IWK Research Ethics
Standard Operating Procedures

Document # **RE 1.105**	Title: **SOP Policy Development and Maintenance**	Effective Date: **February 1, 2023**
Pages**: 3**	Responsibility of: **Research Ethics Board**	Date Approved: **February 1, 2023**

POLICY STATEMENT

These SOPs have been written in compliance with the principles outlined in the Tri-Council Policy Statement. If there are any discrepancies between the national standards and an SOP, the national standards shall prevail.

Written SOPs provide the framework to promote ethical standards in the review, oversight and conduct of research involving human subjects and/or human materials. SOPs describe the processes that must be followed and documented to assure that the rights and welfare of the human subjects of such research are overseen and protected in a uniform manner.

DEFINITIONS

See Glossary of Terms

RESPONSIBILITY

This SOP applies to all REB members, Manager, and REO staff. The Manager (or designee) is responsible for coordinating the development, review and revision of the SOPs. The Manager and REB Chair are jointly responsible for granting final SOP approval.

PROCEDURES

Documentation of the SOP system

Each REB SOP shall use the current SOP as a template and shall contain the following:

- Version control
- Effective date
- Approved by: signature
- Purpose, Policy Statement, Definitions, Responsibilities, Procedures, References

Generating a SOP

Each SOP will be identified by a number. The number format follows the sequence:

- The letters REB, followed by the letters SOP, followed by the section number, followed by the SOP

number and version date (i.e. REB SOP 1.101). For revisions to previous SOPs, the version date must be revised. This new version supersedes any previous versions
- For an original SOP, the original issue date will be recorded in the header. For subsequent SOPs, the version date will be recorded in the header
- A Historical Record will be maintained for each SOP, consisting of a table documenting nature and dates of amendments and periodic reviews

Editing/Backup/Archiving
Original pages and Historical Record pages are printed on coloured paper and stored in SOP binders maintained in the Research Ethics Office, and the updated pages are inserted in the SOP binder. Current SOP files are stored in the Research & Innovation Advancement directory that is backed up nightly by the IWK Health Centre IT Department.

SOP Review Cycle
All SOPs shall be reviewed every 2 years, or more frequently as required.

SOP amendments may be triggered by changes in, applicable regulations or guidance documents; new policies determined by the REB; and changes in REB or REO administrative practices. The Manager or designee will execute such amendments.

SOP Communication
The Manager is responsible for ensuring new or revised SOPs are tabled for REB attention and approval and will provide notice of the changes to all individuals affected by them.

REO staff will ensure that all REB members are provided with a copy of any new or revised SOP.

SOP Training
REB Members and REO Staff should read applicable SOPs at least every 2 years or less if revisions or new SOPs are made.

Training will be provided to all members of the REBs and REO staff for any new or revised policy or relevant procedure as applicable.

Each new REB member must review all applicable SOPs prior to undertaking their responsibilities as an REB member.

Each new REO employee must review all applicable SOPs within the first month of undertaking their responsibilities with the REO.

The REO shall maintain all documentation of training in the SOP training record.

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);
2. International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines as adopted by Health Canada;
3. Health Canada Therapeutic Products Directorate Food and Drug Regulations for Clinical Trials, Division 5;
4. US Food and Drug Administration (FDA) Code of Federal Regulations (CFR), Title 21, Parts 56.108, 56.115;
5. US Department of Health and Human Services (HHS) CFR Title 45 Part 46.103, 46.108.

Forms/Records:

Form #	Form/Record Name
SOP 105	SOP Policy Development and Maintenance

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