IWK Research Ethics
Standard Operating Procedures

Document # **RE 7.703**	Title: **Documentation of Informed Consent**	Effective Date: **November 19, 2024**
Pages**: 4**	Responsibility of: **Research & Innovation Advancement**	Date Approved: **November 19, 2024**

POLICY STATEMENT

Documentation of informed consent is obtained unless alternate procedures are approved by the IWK REB.

The IWK REB may approve in limited circumstances, waiver or alteration of documentation of consent. It is the responsibility of the REB to determine whether the proposed method of consent is appropriate.

Participants who do not speak English should be presented with an informed consent document written in a language understandable to them.

DEFINITIONS

See Glossary of Terms

RESPONSIBILITY

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

PROCEDURES

Documentation of Informed Consent

Unless the requirement is waived by the REB, each participant or his/her legally authorized representative **must sign and date** a copy of the current REB-approved consent form prior to enrollment or any participation in any phase of the study and be given a copy of the signed and dated document.

The research team member who obtained informed consent must record evidence of the informed consent discussion in the source documentation including statements of:

- The participants comprehension/understanding of the material presented and reviewed

- The participant having been given the opportunity to read the information and consent form and to decide whether or not to participate
- The participant being given adequate time to ask questions about the research study and that the questions were answered to the satisfaction of the participant
- Confirmation that informed consent has been obtained and that the participant signed the information and consent form prior to initiating any study-related procedures

Participants who do not understand English should be presented with an informed consent document written in a language understandable to them. The investigator (or Sponsor) may submit the REB-approved version of the consent to a translator for translation. A copy of the translated consent with accompanying certification should be submitted to the REB for review and approval. Certified translated consent will be required when it is reasonably expected that non-English-speaking participants will be recruited. In the case of unexpected non-English participants, a Short Form Consent and procedures may be used with prior approval of the REB.

When a written translation is not available, an oral translation of the REB-approved English consent form may be provided by an interpreter who is fluent in both English and the participant's native language. The interpreter must be impartial and unconnected to the research team. They must sign and date the consent form as a witness, attesting that they accurately translated the content and that the participant demonstrates understanding of the explanation. An interpreter should remain available to the participant throughout the study.

Subjects who are illiterate or physically unable to write may have the consent explained to them verbally and indicate approval or disapproval by other means. In such circumstances, it is essential to document the method of communication, the explanation given (and by whom), and the means by which the subject indicated his/her wish. An impartial third party must witness the entire consent process and sign the consent document.

In the case of a child being recruited as a subject of research, an assent (verbal or written) of the subject of an age 7 or above, sufficiently able to comprehend the nature, risks and benefits of the study, shall be obtained, in addition to the signature of the legally authorised representative.

Use of Facsimile, Mail or e-mail to Document Informed Consent

The REB may approve a process that allows the informed consent document to be delivered by mail, facsimile or e-mail to the potential participant or the potential participant’s legally authorized representative and to conduct the consent interview by telephone when the participant or the legally authorized representative can read the consent document as it is discussed. All other applicable conditions for documentation of informed consent must also be met when using this procedure.

Investigator Responsibilities

All informed consent documents (written documents, oral scripts, and assent forms) will be submitted to the REB with the new study submission.

The IWK REB template for informed consent will be used to draft all written informed consent documents. Appropriate templates, template language, and instructions are located on the IWK REB website.
Informed consent documents will be written in language that is at the appropriate reading and comprehension level for the targeted population. Generally, an eighth grade reading level is recommended for adult consent documents.

The PI does not have to obtain the consent personally, but he or she is ultimately responsible for the informed consent process. Any co-investigators or key study personnel capable of providing sufficient information about the research and listed on the study delegation log may obtain consent from potential participants.

The person obtaining informed consent should be qualified by training to do so and be knowledgeable about the research.

Obtaining Informed Consent
The Investigator will provide a copy of the REB-approved informed consent document to the participant or his/her legally acceptable representative.
The investigator will provide the participants or his or her legally acceptable representative adequate time to read the consent, ask questions, and consider the risks and benefits to participation in the research study prior to obtaining their signature.
When appropriate assent and dissent and documentation of such are to be obtained as directed by the determination of the REB.
Participants or the participant's legally authorized representative will provide a signature and the date of signature on all informed consent documents, unless a waiver of documentation has been requested by the Investigator and approved by the REB.
When authorization for participation was granted by an authorized third party, and the participant acquires or regains capacity during the research, the Researcher will seek the participant's consent as a condition of continuing participation.

REB Responsibilities
The Investigator's plan to obtain informed consent must be reviewed by the REB to assure the appropriate conditions are met.
The REB should consider the nature of the proposed subject population, the type of information to be conveyed, and the circumstances under which the consent process will take place (e.g., manner, timing, place, personnel involved).
All elements of consent as required by the regulations, as well as any appropriate additional elements are incorporated into the documents.
Provisions have been made if the study is to include non-English speaking participants and the translated documents have been verified to be in a language understandable to the participant;
The reviewers are to verify that the informed consent documents are congruent with the study protocol and REB application. If not, the Reviewer or Committee will request revisions prior to granting final approval.

When the research includes minors, the REB must determine whether assent and dissent is required, for what ages assent and dissent is required, and how assent and dissent is to be documented.

Note: US regulations will be applied as applicable.

REFERENCES

1. The International Conference on Harmonization (ICH) Guidelines for Good Clinical Practice (GCP), Section 4.8.2;
2. Tri-Council Policy Statement: Ethical conduct for Research Involving Humans, 2018: (short name: TCPS 2), Article 3,12;
3. US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.103, 46.109;
4. US Food and Drug Administration (FDA) CFR Title 21 Part 56.108, 56.109

Forms/Records:

Form #	Form/Record Name
SOP 703	Documentation 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 18, 2024	Added clarity on oral translation, added note regarding compliance with US regulations where applicable & update to responsibility (RIA)