TRINITY WESTERN UNIVERSITY

SOP 303

TITLE	**303: Document Management**
SCOPE	The activities of the Human Research Ethics Board operating under the direct authority of Trinity Western University
RESPONSIBILITIES	The Vice-Provost, Research & Graduate Studies, all Human Research Ethics Board (HREB) members, including the Chair(s) and Coordinator
APPROVAL AUTHORITY	The Vice-Provost, Research & Graduate Studies
EFFECTIVE DATE	November 14, 2019
Supersedes documents dated	N/A

1.0 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 Human Research Ethics Board (HREB) for initial or for continuing review, as well as to all HREB administrative documents.

2.0 DEFINITIONS

See Glossary of Terms.

3.0 PROCEDURE

The HREB office must retain all relevant records (e.g., documents reviewed and approved or disapproved, HREB meeting minutes, correspondence with Researchers, written SOPs, HREB membership rosters) to provide a complete history of all actions related to the HREB review and approval of submitted research. 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 organizations, Researchers and funding agencies within a reasonable time upon request.

3.1 Research-Related Documents

3.1.1 The HREB office retains the submission materials for all research that have been submitted for HREB 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 HREB initial application form and all associated attachments;
- Correspondence between the HREB and the Researcher, including HREB 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 HREB and regulatory agencies;
- Reports of any complaints received by the HREB and their resolution.

3.2 HREB Administrative Documents

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

3.2.2 HREB administrative documents include, but are not limited to, the following:

- Agendas and minutes of all HREB meetings;
- Submitted HREB member reviews;
- HREB member records:
    - Current and obsolete HREB membership rosters, including alternate HREB members,
    - CVs and training/qualification documentation of current and past HREB members;
- Signed conflict of interest and confidentiality agreements;
- Current and obsolete SOPs;
- Current and obsolete documentation of the HREB Chair or designee's delegation of authority, responsibilities, or specific functions;
- Records of registration of the HREB with the US Office of Human Research Protection, if applicable, and HREB membership updates.

3.3 Document Access, Storage and Archiving

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

3.3.2 The HREB 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 HREB are considered confidential and are accessible only to HREB members (including the HREB Chair and Vice-Chair), as well as to the organizational official(s) and the HREB 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 HREB will retain required records (e.g., research-related or HREB 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;

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

4.0 REFERENCES

See References.

5.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP 303	November 14, 2019	Original version