RA0500 – RESEARCH ETHICS BOARD RECORDS MANAGEMENT

Interior Health would like to recognize and acknowledge the traditional, ancestral, and unceded territories of the Dãkelh Dené, Ktunaxa, Nlaka'pamux, Secwépemc, St'át'imc, Syilx, and Tŝilhqot'in Nations, where we live, learn, collaborate and work together.

Interior Health recognizes that diversity in the workplace shapes values, attitudes, expectations, perception of self and others and in turn impacts behaviors in the workplace. The dimensions of a diverse workplace includes the protected characteristics under the human rights code of: race, color, ancestry, place of origin, political belief, religion, marital status, family status, physical disability, mental disability, sex, sexual orientation, gender identity or expression, age, criminal or summary conviction unrelated to employment.

1.0 PURPOSE

To describe requirements for the maintenance, retention, and archiving of Records related to the ethical review of research projects and the operations of the Interior Health (IH) Research Ethics Board (REB). To ensure compliance with regulatory and institutional requirements.

2.0 DEFINITIONS

TERM	DEFINITION
Record	Information created, received and maintained as evidence by an organization or person in the transaction of business, or in the pursuance of legal obligations, regardless of media.
RISe File	RISe is the Research Information System electronic platform housed at the University of British Columbia and used for REB review of all research in British Columbia (BC) involving two or more Research Ethics BC (REBC) partner institutions.

3.0 POLICY

3.1 The REB will retain all relevant Records to provide a complete history of all actions related to REB review and approval of submitted research. Such Records will be retained for the length of time required by applicable regulations and IH policy.

3.2 The REB retains the submission materials for all research projects that have been submitted for REB review via the IH application process on a secure IH server. All studies undergoing harmonized (multi-jurisdictional) review have a RISe File associated with them. The RISe File is the permanent Record for those research projects.

3.3 Research related documents include, but are not limited to, the following (as applicable):

3.3.1 REB initial application form and all associated documents;

3.3.2 Correspondence between the REB and the researcher, including REB approval certificates;

3.3.3 Written reviews of applications for ethical approval completed by REB members;

3.3.4 Records of ongoing review activities such as: Reportable event submissions, including reports of significant new findings, Data and Safety Monitoring Board (DSMB) reports, interim analysis reports, local adverse events and reported non-local (external) adverse events, research protocol deviations, and privacy breaches;

3.3.5 Any investigations into allegations of serious or continuing non-compliance;

3.3.6 Continuing Review applications;

3.3.7 Correspondence between the REB and regulatory agencies;

3.3.8 Reports of any complaints received by the REB and their resolution.

3.4 The REB retains all administrative Records related to REB review activities. REB administrative documents include, but are not limited to, the following:

3.4.1 Agendas and minutes of all REB meetings;

3.4.2 REB member Records including current and obsolete REB membership rosters, CVs and training/qualification documentation of current and past REB members;

3.4.3 Signed conflict of interest and confidentiality agreements;

3.4.4 Current and obsolete policies and standard operating procedures (SOPs);

3.4.5 Current and obsolete documentation of the REB Chair or designee's delegation of authority, responsibilities, or specific functions;

3.4.6 Records of registration of the REB with the US Office of Human Research Protections (Federal Wide Assurance Program), and REB membership updates.

3.5 Research project documents and REB administration Records are considered confidential and will be distributed to authorized persons only. Following approval of any research project, REB members will be asked to securely delete all electronic documents from their files.

3.6 Relevant Records will be made accessible to authorized regulatory authorities, researchers and funding agencies within a reasonable time upon request. Access by other parties will be only with the express permission of the Data Steward or where authorized under statute.

3.7 All Records must be clearly labelled and filed.

3.8 Only authorized REB staff will destroy Records pertaining to the ethical review of research and the administration of the REB.

3.9 Records pertaining to the ethical review of research projects will be retained as described in AL0700 Records - Retention, Storage and Destruction of..

3.10 Storage:

3.10.1 Records that are not stored automatically in RISe will be stored electronically on the IH network in a secure drive and accessed by authorized REB staff only, using a password.

