SOP Title	Document Management
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Approvals

Name and Title of Signatories	Signature	Date mm/dd/yyyy
Erika Basile Director, Research Ethics and Compliance		Oct 1, 2021
Dr. Philip Jones Chair, Health Sciences Research Ethics Board		Oct 1, 2021

1. PURPOSE

The purpose of this standard operating procedure (SOP) is to describe the requirements for document management, including document retention and archiving. This SOP applies to documents submitted to and reviewed by the Health Science Research Ethics Board (HSREB), as well as HSREB administrative documents.

2. GENERAL POLICY STATEMENT

The Office of Human Research Ethics (OHRE) must 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 HSREB review, approval and oversight of submitted research. Such records must be retained securely as per Part C Division 5 of the Food and Drug Regulations of Health Canada.

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

3. RESPONSIBILITY

This SOP applies to the HSREB Chair, Vice-Chair(s), HSREB members, and Office of Human Research Ethics (OHRE) staff.

The OHRE staff is responsible for maintaining complete files on all research submitted to and reviewed by the HSREB, and for maintaining administrative documents related to such research (e.g., agendas, minutes, correspondence).

The Director or designee is responsible for retention and archiving of the HSREB files.

The HSREB Chair, HSREB members, and OHRE staff, are responsible for maintaining the confidentiality of the HSREB files.

4. DEFINITIONS

See Glossary of Terms.

5. SPECIFIC POLICIES AND PROCEDURES.

5.1. Study-Related Documents

5.1.1 The current system of record is ROMEO.

5.1.2 Upon receipt of an initial submission, the OHRE Administrative Assistant creates a research project-specific file;

5.1.3 The OHRE retains records of the research submitted for HSREB review - regardless of whether the research is approved - as per Part C Division 5 of the Food and Drug Regulations of Health Canada regulations;

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

- HSREB application forms,
- Research protocol,
- Scientific evaluations,
- Investigator brochures or product monographs,
- Participant recruitment materials, survey instruments and questionnaires,
- Approved consent documents,
- Research budgets,
- Health Canada No Objection Letters,
- Correspondence between the HSREB 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 HSREB and regulatory agencies;
- Reports of any complaints received from research participants or regulatory agencies, and their resolution.

5.2. **HSREB Administrative Document**

5.2.1. The OHRE retains all administrative records related to the HSREB review activities as per Part C Division 5 of the Food and Drug Regulations of Health Canada;

5.2.2. HSREB administrative documents that are retained include, but are not limited to, the following:

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

5.3. **Document Access, Storage and Archiving**

5.3.1. Access to individual research projects and related documents, is role-based to ensure that users only have access to documents and activities that are required by their role;

5.3.2. Closed research project files are barcoded and archived at the University of Western Ontario's Archives and Research Collections Centre (ARCC);

5.3.3. The HSREB records are housed securely with back up, disaster and recovery systems in place.

5.4. **Confidentiality and Document Destruction**

5.4.1. All materials received by the HSREB are considered confidential and are distributed only to HSREB members, consultants (as appropriate), HSREB Chair, Vice-Chair(s), and OHRE staff;

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

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

5.4.4. 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;

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

6. REFERENCES

6.1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2010 (TCPS2), Article 6.17;
6.2. The International Conference on Harmonization Guidelines for Good Clinical Practice, Section 3.4;
6.3. US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.103, 46.115;
6.4. US Food and Drug Administration (FDA) Code of Federal Regulations Title 21 Part 56.115;
6.5. OHRP Guidance on Written IRB Procedures;
6.6. FDA Information Sheets

7. SOP HISTORY

SOP Number.Version	Key Changes	Effective Date mm/dd/yyyy
303.001	Original	01/22/2014
303.002	Revisions to section 5.4	10/24/2014
303.003	Minor Administrative Changes	05/11/2016
303.004	5.3.1: Revised to state that access to individual research projects and related documents, and to center and Researcher profiles is role-based to ensure that users only	06/15/2016

	have access to documents and activities that are required by their role; 5.3.2: Updated University name to Western University; 5.3.3: Revise to state that the HSREB records are housed securely with back up, disaster and recovery systems in place.	
303.005	Minor Administrative Changes	09/06/2018
303.006	Minor Administrative Changes	02/21/2020