Section 700:	**Informed Consent**
Title:	**Consent for Research Involving Individuals who Lack Capacity**
SOP Code:	**703.001**
Effective Date:	**2016MARCH30**

Site Approvals

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

1.0 PURPOSE

This SOP describes the process for obtained informed consent from individuals lacking capacity.

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 participants who lack capacity to give consent from themselves.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURES

Certain individuals may lack capacity temporarily or permanently to give capacity for themselves to take part in research. In these instances, an authorized third party may give consent on behalf of a research participant.

5.1 Consent for Research Involving Individuals who Lack Capacity

5.1.1 For research involving individuals who lack capacity, either permanently or temporarily, to decide for themselves whether or not to participate, GREB must ensure that at a minimum the following conditions are met:

- Researchers involve to the greatest extent possible participants who lack the capacity to consent on their own behalf in the decision-making process,
- Researchers seek and maintain consent from authorized third parties,
- The authorized third party is not one of the researchers or any other member of the research team,

- Researchers demonstrate that the research is being carried out for the participant's direct benefit or for the benefit of other persons in the same category. If the research does not have the potential for direct benefit to the participant, researchers shall demonstrate how the research will expose the participant to only a minimal risk and how the participant's welfare will be protected during participation in the research;

5.1.2 If an authorized third party has consented on behalf of a person who lacks legal capacity but that person has some ability to understand the significance of the research, researchers ascertain the wishes of the person who lacks capacity with respect to participation;

5.1.3 Assent from participants is not sufficient to permit them to participate in a research project in the absence of consent by an authorized third party; however, their expression of dissent must be respected;

5.1.4 Prospective participants who may be capable of verbally or physically assenting to, or dissenting from, participation in research include:

- Those whose capacity is in the process of development, such as children whose capacity for judgment and self-direction is maturing,
- Those who were once capable for making an autonomous decision regarding consent but whose capacity is diminishing or fluctuating, and
- Those whose capacity remains only partially developed, such as those living with permanent cognitive impairments;

5.1.5 If assent for research is requested, researchers must submit to GREB the proposed procedures for obtaining consent from the authorized third parties and assent from the research participants;

5.1.6 When authorization for participation was granted by an authorized third party, and the participant acquires or regains capacity during the research, researchers will seek the participant's consent as a condition of continuing participation;

5.1.7 If individuals have signed a research directive indicating their preference for ongoing and/or future participation in research, in the event that they lose capacity or die, an authorized third party may be guided by these directives during the consent process.

6.0 REFERENCES

TCPS2 (2014), Section C, Article 3.9, 3.10, and 3.11.

7.0 APPENDICES

None.

8.0 REVISION HISTORY

SOP Title	Version	Updates
Consent for Research Involving Individuals who Lack Capacity	v.703.001 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).