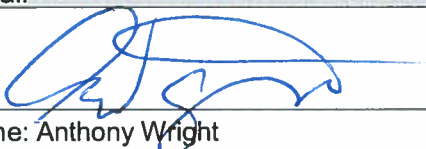
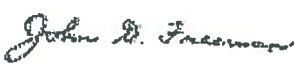



<b>Section 700:</b>	<b>Informed Consent</b>
<b>Title:</b>	<b>Informed Consent Form Requirements and Documentation</b>
<b>SOP Code:</b>	<b>701.001</b>
<b>Effective Date:</b>	<b>2016MARCH30</b>

## Site Approvals

<b>Signature of Responsible Individual:</b>		
Ethics Compliance Advisor		Date: 2016MAR30
	Name: Anthony Wright	
<b>Approval Authority:</b>		
Chair, GREB		Date: 2016MAR30
	Name: Dr. John Freeman	
<b>Approval Authority:</b>		
Director, Research Ethics Compliance		Date: 2016MAR30
	Name: Dr. Andrew Winterborn	

## 1.0 PURPOSE

This SOP describes the requirements for the Consent Form and the process for waiving or obtaining and documenting initial and ongoing informed consent.

## 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 and GREB office personnel are responsible for ensuring that the requirements of this SOP are met.

Researchers are responsible for providing GREB with a detailed description of the rationale for consent documents (or waiving consent), a description of the consent process, and the process for withdrawing consent. Researchers also are responsible for providing a description of the recruitment methods and materials.

When a Consent Form is used, the researchers and GREB are jointly responsible for ensuring that the Consent Form contains all of the basic elements of consent.

The GREB Chair or designee is responsible for reviewing Consent Forms or changes to Consent Forms if the changes meet the criteria for delegated review.

### **4.0 DEFINITIONS**

The TCPS2 (2014), Chapter 3, uses the words “consent form” to describe the process of obtaining informed consent. However, for some GREB ethics applications, no signed consent is needed such as anonymous surveys where completion of the survey is considered implied consent. Therefore, components of the consent process are often broken into two parts called the Letter of Information (LOI) and the Consent Form (CF). In this SOP, the required elements are described as one process.

### **5.0 PROCEDURES**

Researchers must provide prospective participants or authorized third parties with full disclosure of all of the information necessary for making a voluntary informed decision to participate in a research project.

Research participants should be able to voice in confidence their concerns and questions and request information regarding their participation or potential participation in research to an informed individual on GREB or in the GREB office.

## **5.1 Documentation of Informed Consent**

- 5.1.1 GREB typically requires documentation of informed consent by the use of a written Consent Form ethically cleared by GREB and signed and dated by the research participant (or the research participant's legally acceptable representative);
- 5.1.2 A copy of signed Consent Forms shall be provided to research participants;
- 5.1.3 GREB may ethically clear a process that allows the Consent Form to be delivered by regular mail, email, internet, or facsimile to the potential participant, and to conduct a consent interview by telephone when the participant can read the Consent Form as it is discussed. All other applicable conditions for documentation of informed consent must be met when using this procedure;
- 5.1.4 Where consent is not documented in a signed Consent Form, researchers may use a range of consent procedures (e.g., oral consent, field notes, implied consent through the return of a completed questionnaire). The alternate procedures used to seek consent must be documented by the researchers and ethically cleared by GREB;
- 5.1.5 Whenever possible, research participants should have written documentation of participation in a research project unless it may compromise their safety or confidentiality;
- 5.1.6 Consent must be maintained throughout the research project;
- 5.1.7 All participants must be provided with information relevant to their ongoing consent to participate in the research.

