



SOP Title	HSREB 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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Dr. Philip Jones Chair, Health Sciences Research Ethics Board		2 November 2021

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 Health Sciences Research Ethics Board (HSREB) 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 HSREB 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
- Indigenous individuals and communities
- Prisoners

3. RESPONSIBILITY

This SOP applies to all HSREB members including the HSREB 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 HSREB 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 HSREB 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. If research involves prisoners, children, pregnant women, fetuses and/or neonates, and is funded or supported by the US Federal Government, the REB shall apply the requirements of 45 CFR 46, including as appropriate, Sub-Parts, B, C and D.
- 5.1.3. The HSREB 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. TCPS 2 does not specify an age when a child can consent to research. Determining whether consent can be sought from children should not solely be based on their age. The HSREB considers capacity, not only age, for all participants in determining the appropriate consent model for each study.
Parental consent (by at least one parent/guardian or substitute decision maker), and child assent, may be required in particular situations. Exceptions may be made if the child is an emancipated minor or if needed based on the content of the project. If the content of the project requires the HSREB to not seek parental consent, justification must be made and this is reviewed on a case-by-case basis.

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 HSREB should also consider whether or not a reassessment of decision-making capacity is required.

5.4. Research Involving Indigenous Peoples

- 5.4.1. CIHR has identified health research studies involving Indigenous People as requiring special consideration. The TCPS2 provides an expanded chapter-providing framework for the ethical conduct of research involving Indigenous Peoples;
- 5.4.2. While not all studies involving Indigenous 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 (TCPS2);

7. SOP HISTORY

SOP Number.Version	Key Changes	Effective Date mm/dd/yyyy
501.001	Original	01/21/2014
501.002	Minor administrative corrections	05/29/2014
501.003	Minor administrative corrections for clarity	05/10/2016
501.004	Minor administrative corrections	09/10/2018
501.005	Minor administrative corrections Inclusion of U.S. regulations and minor administrative updates (section 5.1.2) and update to section 5.2	02/21/2020 and 11/02/2021