IWK Research Ethics
Standard Operating Procedures

Document # **RE 2.204**	Title: **Authorized Signatory / Signing Authority**	Effective Date: **November 19, 2024**
Pages**: 3**	Responsibility of: **Research & Innovation Advancement**	Date Approved: **November 19, 2024**

POLICY STATEMENT

Any document issued by or on behalf of the REB that grants or may appear to grant investigators with initial or continuing approval of research involving human subjects, or suspends or terminates such research, must be signed by the REB Chair, or as otherwise designated in writing by the Chair, in accordance with the procedures defined below:

DEFINITIONS

See Glossary of Terms

Authorized Signatory/Signing Authority: A person or persons authorized to sign documents on behalf of the IWK REB.

Manager: The appointed manager of the IWK Research Ethics Office (REO) or as otherwise designated by the Director, Research & Innovation Advancement.

RESPONSIBILITY

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

IMPLEMENTATION and PROCESSES

The IWK REB Chair is the signing authority for documents related to REB review and approval of research under the jurisdiction of the IWK Health Centre. Although the Chair may delegate this authority to the REB members or staff with the skill and knowledge necessary to effectively exercise this authority, responsibility for oversight remains with the Chair.

- The Chair may delegate signing authority to REB members or REO staff with the skill and knowledge necessary to effectively exercise the authority
- The Chair may not delegate his/her signing authority to consultants or independent contractors

- The Chair may delegate signing authority indefinitely, or for defined periods of time (e.g., for absences)
- Delegation of signing authority must be made in writing and kept on file in the REO
- Any letters, memos, or e-mails between the REB and or REO and investigators that provide information concerning the review of research (e.g., requests for consent form changes, requests for additional information, renewal reminder notices) and that do not grant or appear to grant approval of the research, may be signed by the appropriate REO staff member as delegated by the REB Chair
- Individuals sending letters, memos or emails to investigators must sign their own name using either manual or electronic instruments
- Unless authorizing signature by the VP Research is required, the REB Chair, Manager or designee signs all correspondence to federal government agencies (Health Canada, FDA) and funding agencies or sponsors as applicable

Note: US regulations will be applied as applicable.

REFERENCES:

1. Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical conduct for Research Involving Humans, 2018: (short name: TCPS 2), Article 6.17
2. The International Conference on Harmonization Guidelines for Good Clinical Practice, Section 3
3. US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.103, 46.115
4. US Food and Drug Administration (FDA) Code of Federal Regulations Title 21 Part 56.108,56.115.

Forms/Records:

Form #	Form/Record Name
SOP 204	Authorized Signatory / Signing Authority

Revision History:

Revision	Date	Description of changes
0.0	April 1, 2017	Initial Release
1.0	September 8, 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)