



IWK Research Ethics Standard Operating Procedures

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POLICY

Research participants may voice their concerns or questions, or request information regarding their participation or potential participation in a research project, to the Research Ethics Office (REO) or to the REB

DEFINITIONS

See Glossary of Terms

RESPONSIBILITY

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

PROCEDURES

Communication with Research Participants

Research participants are encouraged to contact (telephone or in writing) the REO with questions and concerns using the contact information provided in the informed consent document. If requested, the identity of the participant will not be recorded or shared.

Research Ethics Office staff will relay communications promptly to the Manager when the participant shares concerns or problems encountered with a research project.

The Manager (or delegate) will promptly communicate participant concerns or problems to the REB Chair.

The REB Chair or designee works to resolve participant issues, including follow-up with the investigator or the investigator’s supervisor or institutional official and appropriate federal agencies, as indicated.

The REB Chair or delegate documents communication with the research participant and keeps a record on file at the REO.

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), Chapter 1 Section B;
2. US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.103, 46.109, 46.115;
3. US Food and Drug Administration (FDA) CFR Title 21 Part 56.115

Forms/Records:

Form #	Form/Record Name
SOP 602	REB and Research Office Communications to Participants

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 & update to responsibility (RIA)