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| Section 700: | Informed Consent |
| Title: | Waiver or Alteration of Informed Consent |
| SOP Code: | 702.001 |
| Effective Date: | 2016MARCH30 |

Site Approvals

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

1.0 PURPOSE

This SOP describes the process for waiving or altering 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 waiving or altering informed consent.

GREB is responsible for determining whether or not informed consent exemptions or alterations are applicable and appropriate (see [TCPS2 \(2014\), Article 3.7A](#)).

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURES

There are instances where the normal consent procedures for research need to be waived or altered.

5.1 Waiver or Alteration of Informed Consent

5.1.1 GREB may approve a consent procedure that does not include, or which alters, some or all of the elements of informed consent, or waive the requirements to obtain informed consent, provided that GREB finds and documents that:

- The regulatory and TCPS2 (2014) ethics guidance framework supports the waiving of consent,
- The research involves no more than minimal risk to the participants,
- The waiver or alteration is unlikely to adversely affect the rights and welfare of the participants,

- The research could not practicably be carried out without the waiver or alteration,
- The precise nature and extent of the alteration is defined,
- The information is used in a matter that will ensure its confidentiality,
- Whenever appropriate, the participants are provided with additional pertinent information after participation (see [TCPS2 \(2014\), Article 3.7B, Debriefing in the Context of Alterations to Consent Requirements](#)),
- The research project is not prohibited by law;

5.1.2 These findings and their justifications should be clearly documented in the Human Ethics Application System as part of the delegated reviewers' comments or in the GREB Meeting minutes.

6.0 REFERENCES

[TCPS2 \(2014\), Article 3.7A](#), and [3.7B](#)

7.0 APPENDICES

None.

8.0 REVISION HISTORY

| SOP Title | Version | Updates |
|------------------------------------------|------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Waiver or Alteration of Informed Consent | v.702.001 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). |

