Title	Document Management
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1 PURPOSE

This standard operating procedure (SOP) describes the requirements for document management, including document retention and document archiving. This SOP applies to documents submitted to the Research Ethics Board (REB) for initial or continuing review, as well as to all REB administrative documents.

2 SCOPE

This SOP pertains to REBs that review human participant research in compliance with applicable regulations and guidelines.

3 RESPONSIBILITIES

All REB members and designated REB staff are responsible for ensuring that the requirements of this SOP are met.

4 DEFINITIONS

See Glossary of Terms.

5 PROCEDURES

The REB office must retain all relevant records[1] (e.g. all documents related to submitted research projects, REB meeting minutes, correspondence with Researchers, SOPs, REB membership rosters, etc.) to provide a complete history of all actions related to REB activities. Such records must be retained for the length of time required by applicable regulations and guidelines.

Relevant records must be made accessible to authorized regulatory authorities, representatives of the Board of Directors of the institution, Researchers and funding agencies within a reasonable time upon request.

5.1 Research Files

5.1.1 Research files include, but are not limited to, the following (as applicable):

- Requests for initial and continuing REB review and all associated attachments,
- Correspondence between the REB and the Researcher,
- REB approval letters,
- Reports of any complaints managed by the REB regarding a particular research project.

[1] *Plan d'action ministériel en éthique de la recherche et en intégrité scientifique, Gouvernement du Québec, Ministère de la Santé et des Services sociaux*, June 1998, hereafter "PAM", measure 5; ICH Harmonised Tripartite Guideline – Guidelines for Good Clinical Practice E6(R1), Health Canada, 1997, hereafter "ICH GCP", s. 3.4; Operational Guidelines for Ethics Committees that Review Biomedical Research, World Health Organization (WHO), 2000, hereafter "TDR", s. 10; *Modèle de règles de fonctionnement d'un comité d'éthique de la recherche*, Ministère de la Santé et des Services sociaux, DGAERA, 2004, hereafter "*Modèle*", s. 14.1; 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, December 2014, hereafter "TCPS2", art. 6.17.

5.2 REB Administrative Documents

5.2.1 REB administrative documents include, but are not limited to, the following:

- Agendas and minutes of all REB meetings,
- Submitted REB member reviews,
- REB member records:
  - Current and obsolete REB membership rosters,
  - CVs and training/qualification documentation of current and past REB members,
- Signed conflict of interest and confidentiality agreements,
- Current and obsolete documentation of the REB Chair or designee's delegation of authority, responsibilities, or specific functions,
- REB working notes,
- REB correspondence,
- REB internal memos,
- REB annual reports,
- Records of registration of the REB and the institution with the US Office of Human Research Protection and Federalwide Assurance, as well as REB membership updates.

5.3 Document Confidentiality

5.3.1 All research files held by the REB are considered confidential;

5.3.2 The following REB information and administrative documents are considered confidential:

- Agendas and minutes of all REB meetings,
- Assessments made by REB members,
- Current and obsolete documentation of the REB Chair or designee's delegation of authority, responsibilities, or specific functions,
- REB correspondence, including discussions on Nagano,
- REB internal memos,
- REB annual reports,
- Names of individuals assessing the research or, if applicable, constituting the quorum,
- Conflict of interest statements.

5.4 Access to Documents[2]

5.4.1 Research Files

- All individuals working for the REB may access research files when required in the performance of their duties,
- Individuals responsible for assessing institutional suitability as well as the person formally mandated to authorize the research have access to research files as provided by the terms of the institutional regulatory framework,
- All other individuals must communicate with the Principal Investigator for access to research files;

5.4.2 REB Administrative Documents

- Individuals may access REB administrative documents, as follows:
  - Everyone: SOPs and REB procedures and policy statements,
  - Researchers: up to date REB membership listings that specify member qualifications (profession and professional affiliations) and role; true copies of excerpts from the REB minutes relevant to the research project,
  - Sponsors or funding agencies or regulatory authorities: up to date REB membership listings that specify member qualifications (profession and professional affiliations) and role,
  - Representatives of Board of Directors: all REB files;

5.4.3 Anyone with access to confidential REB records is subject to the duty of confidentiality.[3]

5.5 Document Storage and Archiving

5.5.1 REB records are securely housed in locked premises. Back-up and recovery systems are in place;

5.5.2 The REB will maintain all research-related materials submitted for REB review, whether they were approved, rejected, or stamped as received[4];

5.5.3 The REB will maintain all administrative documents related to REB assessment activities[5];

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2 *Modèle*, s. 14.3; ICH GCP, s. 3.4.
3 *Modèle*, s. 14.3.
4 *Modèle*, s. 14.4.3; PAM, measure 5; TDR, 10.7 to 10.12; TCPS2, art. 6.17.
5 ICH GCP, s. 3.4; TDR, 10.1 to 10.6; *Modèle*, s. 14.1; TCPS2, p. 85.

5.5.4 Files will be kept for[6]:

- 25 years, for research files related to research regulated by Health Canada,
- 7 years or more, according to local requirements, for research files related to all other research,
- 25 years after the date of the last REB research assessment, for REB administrative documents.

5.6 Document Destruction

5.6.1 At the end of the storage period, all documents will be destroyed according to the policies of the institution.

6 REFERENCES

See footnotes.

7 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
REB-SOP 303.001	2020-03-20	Original version

8 APPENDICES

[6] ICH GCP, s. 3.4; TDR, 10; *Modèle*, s. 14.4.3.