IWK Research Ethics
Standard Operating Procedures

Document # **RE 3.303**	Title: **REB Documentation and Document Management**	Effective Date: **November 19, 2024**
Pages**: 4**	Responsibility of: **Research & Innovation Advancement**	Date Approved: **November 19, 2024**

POLICY STATEMENT

The Research Ethics Office will retain all relevant records (e.g., documents reviewed and approved or rejected, meeting minutes, correspondence with investigators, written SOPs, membership lists) to provide a complete history of all actions related to REB activities respecting review, approval and oversight of submitted research. Relevant records will accessible to those with a legitimate interest (e.g., authorized regulatory authorities, investigators, and funding agencies).

DEFINITIONS

See Glossary of Terms

RESPONSIBILITY

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

PROCEDURES

Confidentiality

All application documents and associated materials are classified as 'Confidential' and will be managed accordingly, with access limited to REB Members and REO Staff. Third parties with a need-to-know case may be allowed access on specific request to the Chair or Manager.

Study-Related Documents

- Upon receipt of an initial electronic application, REO staff will review the file to ensure all study related documentation has been included
- The investigators and REO staff will add any application-related documents received throughout the course of the research project to this electronic file

- The electronic application file will be retained as a permanent record regardless of whether the research is approved
- Documents so retained may include, but are not limited to, the following:
    - Research protocol
    - Investigator brochures or product monographs
    - Participant recruitment materials
    - Survey instruments and questionnaires
    - Consent documents
    - Scientific evaluations
    - Research budgets
    - Health Canada No Objection Letters
    - Correspondence between the REB and the Investigator,
    - Records of ongoing review activities such as: reports of unanticipated problems involving risks to participants and others, including reports of local serious adverse events, amendments or modifications to the research protocol, reported significant deviations from the research protocol, reports of significant new findings provided to participants, monitoring reports
    - Progress reports and study completion reports
    - Copies of correspondence between the REB and regulatory agencies
    - Reports of any complaints received from research participants or regulatory agencies, and their resolution

REB Retention Period (Application/Project file)

The REB must retain all records of individual project or protocol applications (regardless of whether they are approved) for at least five years and for twenty-five years if the project is subject to Health Canada regulations (i.e. a drug, device or natural health product clinical trial). For all other applications in which the research is initiated, the REB must retain the records for at least five years after completion of the research or termination of REB approval.

The REO maintains a permanent record of all Research Ethics Board administrative documents, including but are not limited to, the following:

- Agendas and minutes of all REB meetings
- Submitted REB member reviews/reports
- REB member records
- Current and archived membership lists
- Curricula Vitae and training records (as applicable) of current and past REB members
- Signed Conflict of Interest and Confidentiality Agreements
- Current and archived Standard Operating Procedures
- Current and archived documentation of the REB Chair's delegations of authority, responsibilities or specific functions
- Records of registration of the REB with the US Office of Human Research Protection

Research Data Retention

- All records relating to a specific application/project will be retained by the Principle Investigator for a minimum period according to the category of research:
    - Drug Trials: Regulated Trials: Health Canada Division 5 regulations (Drugs for Clinical Trials Involving Human Subjects) stipulate that the Sponsor or Investigator shall maintain all records referred to in the regulations for a period of 25 years.
    - Drug Trials: Regulated Trials: IWK policy stipulates that the Investigator shall maintain all records referred to in the regulations for a period of 25 years or 10 years past the age of majority.
    - Non-intervention Trials: The investigator shall maintain all records referred to in the regulations for a period of 5 years.

Document Storage

- Physical (paper) files associated with active research will be stored securely within the REO office in the IWK Health Centre, where they will be readily available to REB Members and REO Staff
- Physical files for closed projects will be archived in a secure off-site facility for the balance of the required retention period specified above
- Electronic files will be secured, backed-up, and managed according to IWK Health Centre Information Technology policies and procedures

(See Documentation and Document Management REB SOP 3.301)

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), 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 56.103, 56.108,56.115.
5. Health Canada Guidance for Records related to Clinical Trials (Article 6.2)

Forms/Records:

Form #	Form/Record Name
SOP 303	REB Documentation and Document Management

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	Update to clarify IWK record retention policy, added note regarding compliance with US regulations where applicable & update to responsibility (RIA)