## **5.2 GREB Review of Required Elements of Informed Consent**

- 5.2.1 GREB members will review the proposed consent process for appropriateness;

5.2.2 GREB members will review the proposed consent forms for:

- general readability,
- appropriateness of the language and content,
- voluntariness of consent,
- withdrawal procedures,
- adequate information to safeguard the privacy and confidentiality of research participants and prospective participants, and
- any inadmissible language that causes the participant or the legally acceptable representative to waive or appear to waive any legal rights, or that releases or appears to release the investigator, the institution, or the sponsors from liability or negligence (see also Informed Consent Required Elements for all GREB Research [Appendix 1] for applicable consent form required elements);

5.2.3 GREB may require a separate consent form for optional procedures or sub-studies (e.g., completing a multi-stage study);

5.2.4 Following the review, GREB may approve the consent forms as submitted or require changes;

5.2.5 When changes are required by GREB and are made by the researchers, the GREB Chair or designee will review the consent forms to confirm that the required changes have been made and that the version date has been updated;

5.2.6 When the changes meet the criteria of GREB for either delegated or full board review, researchers will be asked to remove all previous versions in the Human Ethics Application System;

5.2.7 Once the ethics application and its attachments receive the final ethics clearance letter from the GREB Chair, the application will be locked from further changes by the Ethics Coordinator in the Human Ethics Application System;

5.2.8 If researchers wish to make changes to the Consent Form, these changes must be done through a GREB amendment form with justification provided.

### **5.3 Recruitment Materials**

5.3.1 **Advertising:** GREB must first review and approve the text and the use of any advertisements, notices, media, and internet messages according to GREB requirements;

5.3.2 GREB reviews the recruitment materials (e.g., advertisements, letters, notices) for evidence of coercion or undue influence and consistency with the GREB ethically-cleared research, the Consent Form, and the TCPS2 (2014);

5.3.3 All recruitment materials that have been ethically cleared by GREB must also be approved for use by each organization where the recruitment material will be displayed.

### **5.4 Translation of Informed Consent Documents**

5.4.1 The informed consent document should be in language understandable to the research participants (or acceptable representatives);

5.4.2 When a research participant is non-English speaking, documentation of informed consent can be by one of two methods:

- **Written consent:** GREB ethically cleared English version of the Consent Form is translated into the research participant's native language. GREB may require that translated Consent Forms be accompanied by an attestation from a translator certifying that the translated informed consent accurately reflects the GREB ethically-cleared English Consent Forms. A translated Consent Form does

not replace the need for an interpreter to be present during the consent process and throughout the research. The research participant and the interpreter will sign and date the translated version of the informed consent form document,

- **Oral consent:** If applicable/acceptable, a qualified interpreter fluent in both English and the research participant's native language may orally interpret the GREB ethically-cleared English Consent Form to the research participant. The oral consent process is interactive in that participants are asked if they understand and give consent to smaller segments of required statements as well as overall consent after the complete Consent Form has been read. If an audio recorder is used, the final verbal consent should be recorded before the study is conducted. If no audio recorder is used, the researcher and interpreter should record the name (or pseudonym/code number) and date of each participant's consent in a notebook. If a research participant is unable to read, the researcher should follow the oral consent process. An interpreter should be impartial and available to the research participant throughout the research.

## **5.5 Consent Update for Ongoing and Completed Research Participants**

- 5.5.1 Researchers must inform ongoing and completed participants of any new information that might affect their willingness to participate in the research or may alter the risks of harm. If required, written documentation of ongoing consent for currently enrolled participants may be obtained by having the research participants sign a GREB ethically-cleared Consent Form containing the updated information;

- 5.5.1 If applicable, ongoing consent may be obtained orally by contacting the research participants by phone, providing the updated information, and documenting their agreement to continue;
- 5.5.2 The nature of the provision of the new information to currently enrolled participants and the documentation required will be determined by the GREB.

## **5.6 Consent Monitoring**

- 5.6.1 In considering the adequacy of informed consent procedures, GREB may require monitoring of the consent process by an impartial observer;
- 5.6.2 Such monitoring may be particularly warranted when the research presents significant risks to participants, or if participants are likely to have difficulty understanding the information provided;
- 5.6.3 Monitoring may also be appropriate as a corrective action when GREB has identified problems associated with particular researchers or research projects.

## **6 REFERENCES**

[TCPS2 \(2014\), Chapter 3, Article 3.2](#)

## **7 APPENDICES**

1. Informed Consent Required Elements for all GREB Research (TCPS2)

## 8 REVISION HISTORY

<b>SOP Title</b>	<b>Version</b>	<b>Updates</b>
Informed Consent Form Requirements and Documentation	v.701.001 2016MAR30	Original: This SOP was developed based on information from the TCPS2 (2014) and Queen's University previous reports and policies (using the format of CAREB/N2).