IWK Research Ethics
Standard Operating Procedures

Document # **RE 7.701**	Title: **General Requirements of Informed Consent**	Effective Date: **November 19, 2024**
Pages**: 5**	Responsibility of: **Research Ethics Board**	Date Approved: **November 19, 2024**

POLICY STATEMENT

The Board recognizes that consent to participate in research should be a process of communication rather than merely a signature on a document, but does require documented evidence that an approved consenting process has been followed. Unless specifically waived by the Board for special circumstances, consent must be obtained from all potential participants who are legally competent or, in the face of incompetency, from their legally authorized representatives. No subject will be involved in any aspect of the research before giving informed consent.

In judging the adequacy of consent procedures detailed in Applications, the Board will look for evidence that those invited to participate:

- *Will be given a clear, complete, and understandable description of the research, tailored to the degree of risk involved but sufficient to enable the potential participants to properly judge whether or not they want to become subjects. Consent forms and other informational documents should be written in simple language and be free from technical jargon*
- *Will be offered the opportunity to ask questions for clarification of the information given*
- *Will be allowed sufficient time to consider the information received before being asked to make their decision*
- *Will be informed that if they agree to participate they may nonetheless withdraw their consent at any later time*
- *Will be given a copy of any form relating to consent that they have signed*

And that the consenting process:

- *Is free from undue influence or coercion to participate*
- *And nothing in the information offered, written or otherwise, includes any exculpatory provisions appearing to waive the subjects' rights or to release the investigators from their professional and legal obligations*

DEFINITIONS
See Glossary of Terms

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

PROCEDURES
Administrative Processing
REO staff will ensure that each Application includes the required informed consent documents before Applications are distributed to Board Members for review

Review
Reviewers will ensure that the consent process described complies with the provisions of the Policy Statement above, guided by the REB Consent Review Template (see IWK web site https://www.iwk.nshealth.ca/research/research-ethics).

A separate consent may be required for optional procedures for which the research purpose is not yet known (e.g. tissue, blood, genetic testing or specimen banking for future research).

Following the review, the Board may approve the consent documents as submitted, or require changes. Changes to the documents will be reviewed by the Chair for approval or may, at the Chair's discretion, be brought back to the next Board meeting.

Documentation of Informed Consent
Investigators must plan to obtain and retain documentary evidence of consent from each participant unless the Board has provided a waiver for the specific study. This evidence may be:

- A study-specific consent form approved by the Board signed and dated by the participant (or the participant's authorised representative in cases of legal incapacity) and the person obtaining consent
- The person obtaining consent must attest:
  - The participants understanding of the material presented
  - That the participant has been allowed sufficient time to read the consent form, and opportunity to have any questions answered, before being allowed to sign
- In circumstances where the Board has approved telephone or email consent, a signed and dated statement from the person obtaining consent
- Participants who do not understand English should be presented with an informed consent document written in a language understandable to them. (See 'Translation' below)
- In the case of subjects who are illiterate or physically unable to write the process for recording oral consent (see 'Translation' below) should be followed

In addition to the signature of their legally authorised representative, an assenting signature is

recommended from participating children of age 7 and above who are deemed capable of understanding to some extent the nature, risks and benefits of the study

Translation
In the IWK, consent processes are normally conducted in English: When a potential participant is not fluent in English, the following adaptations may be considered:

- Written consent: The REB approved English version of the informed consent document is translated to the participant's native language. Translated informed consents must be accompanied by an attestation from the translator certifying that the translated informed document accurately reflects the REB approved English informed consent
- Oral consent: An interpreter/intermediary fluent in both English and the participant's native language translates the REB approved English consent form orally to the participant. The interpreter should be an impartial person otherwise unconnected to the research or investigators involved. The interpreter must sign and date the consent form, attesting that the research was accurately explained to the potential participant and that it appeared to have been understood

An interpreter/intermediary should be available to the participant throughout the study.

The REB may follow delegated review procedures to review and approve translated materials if the English language materials have already been approved and the signed translation certificate or statement is on file.

Re-Consenting Participants
The investigator must inform research participants of any new information arising during the course of the research that might affect the participants' willingness to continue in the research. Where there is a significant change to protocol or risk, investigators are required to obtain renewed consent form the participants:

- Written documentation of re-consent may be obtained by having the participant sign an updated REB approved version of the informed consent document or an REB approved addendum to the original consent form
- Any revisions made to consent documents must be submitted to the Board for review and approval prior to use, following the procedure defined in: Amendments, notifications REB SOP 4.404.

Recruitment Methods
Investigator's Patients: If the patient is under the care of the investigator, the investigator may approach the patient directly about participation, but in such a manner that the patient does not feel pressured or obligated in any way. If the patient agrees to consider participation, a person other than the investigator should obtain formal consent.

Other Patients/Referrals: The investigator may send an REB-approved letter to colleagues asking for referral of potential participants. The investigator may provide colleagues with an REB-approved consent form or study information sheet to give to their patients. The patient will

then be asked to contact the investigator directly, or with documented permission from the patient, the investigator may initiate the call.

Advertising: The REB must first review and approve the text and the use of any advertisements, notices or media messages.

Recruitment Materials
Copies of all recruitment materials (e.g., advertisements, letters, notices) must be included in the Application. These will be reviewed to ensure:

- Freedom from coercion or undue influence
- Consistency with the study protocol and informed consent documents
- That contained information is limited to what the prospective participant needs to determine their potential eligibility
- And that compensation for participation is not unduly emphasised

The Board must approve all recruitment materials prior to use.

Consent Monitoring
In considering the adequacy of informed consent procedures, the REB may require monitoring of the consent process by an impartial observer; such monitoring may be particularly warranted where the research presents significant risks to participants, or if participants are likely to have difficulty understanding the information to be provided.

Waiver or Alteration of Informed Consent
The Board may, in its discretion, approve a consent procedure that does not include, or which alters some or all of the elements of informed consent, or waive the requirement to obtain informed consent. Requests for such waivers will be examined on a case to case basis, and the grounds for waiver, and any special conditions pertaining thereto, will be fully explained in the letter of approval sent to Principle Investigators following satisfactory Board review. (See Waiver or alteration of informed consent REB SOP 7.702)

Revisions to the Informed Consent Form
The consent documents must be amended whenever important new information becomes available that may be relevant to the participants' consent and willingness to continue in the study. Revisions must be submitted to the REB for review and approval prior to use. (See Amendments, notifications REB SOP 4.404)

Note: US regulations will be applied as applicable.

REFERENCES
1. Health Canada, Division 5 of the Food and Drug Act;
2. Tri-Council Policy Statement: Ethical conduct for Research Involving Humans, 2018:

(short name: TCPS 2), Chapter 3;
3. The International Conference on Harmonization (ICH) Guidelines for Good Clinical Practice (GCP), Section 4.8;
4. US Food and Drug Administration (FDA) Code of Federal Regulations (CFR) Title 21 Part 50.20, 50.23, 50.24, 50.25, 50.27;
5. US Department of Health and Human Services (HHS) CFR Title 45 Part 46.116, 46.117;

Forms/Records:

Form #	Form/Record Name
SOP 701	General Requirements of Informed Consent

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	February 1, 2023	Updated logo
1.2	November 19, 2024	Added note regarding compliance with US regulations where applicable