IWK Research Ethics

Standard Operating Procedures

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POLICY STATEMENT

The REB will ensure whatever additional measures may be needed to protect potentially vulnerable research participants. Potentially vulnerable groups may include, but are not limited to:

- *Children*
- *Individuals with mental illness*
- *Individuals with cognitive impairment*
- *Students or employees*
- *Individuals with limited language skills.*
- *Indigenous individuals and communities*
- *Prisoners*

DEFINITIONS

See Glossary (REB SOP 102)

RESPONSIBILITY

This policy applies to the REB Chair, Manager, REB Members, Research Ethics Office (REO) Staff, and Investigators involved in research affecting vulnerable populations.

PROCEDURES:

REB Review of the Research Plan

The IWK REB review of research involving vulnerable subjects will give particular attention to:

- Inclusion and exclusion criteria for selecting and recruiting participants, informed

consent and willingness to volunteer; possibility of coercion and/or undue influence; and strict confidentiality of data
- Group characteristics such as economic, social, physical, and environmental and cultural conditions
- Over-selection or exclusion by investigators of certain groups based on perceived limitations or complexities associated with those groups. For example, it is not appropriate to target prisoners as research subjects merely because they are a readily available "captive" population
- Capacity to consent for research, including, where appropriate, special consideration of emancipated minors, legally authorized representatives, the age of majority for research consent, and the waiver of parental permission for research
- Assessment of competency, where competency and understanding are potentially impaired
- Where children are involved, additional special considerations will be applied. The proposed research must fall within one of four categories:
    - Research not involving greater than minimal risk
    - Research involving greater than minimal risk, but presenting the prospect of direct benefit to the individual subjects
    - Research involving greater than minimal risk, but likely to yield knowledge that can be generalized about the subject's disorder or condition
    - Research not otherwise approvable, which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health and welfare of children

Parental Permission

Parental or legal guardian consent is required where a child is incapable of understanding the implications of taking part in a study or where the child is deemed incompetent to consent. The REB will also consider whether one or both parent's permission should be obtained.

Subject to applicable regulations, where special circumstances dictate that parental permission is inappropriate, the Board may exceptionally waive the consent requirements provided a satisfactory substitute method for protecting the children would be used, and further providing the waiver is not inconsistent with local law.

Although parental permission may have legal primacy, the Board may also require Investigators to obtain assent (see following) from those children who have some, albeit incomplete, capacity and understanding.

Assent of the Child

The Board will normally require that formal assent to participate be obtained from all child participants who have at least some capacity to understand the research proposed and its implications for the participant. The form of assent will be determined at the time of approval of the research, but will be tailored to the child's level of understanding, and be constructed in simple, age-appropriate, language.

Participants with Impaired Decision-Making Capacity

Before approving research involving participants who by reason of mental or behavioural disorders are not capable of giving adequately informed consent, the REB must be satisfied that:

- The purpose of the research is to obtain knowledge relevant to the particular health needs of persons with mental or behavioural disorders
- The consent of each participant will be obtained to the extent of that participant's capabilities, and a prospective participant's refusal to participate in research will be always respected
- In the case of incompetent participants, informed consent will be obtained from the legally authorized representative or other duly authorized person
- The degree of risk attached to interventions that are not intended to benefit the individual is low and commensurate with the importance of the knowledge to be gained
- Research interventions that are intended to provide therapeutic benefit are likely to be at least as advantageous to the individual as any alternative

For long-term studies involving participants with impaired decision-making capacity, the Board may also require periodic re-consenting to ensure the participant's involvement continues to be voluntary. Periodic re-consenting may also be required if there is the possibility of changing capacity.

Irrespective of otherwise acceptable consent to participate in research from the subject's representative, the Board requires investigators to respect resistance to participation by the subject.

Pregnant Women, Infants and Foetuses

The Board will not approve research in which women are excluded from participation solely on the basis of sex or reproductive capacity.

In considering research on pregnant or breastfeeding women, the Board will take into account potential harms and benefits for the woman and her embryo, foetus or infant.

Research involving Foetuses

Where a research application involves foetuses alone, the Board will require informed consent from the mother.

Research Involving Prisoners

The Board will require evidence that prisoners consenting to participate in research have done so free from any pressure or coercion, including covert inducements.

Research Involving Indigenous Peoples

Applications for research involving Indigenous peoples will be assessed by the Board in the context of the CIHR Guidelines for health research involving aboriginal people and applicable sections of TCPS2. Principal Investigator's are required to take the online training course for the OCAP® principles, complete TCPS2 Chapter 9 and complete the online TCPS2 CORE Tutorial - Module 9 Research Involving the First Nations, Inuit and Métis Peoples of Canada.

If research involves prisoners, children, pregnant women, fetuses and/or neonates, and is funded or supported by the U.S. Federal Government, the REB shall apply the requirements of 45 CFR 46, including as appropriate, Sub-Parts, B, C and D

Note: US regulations will be applied as applicable.

REFERENCES

1. The International Council on Harmonisation Good Clinical Practices, Section 4.13;
2. Tri-Council Policy Statement: Ethical conduct for Research Involving Humans, 2018:
(short name: TCPS 2), Article 3.9; 3.10;4.2; 4.3; 4.4; 4.6; 12.9; Chapter 9
3. CIHR Guidelines for Health Research Involving Aboriginal People, May 2007

Forms/Records:

Form #	Form/Record Name
SOP 502	Vulnerable Populations

Revision History:

Revision	Date	Description of changes
0.0	April 1, 2017	Initial Release
1.0	September 9, 2022	Additions to comply with TCPS2-2018
1.1	March 12, 2024	Updates as per CHEER Qualification
1.2	November 19, 2024	Added note regarding compliance with US regulations where applicable