



## IWK Research Ethics Standard Operating Procedures

Document # <b>RE 7.702</b>	Title: <b>Waiver of Informed Consent</b>	Effective Date: <b>February 1, 2023</b>
Pages: <b>3</b>	Responsibility of: <b>Research Ethics Board</b>	Date Approved: <b>February 1, 2023</b>

### 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 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

**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