3.10.2 Paper Records have been securely archived off-site with Iron Mountain.

3.10.3 New Records are created electronically. Should a new Record only exist in hard copy, it will be scanned into a secure electronic folder at the earliest opportunity.

3.11 REB staff must ensure confidential destruction of Records that have been kept beyond the required retention limits as well as confidential documents that are not covered under these retention requirements. Records will be destroyed

according to IH policy *AL0700 Records – Retention, Storage and Destruction Of*.

4.0 PROCEDURES

4.1 The Research Ethics Board Coordinator establishes and maintains a file for each research study that is not house in RISe. The IH file will include as appropriate:

4.1.1 Initial REB Application Form and all attachments;

4.1.2 Records of ethical review and REB decisions;

4.1.3 PI Response to Provisos;

4.1.4 Correspondence between the REB and the researcher, including approval certificates;

4.1.5 Budget pages of the Clinical Trial Agreement, Sub-site agreement, or other contract pertaining to the research;

4.1.6 Privacy Impact Assessment;

4.1.7 Records of continuing ethics review activities including: requests for renewal; requests for amendment; protocol deviations, safety reports; reports of unanticipated problems; completion reports; and all related documentation;

4.1.8 Correspondence between the REB and regulatory agencies;

4.1.9 Statements of significant new findings provided to participants, as required by regulation;

4.1.10 Reports of any complaints received from participants, regulatory agencies and their resolution.

4.2 Electronic Records are stored on a password-protected secure drive on the IH network with authorized access only.

4.3 Electronic tracking tools are maintained to track progress of reviews and approvals of all research projects submitted for ethics review.

4.4 The REB Coordinator establishes and maintains files for documents pertaining to the operations of the REB including:

4.4.1 Agendas and minutes of each REB meeting, recorded as per policy RA0400 Research Ethics Board Meeting Administration.

4.4.2 REB membership list showing the REB members' name, sex and representative capacity, in compliance with regulatory requirements. This list must be submitted to the Office for Human Research Protections (OHRP) to maintain Federal Wide Assurances of IH. Any changes in institutional signatory official or Chair must be reported to OHRP to maintain Federal Wide Assurances of IH. *Note: This list is posted on the IH REB website and all investigators of clinical trials must retain a copy with their trial documents and make it available to clinical trial sponsors.*

4.4.3 The *REB Terms of Reference*. The Terms of Reference are reviewed at least every three years by the REB and recommendations for revision are forwarded to the President & CEO and IH Board of Directors.

4.4.4 A REB member file is established for each member of the REB and includes qualifications, education and training Records, and letters of appointment.

4.4.5 All REB policies and Standard Operating Procedure documents are developed and maintained by the REB staff.

5.0 REFERENCES

Canadian Association of Research Ethics Boards and N2 Network of Networks. (2023). Standard Operating Procedure 303.003: *Document Management*.

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*, December2022.

Health Canada, Food and Drug Regulations, Part C, Division 5, *Drugs for Clinical Trials Involving Human Subjects.* September 27, 2022.

Interior Health. (2022). Administrative Policy Manual: AL0700 Records - Retention, Storage and Destruction of.

Interior Health. (2023). *Research Ethics Board, Terms of Reference*.

Interior Health. (2021). Research Policy Manual: RA0400 Research Ethics Board Meeting Administration.

International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), ICH Harmonized Guideline, Integrated Addendum to ICH E6(R1); *Guideline for Good Clinical Practice*, E6(R2), November 9, 2016.

UBC Office of Research Ethics. (2022). Standard Operating Procedure 304: *Documentation and Document Management*.

US Department of Health and Human Services, Code of Federal Regulations, Title 45, Part 46, Protection of Human Subjects (45CFR46, Subpart E).

US Food and Drug Administration Code of Federal Regulations, Title 21, Volume 1:

- Part 56, Institutional Review Boards, (21CFR56, Subpart D).

**This policy replaces the following policy which is no longer active:

IH REB Policy: *B0700 – Record Keeping* approved March 6, 2008.