



IWK Health

**IWK Research Ethics
Standard Operating Procedures**

Document # RE 8.802	Title: Signature Page (new projects and amendments)	Effective Date: November 19, 2024
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PURPOSE

The purpose of this standard operating procedure (SOP) is to outline when the Research Ethics Board (REB) requires the signature page.

DEFINITIONS

See Glossary of Terms.

RESPONSIBILITY

This SOP applies to the IWK research community (including employees, investigators, physicians, management, consultants, students, volunteers or other personnel) involved in conducting research with human subjects.

PROCEDURES

What is meant by “signature page”?

The signature page is a mandatory component for all projects, ensuring that individuals listed on the project are aware of their involvement and have agreed to participate.

Background/Rationale

The requirement for a signature page ensures that all individuals are knowledgeable of, and actively involved in, all aspects of the research project from execution to publication.

When is the signature page needed?

New applications

- The signature page must be completed for all new applications submitted to the REB for review and signed by the PI, CO-PI, co-investigators and research coordinators, research managers, administrative coordinators.

Amendments

- The signature page for amendments must be completed and signed by the PI. The substitution of an email from the PI approving the changes is permitted. The email must outline the changes made and approved by the PI.
- Include the event reference number when completing the form.
- For studies where the IWK is a site the lead investigator/sponsor must also provide support of the amendment. This support can be indicated by a signature on the provided template or through email correspondence outlining the requested changes from the lead site or sponsor.

Note: US regulations will be applied as applicable.

DEFINITIONS

Delegation Log – A comprehensive list of study staff members and the duties that have been delegated to them by the Principal Investigator.

Principal Investigator (PI) - The person responsible for the conduct of a research study at IWK Health.

Researchers - Anyone who conducts research activities falling under the jurisdiction of the IWK Research Ethics Board.

REFERENCES

TCPS2 [Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS 2 \(2022\) – Glossary \(ethics.gc.ca\)](#)

Revision History:

Revision	Date	Description of changes
0.0		Initial Release
1.0		