IWK Research Ethics
Standard Operating Procedures

Document # **RE 7.702**	Title: **Waiver of Informed Consent**	Effective Date: **November 19, 2024**
Pages**: 3**	Responsibility of: **Research Ethics Board**	Date Approved: **November 19, 2024**

POLICY

The REB may approve research without requiring the participant's consent, or in which only partial disclosure is made at the time of consenting, when all of the following apply:

- *The research does not involve a therapeutic intervention, or other clinical or diagnostic interventions*
- *The research involves no more than minimal risk to the participants*
- *The lack of the participant's consent is unlikely to adversely affect the rights and welfare of the participant*
- *It is impossible or impracticable to carry out the research and to answer the research question properly, given the research design, if the prior consent of the participant is required*
- *Whenever possible and appropriate, participants will be fully informed after participation, being given all the information that would have been offered in the normal pre-participation consenting process, and afforded the opportunity to withdraw their data retrospectively*

DEFINITIONS

See Glossary of Terms

RESPONSIBILITY

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

PROCEDURES

Waiver or alteration of informed consent

The REB will grant waivers or partial waivers of consent only if the Board is assured that:

- The provisions of the above policy statement are met

- Or, where the express circumstances of the research in question have otherwise been endorsed in Section 3.7 of TCPS2
- And that full account has been taken of any vulnerability of participants drawn from specific groups, e.g. Children (See Vulnerable Populations REB SOP 5.502.)

Research Involving Partial Disclosure or Deception

In cases where the researcher wishes to withhold or partially disclose pertinent information or deceive participants, the REB may approve research that meets the above requirements of a waiver or alteration of consent if, in addition:

- The nature of the information to be withheld is fully described in the Application
- There is a satisfactory plan for after-event briefing of participants, including:
  - An explanation of why participants received less than full disclosure and the necessity for deception
  - Details of the importance of the research
  - Telling participants that they can retrospectively withdraw
  - Obtaining specific post-event consent from the participants allowing use of their data
  - Annotating on the research record any complaints the participant expresses about the research generally or the nature of the limited disclosure or deception involved
  - Referring participants to Research & Innovation Advancement if they wish to make a formal complaint

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 3.7;
2. US Department of Health and Human Services (HHS) CFR Title 45 Part 46.116
3. Nova Scotia Personal Health Information Act

Forms/Records:

Form #	Form/Record Name
SOP 702	Waiver 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	Updated wording for clarity, added note regarding compliance with US regulations where applicable