SOP Title	Document Management
Number.Version	N303.002
Effective Date	05/11/2018

Approvals

Name and Title of Signatories	Signature	Date mm/dd/yyyy
Erika Basile Director, Research Ethics		
Dr. Randal Graham Chair, Non-Medical Research Ethics Board		

1. PURPOSE

The purpose of this standard operating procedure (SOP) is to describe the requirements for docu management, including document retention and archiving. This SOP applies to documents subm and reviewed by the Non-Medical Research Ethics Board (NMREB), as well as NMREB administrative documents.

2. GENERAL POLICY STATEMENT

The Office of Human Research Ethics (OHRE) must retain all relevant records (e.g., documents revie and approved or rejected, meeting minutes, correspondence with investigators, written SOPs, me lists) to provide a complete history of all actions related to NMREB review, approval and oversight of submitted research. Such records must be retained securely.

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

3. RESPONSIBILITY

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

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

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

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

4. DEFINITIONS

See Glossary of Terms.

5. SPECIFIC POLICIES AND PROCEDURES.

5.1. Study-Related Documents

5.3.2. Previous hard copy files that are closed are barcoded and archived at the University of Archives and Research Collections Centre (ARCC);

5.3.3. The NMREB 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 NMREB are considered confidential and are distributed only to NMREB members, consultants (as appropriate), NMREB Chair, Vice-Chair(s), as well as organizational official(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 guest 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 NMREB will retain required records (e.g., research related or NMREB 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).

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. US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.103, 46.115;

6.3. OHRP Guidance on Written IRB Procedures;

7. SOP HISTORY

SOP Number.Version	Key Changes	Effective Date mm/dd/yyyy
303.001	Original	07/07/2016
303.002	Update to NMREB Chair and online submission system	05/11/2018