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THE UNIVERSITY OF BRITISH COLUMBIA

SOP 304

TITLE	**304: Documentation and Document Management**
SCOPE	The activities of the Research Ethics Boards operating under the direct authority of the University of British Columbia
RESPONSIBILITIES	The Vice-President, Research & Innovation, delegated to the Director, Research Ethics, all Research Ethics Board (REB) Chairs and members and all REB Office Personnel
APPROVAL AUTHORITY	The Vice-President, Research & Innovation
EFFECTIVE DATE	May 2018
Supersedes documents dated	May 2011; April 2009; July 2003

1.0 PURPOSE

The purpose of this standard operating procedure (SOP) is to describe the requirements for document management, including document retention and document archiving. This SOP applies to documents submitted to the REB for initial or for continuing review, as well as to all REB administrative documents.

2.0 DEFINITIONS

See the Glossary of Terms.

3.0 PROCEDURE

The REB office must retain REB files in a manner that contains a complete history of all REB actions related to review and approval of a protocol, including scientific reviews, approved sample consent documents, progress reports submitted by Researchers, and reports of injuries to participants[1]. The REB office must also retain all relevant records respecting REB activities,

including minutes as described in UBC REB SOP 302, records of continuing review activities, copies of all correspondence between the REB and Researchers, REB membership lists as described in UBC REB SOP 202, and written procedures relating to review and reporting (as described in UBC SOPs 404 and 408), and statements of significant new findings. Such records must be retained for the length of time required by applicable regulations and guidelines[2].

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

3.1 Research-Related Documents

3.1.1 The REB office retains the submission materials for all research that have been submitted for REB review and have been either approved, acknowledged or disapproved;

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

- Signed REB initial application form and all associated attachments;
- Correspondence between the REB and the Researcher, including REB approval letters, requests for modifications, etc.;
- 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 non-local (external) adverse events, research deviations, privacy breaches, any investigations into allegations of serious or continuing non-compliance, and reports of inspections and audits by regulatory agencies or others,
    - Modifications to the application including amendments to the research and/or any changes to the consent(s), participant materials or Investigator Brochures;
- Continuing review applications;
- Copies of correspondence between the REB and regulatory agencies;
- Reports of any complaints received by the REB and their resolution.

3.2 REB Administrative Documents

3.2.1 The REB office retains all administrative records related to the REB review activities;

3.2.2 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, including alternate REB members,
    - CVs and training/qualification documentation of current and past REB members;
- Signed conflict of interest and confidentiality agreements;
- Current and obsolete SOPs;
- Current and obsolete documentation of the REB Chair or designee's delegation of authority, responsibilities, or specific functions;
- Records of registration of the REB with the US Office of Human Research Protection (OHRP) and REB membership updates;
    - The roster of REB members must be submitted to the Office for Human Research Protections to maintain the Federal Wide Assurances of the University of British Columbia. Any changes in REB membership must be reported to the OHRP[3].

3.3 Document Access, Storage and Archiving

3.3.1 Access to individual research projects and related documents, and to University and Researcher profiles, is role-based in the RISe online system to ensure that users only have access to documents and activities that are required by their role;

3.3.2 The REB records are housed securely with back-up, disaster and recovery systems in place.

3.4 Confidentiality and Document Destruction

3.4.1 All submissions received by the REB are considered confidential and are accessible only to REB members (including the REB Chair and Co-Chair), as well as to the organizational official(s) and the REB Office Personnel;

3.4.2 Relevant research projects and associated documents may be made accessible to other organizational officials, as well as to sponsor or CRO representatives, if the Researcher or his/her research team submits a request for guest access to the research;

3.4.3 Relevant research projects and associated documents may be made accessible to members of regulatory agencies, or representatives of the sponsor or Researcher for review. Access is limited to the applicable research and research-related submissions;

3.4.4 The REB will retain required records (e.g., research-related or REB administrative documents, as applicable) for a minimum of 3 years after completion/termination of the

trial, or for the maximum amount of time stipulated in any applicable governing regulation(s) e.g., 25 years for Health Canada regulated research[4];

3.4.5 Any confidential materials in paper format in excess of the required documentation will be shredded.

4.0 REFERENCES

1. *Health Canada Food and Drug Regulations, Part C, Division 5, Drugs for Clinical Trials Involving Human Subjects* (Schedule 1024):
https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/clinical-trials/links.html

2. *Health Canada Natural and Non-prescription Health Products Directorate, Part 4:*
https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/legislation-guidelines/guidance-documents/clinical-trials.html#a4.0
Health Canada Guidance for Industry, Good Clinical Practice: Consolidated Guideline, ICH Topic E6, 1997, Section 3.4:
https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/efficacy/guidance-document-good-clinical-practice-integrated-addendum-e6-r1-topic-e6-r2.html#a3.4

U.S. Department of Health and Human Services – Title 45 Code of Federal Regulations Part 46 (45 CFR 46.115):
https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.115

U.S. Department of Health and Human Services – Title 21 Code of Federal Regulations Part 56 (21 CFR 56.115):
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=56.115

3. *U.S. Department of Health and Human Services – Title 45 Code of Federal Regulations Part 46* (45 CFR 46.103(b)(3))
https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.103

U.S. Department of Health and Human Services – Title 21 Code of Federal Regulations Part 56 (21 CFR 56.115(5)):
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=56.115

4. *Health Canada Food and Drug Act Regulations Part C – Division 5*, C.05.012:
http://laws-lois.justice.gc.ca/eng/regulations/c.r.c.,_c._870/page-129.html#h-267

Health Canada Guidance for Records related to Clinical Trials, Article 6.2:
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-clinical-practices/guidance-documents/guidance-records-related-clinical-trials-guide-0068.html#a62