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

Approvals

| Name and Title of Signatories | Signature | Date mm/dd/yyyy |
|---|---|----------------------------|
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| Dr. Randal Graham Chair, Non-Medical Research Ethics Board |  | 2019-03-06 |

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 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 reviewed and approved or rejected, meeting minutes, correspondence with investigators, written SOPs, membership 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 of the 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 reviewed by the NMREB, 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 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

- 5.1.1 The current system of record is Western Research Ethics Manager (WREM).
- 5.1.2 The OHRE retains records of the research submitted for NMREB review - regardless of whether the research is approved;
- 5.1.3 Research-related documents that are retained include, but are not limited to, the following (as applicable):

- NMREB application forms,
- Research protocol,
- Participant recruitment materials, survey instruments and questionnaires,
- Approved consent documents,
- Correspondence between the NMREB 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 NMREB and regulatory agencies;
- Reports of any complaints received from research participants or regulatory agencies, and their resolution.

5.2. NMREB Administrative Document

5.2.1. The OHRE retains all administrative records related to the NMREB review activities.

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

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

5.3.2. Previous hard copy files that are closed are barcoded and archived at the University of Western Ontario's 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 |