



SOP Title	NMREB Reviews Requiring Special Consideration – Vulnerable Populations
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Approvals

Name and Title of Signatories	Signature	Date mm/dd/yyyy
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1. PURPOSE

This standard operating procedure (SOP) describes the review of research that involves groups that could be potentially vulnerable to coercion in regard to autonomy or bearing unequal burden in research.

2. GENERAL POLICY STATEMENT

The Non-Medical Research Ethics Board (NMREB) shall apply additional protections to protect potentially vulnerable research participants. The extent of additional protection afforded should depend on the risk of harm and the likelihood of benefit. In addition, when the NMREB regularly reviews research involving a vulnerable population, consideration will be given to inclusion of one or more individuals who are knowledgeable about working with these participants.

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

- Children
- Individuals with mental illness
- Individuals with cognitive impairment
- Pregnant women and infants
- Students
- Employees
- Members of the armed forces
- Individuals with limited language skills
- Aboriginal individuals and communities
- Prisoners

3. RESPONSIBILITY

This SOP applies to all NMREB members including the NMREB Chair and Vice-Chair(s) and to all Office of Human Research Ethic (OHRE) staff.

4. DEFINITIONS

See Glossary of Terms

5. SPECIFIC POLICIES AND PROCEDURES.

5.1. Use of Vulnerable Populations in Research

5.1.1. The NMREB considers vulnerable groups to include, amongst others, mentally impaired or disabled persons, employees of the sponsor or investigator or the Institution, terminally ill patients, pregnant women, infants and fetuses, prisoners and the very elderly. The NMREB will determine special protections for these groups on a case-by-case basis taking into account the risks and benefits and other protections afforded by institutional policies, provincial and federal law;

5.1.2. The NMREB follows the guidance of the Tri-Council Policy Statement 2 with regards to research being conducted on vulnerable populations. The following are examples of how vulnerable populations are assessed and managed.

5.2. Children

5.2.1. Individuals may be consented for research participation if the individual is able to adequately evaluate the purpose of the research, study procedures, risks/benefits, and implications of their participation. Parental consent (by at least one parent/guardian or substitute decision maker) is required for all children who lack sufficient capacity to consent for themselves. If a minor’s capacity cannot be determined, both parental/guardian or substitute decision maker consent and minor assent are required. If the investigator requests to not seek parental consent, justification must be made and this is reviewed on a case-by-case basis by the NMREB. Researchers must be sensitive to any signs of dissent from young children and discontinue their participation, as applicable. For longitudinal studies, children must provide assent/consent as soon as they reach decision-making capacity.

5.3. Cognitively Impaired Participants

5.3.1. Studies which involve participants with impaired decision making capacity that take place over an extended period of time should take into consideration the issue of re-consent. That is whether or not periodic re-consent of individuals should be required for continued involvement;

5.3.2. If re-consent is needed the NMREB should also consider whether or not a reassessment of decision-making capacity is required.

5.4. Research Involving Aboriginal Peoples

5.4.1. The TCPS2 provides an expanded chapter-providing framework for the ethical conduct of Research Involving First Nations, Inuit and Metis Peoples of Canada;

5.4.2. While not all studies involving First Nations, Inuit and Metis Peoples require review by the Full Board, special consideration should be given based on the TCPS2 guidelines.

6. REFERENCES

6.1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2010 (TCPS2);

7. SOP HISTORY

SOP Number. Version	Key Changes	Effective Date mm/dd/yyyy
N501.001	Original	07/07/2016
N501.002	Adjustments to 5.2 and update of NMREB Chair	08/14/2018

