WOMEN'S COLLEGE RESEARCH INSTITUTE
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Research Ethics Board Standard Operating Policies and Procedures

Research Involving Vulnerable Populations

SOP NO:	REB-V-01.001	**Revision Date:**	February 7, 2018
CATEGORY	Research Ethics Board	**Reviewed/Effective Date:**	February 7, 2018
SUB-CATEGORY	Section V: Reviews Requiring Special Considerations	**Original Issue Date:**	February 7, 2018
ISSUED BY:	Research Ethics Office		
APPROVED BY	**Vice President, Research**		

The WCH REO webpage version of this document is considered the most current.

Please ensure that you have reviewed all linked documents and other reference material within this SOP

1.0 POLICY STATEMENT:

The purpose of this Standard Operating Procedure (SOP) is to describe the decisions that Women's College Hospital (WCH) Research Ethics Board (REB) may make resulting from its review of research involving groups that could be potentially vulnerable to coercion in regard to autonomy or bearing unequal burden in research. In accordance with TCPS2, its purpose is also to ensure, to the extent possible, that research involving potentially vulnerable populations is premised on respectful relationships.

The REB shall apply additional safeguards as necessary to protect potentially vulnerable research participants. The extent of additional protection afforded shall depend upon the risk of harm and the likelihood of benefit. The judgment that any individual lacks autonomy or capacity should be periodically re-evaluated and will vary in different situations. In addition, when the REB regularly reviews research involving a vulnerable population, consideration will be given to inclusion of one or more individuals who are knowledgeable about and experienced in working with these participants.

Potentially vulnerable groups may include, but are not limited to:

- Individuals with cognitive or developmental impairments
- Pregnant women and infants
- Indigenous individuals and communities
- Other vulnerable groups (e.g. trainees, marginalized individuals or groups, persons with precarious legal status)
- Persons deemed to be vulnerable by virtue of their inclusion or position in research

2.0 DEFINITION(S):

See Glossary of Terms

3.0 RESPONSIBILITY:

This SOP applies to the REB Chair, Vice-Chair, REB Members and Research Ethics Office (REO) staff, as well as researchers conducting research involving persons deemed to be vulnerable.

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4.0 PROCEDURES:

4.1. Participants with Cognitive or Developmental Impairments:

In studies involving participants with impaired decision making capacity take place over extended periods, the WCH REB should consider whether periodic re-evaluation of consent of individuals should be required to ensure that a participant's continued involvement is voluntary. The WCH REB may require that Investigators re-consent participants after taking into account the study's anticipated length and condition of individuals to be included (e.g., participants with progressive neurological disorders). Additionally, the WCH REB should consider whether, and when, a reassessment of decision-making capacity may be required.

Studies involving participants with impaired decision-making capacity warrant special attention. Research involving these populations frequently presents greater than minimal risk; as it may not offer direct medical benefit to the participant, and may include a research design that calls for washout, placebo, or symptom provocation.

For research involving individuals who lack capacity, either permanently or temporarily, to decide for themselves whether to participate, the WCH REB shall ensure that, as minimum, the following conditions are met:

(a) The researcher involves participants who lack the capacity to consent on their own behalf to the greatest extent possible in the decision-making process;

(b) The researcher seeks and maintains consent from authorized third parties or surrogates in accordance with the best interests of the individual concerned;

(c) The authorized third party or surrogate is not the researcher or any other member of the research team;

(d) The researcher demonstrates 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 but only for the benefit of the other persons in the same category, the researcher shall demonstrate that the researcher will expose the participant to only a minimal risk and minimal burden, and demonstrate how the participant's welfare will be protected throughout the participation in research;

(e) When authorization for participation is granted by an authorized third party, and a participant acquires or regains capacity during the course of the research, the researcher shall promptly re-evaluate the participant's consent as a condition of continuing participation.

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If these conditions are met, the WCH REB may approve the inclusion of participants with impaired decision making capacity in research on the basis of informed consent from authorized representatives or surrogate decision makers.

Both investigators and REB members must be aware that for some participants, their decision-making capacity may fluctuate. For participants with fluctuating decision making capacity or those with decreasing capacity to give consent, a re-consent process with a surrogate may be necessary.

Although incompetent to provide informed consent, some persons may resist participating in a research protocol approved by their representatives.

Where an authorized third party has consented on behalf of an individual who lacks legal capacity, but that person has some demonstrated ability to understand the significance of the research, the researcher shall ascertain the wishes of that individual with respect to participation through an assent process. Prospective participants' dissent will preclude their participation.

4.2. Pregnant Women, Infants and Fetuses

Women shall not be automatically excluded from research solely on the basis of sex or reproductive capacity. In considering research on pregnant or breastfeeding women, researchers and REBs must take into account potential harms and benefits for the woman and her embryo, fetus or infant. These harms and potential risks of harm must be identified clearly along with any mitigating strategies, on all study documentation, including participant-facing documents.

4.3. Research Involving Fetuses

Research may be undertaken on methods to treat, in utero, a fetus that is suffering from genetic or congenial disorders. Because the fetus and the woman cannot be treated separately, any intervention on one involves an intervention on the other. Accordingly, and consistent with the requirements of informed consent, research involving a human fetus requires the free and informed consent of the woman.

4.4. Research Involving Indigenous Persons

CIHR has identified health research studies involving Indigenous persons as requiring special consideration and the Panel on Research Ethics has significantly expanded the chapter within the TCPS that provides a framework for the ethical conduct of research involving Aboriginal people. While studies involving indigenous persons and groups may not necessarily always be reviewed by the full board, they will be given special consideration in accordance with the appropriate guidelines. Research reviewed by the WCH REB is compliant with both the CIHR Guidelines for Health Research Involving Aboriginal People (2007-2010) which informs the current Chapter 9 of the TCPS2.

4.5. Other Vulnerable Groups

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The WCH REB considers that vulnerable groups **may** include, amongst others, persons with mental impairments or disabilities, employees of the sponsor or investigator or the institution, terminally ill patients and the very frail elderly. The REB will determine special protections for these groups on a case by case basis taking into account the potential risks and benefits and other protections afforded by institutional policies, provincial and federal law.

5.0 REFERENCES:

1. CIHR Guidelines for Health Research Involving Aboriginal People (2007-2010). http://www.cihr-irsc.gc.ca/e/29134.html

2. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2014 (TCPS2), Articles 2.7, 6, 6.21,6.22, 6.23;