IWK Research Ethics
Standard Operating Procedures

Document # **RE 4.401**	Title: **Criteria for Research Ethics Board Approval**	Effective Date: **November 19, 2024**
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POLICY STATEMENT

All research involving human participants must meet the guiding ethical principles of the Tri-Council Policy Statement (TCPS2) and be consistent with generally accepted national and international regulations and guidelines. The REB will only consider Applications that provide enough information to assess whether the proposed study meets the ethical principles and mandatory regulatory requirements. Incomplete Applications will be returned to the Applicant for amendment and resubmission before any REB review will take place.

DEFINIATIONS

See Glossary of Terms

RESPONSIBILITY

This SOP applies to the REB Chair, Manager, REB members, and Research Ethics Office (REO) staff.

PROCEDURES

Submission Process

Investigators must submit electronic applications for initial and continuing REB review of studies involving humans using the online ROMEO Researcher Portal https://nsha-iwk.researchservicesoffice.com/Romeo.Researcher/. Guidelines are available on the Research Ethics Board home page of the IWK web site: https://www.iwk.nshealth.ca/research/research-ethics

Minimal Criteria for Approval of Research

In order for a research study to receive REB approval, the REB must find that:

- There is a state of clinical equipoise where interventions are being compared
- The research will generate knowledge that could be generalized and lead to improvements in health or well-being

- The methodology is scientifically sound and capable of answering the research question
- Risks to participants are minimized by: a) using procedures that are consistent with sound research design and that do not unnecessarily expose participants to risk, and b) by using procedures already being performed on the participants for diagnostic or treatment purposes, whenever appropriate
- Risks to participants are reasonable in relation to anticipated benefits, if any, and the importance of the knowledge that may be expected to result. In evaluating risks and benefits, the REB will consider those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies that participants would receive even if not participating in the research). The REB should not consider long-range effects of applying the knowledge gained in the research
- Selection of participants is equitable. In making this assessment, the REB will take into account the purposes of the research and the research setting. The REB will weigh the scientific and ethical reasons for including vulnerable populations where appropriate
- That any exclusion of classes of persons who might benefit from the research are based on sound scientific and ethical reasons, for example:
    - Non-English speaking participants should not be systematically excluded because of inconvenience in translating informed consent documents
    - Participants should not be taken from one group simply because it is convenient
    - The research includes both women and men when appropriate, and does not arbitrarily exclude the participation of persons of reproductive ages
- When some or all of the participants are likely to be vulnerable to coercion or undue influence, additional safeguards have been included in the study and in the REB review process to protect the rights and welfare of these participants
- Informed consent will be sought from each prospective participant or the participant's legally authorized representative, in accordance with and to the extent required by applicable regulations and guidelines
- The informed consent form accurately explains the research and contains the required elements
- The informed consent process is clearly described in the application
- There will be on-going data and safety monitoring appropriate to the size, complexity, phase, and level of risk of the study. The REB may recommend the use of a data and safety monitoring board (DSMB) to enhance participant protection
- There are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data
- There are adequate provisions for continued access to the investigational agent or device, or adequate replacement, after the study is completed, when appropriate
- There are plans for timely publication and dissemination of the research results
- The research has been submitted to Health Canada if required, and the Health Canada No Objection Letter has been issued

Additional Criteria

Studies proposing access to, or collection of, personal health information require consideration of additional items to protect the privacy of the personal health information. Therefore the REB must find that:

- Authorization will be obtained from participants or their legally authorized representative for the collection, use or disclosure of their personal health information, or the REB has approved a waiver of such authorization
- The personal health information will be contained in a manner to ensure appropriate safeguards to maintain privacy

Length of Approval Period

The REB shall periodically review research studies underway appropriate to the degree of risk, but not less frequently than once a year

The REB may require review more often than annually when there is a high degree of risk to participants, relative to the population, for example:

- Where the proposed procedures have not previously been used in humans
- Where the stage of the research is such that many of the risks are unknown
- Where more than minimal risk exists to vulnerable populations with no prospect of direct benefit
- Where there have been previously confirmed serious or continuing non-compliance with the terms of the protocol as approved by the REB
- The REB considers that more frequent review is required

Note: US regulations will be applied as applicable.

REFERENCES

1. Tri-Council Policy Statement: Ethical conduct for Research Involving Humans, 2018: (short name: TCPS 2), Article 11.13.

2. The International Conference on Harmonization Guidelines for Good Clinical Practice, Sections 3, 4.1, 4.8.

3. Nova Scotia Personal Health Information Act (PHIA);

4. Canadian Institutes for Health Research (CIHR) Best Practices for Protecting Privacy in Health Research (September 2005).

5. US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.111.

Forms/Records:

Form #	Form/Record Name
SOP 401	Criteria for Research Ethics Board Approval

Revision History:

Revision	Date	Description of changes
0.0	April 1, 2017	Initial Release
1.0	September 8, 2022	Additions to comply with TCPS2-2018
1.1	February 1, 2023	Updated logo
1.2	November 19, 2024	Added note regarding compliance with US regulations where applicable