Version	Updates
Researcher Qualifications and Responsibilities	v.801.001 2016MAR30	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.
Researcher Qualifications and Responsibilities	v.801.002 2017FEB15	Researchers Qualifications sections were updated to clarify CORE training and faculty supervisor requirements.