
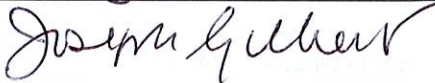


SOP Title	HSREB Reviews Requiring Special Consideration – Vulnerable Populations
Number.Version	501.003
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Approvals

Name and Title of Signatories	Signature	Date mm/dd/yyyy
Erika Basile Director, Research Ethics		05/11/2016
Dr. Joseph Gilbert Chair, Health Sciences Research Ethics Board		05/11/2016

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
- Aboriginal 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. 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. The legal age of majority in Ontario is 18 years of age. Parental consent (by at least one parent/guardian or substitute decision maker) is required for all children under the age of 18. 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, strong 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 Aboriginal Peoples

5.4.1. CIHR has identified health research studies involving Aboriginal People as requiring special consideration. The TCPS2 provides an expanded chapter-providing framework for the ethical conduct of research involving Aboriginal Peoples;

5.4.2. While not all studies involving Aboriginal 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
501.001	Original	01/21/2014
501.002	Minor administrative corrections	05/29/2014
501.003	Minor administrative corrections for clarity	05/10/2016