Section 300:	**Functions and Operations**
Title:	**Document Management**
SOP Code:	**303.001**
Effective Date:	**2015MAY25**

Site Approvals

Signature of Responsible Individual:		
Ethics Compliance Advisor	Name: Jennifer Couture	Date: 2015MAY22
Approval Authority:		
Chair, HSREB	Name: Dr. Albert Clark	Date: May 22, 2015
Approval Authority:		
Director, Research Ethics Compliance	Name: Dr. Andrew Winterborn	Date: May 22, 2015

1.0 PURPOSE

This SOP describes the requirements for electronic documentation and signatures, document management, including document retention and document archiving. This SOP applies to documents submitted to the HSREB for review, as well as to all HSREB administrative documents.

2.0 SCOPE

This SOP pertains to the HSREB that reviews human participant research in compliance with applicable regulations, guidelines and current and emerging best practices.

3.0 RESPONSIBILITIES

All HSREB members and HSREB Office Personnel are responsible for ensuring that the requirements of this SOP are met.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURES

The HSREB office must retain all relevant records (e.g., documents reviewed and cleared or not cleared, HSREB meeting minutes, correspondence with Researchers, written SOPs, HSREB membership rosters) to provide a complete history of all actions related to the HSREB review and clearance 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.

5.1 Research-Related Documents

5.1.1 The Office of Research Ethics retains the submission materials for all research that have been submitted for HSREB review and have been either cleared, acknowledged or not ethically cleared;

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

- Initial application form,
- Correspondence between the HSREB and the Researcher, including HSREB clearance 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,
    - Renewal applications,
- Copies of correspondence between the HSREB and regulatory agencies,
- Reports of any complaints received by the HSREB and their resolution.

5.2 HSREB Administrative Documents

5.2.1 The Office of Research Ethics retains all administrative records related to the HSREB review activities;

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

- Agendas and minutes of all HSREB meetings,
- Submitted HSREB member reviews,
- HSREB member records:
  - Current and obsolete HSREB membership rosters, including alternate HSREB members,
  - CVs and training/qualification documentation of current and past HSREB members,
  - HSREB membership appointment letters,
- Signed conflict of interest disclosure forms and confidentiality agreements,
- Current and obsolete SOPs,
- Current and obsolete documentation of the HSREB Chair or designee's delegation of authority, responsibilities, or specific functions,
- Records of registration of the HSREB with the US Office of Human Research Protection, if applicable, and HSREB membership updates,
- Submission deadlines, guidelines for submitting applications and all associated attachments/templates.

5.3 Document Access, Storage and Archiving

5.3.1 All electronic documents associated with HSREB ethics applications are housed in ROMEO, which is an online system that is accessible only to authorized individuals. Each user is provided with a unique user id and password in order to login to the system;

5.3.2 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;

5.3.3 System validation checks are conducted by Process Pathways to ensure the accuracy, reliability, and program consistency;

5.3.4 Secure, time stamped audit trails are in place to record the data and time of activities, which are identifiable by user;

5.3.5 The HSREB ROMEO and administrative electronic records are stored on Queen's University's local server with back-up, disaster and recovery systems in place. Access to electronic HSREB ROMEO and administrative files are accessible only to authorized individuals;

5.3.6 HSREB closed paper research files are securely stored in the Office of Research Ethics or archived with Iron Mountain, an off-site storage facility.

5.4 Electronic Signatures

5.4.1 All electronic signatures on documents include the printed name of the signer, the date/time the signature was executed and the meaning associated with the signature (i.e. review, clearance, responsibility, authorship, etc.);

5.4.2 All documents containing electronic signatures will be encrypted, to ensure the signatures cannot be excised, copied, transferred or manipulated;

5.4.3 Each electronic signature will be verified as an individual's electronic signature by the HSREB Office Personnel and it will be unique (i.e. not reused by, or reassigned to another individual);

5.4.4 All electronic signatures used on HSREB documentation are intended to be the legally binding equivalent of traditional handwritten signatures;

5.5 Confidentiality and Document Destruction

5.5.1 All submissions received by the HSREB are considered confidential and are accessible only to HSREB members (including the HSREB Chair and Vice-Chair), as well as to applicable Queen's University and/or Affiliated Teaching Hospital Official(s) and the HSREB Office Personnel;

5.5.2 Relevant research projects and associated documents may be made accessible to other Queen's University or Affiliated Teaching Hospital Official(s), 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;

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

5.5.4 The HSREB will retain required records (e.g., research-related or HSREB administrative documents, as applicable) for a minimum of 10 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 clinical trials and Health Canada regulated research);

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

5.6 Storage of Confidential Personal Identifying Information

5.6.1 Any information that is obtained by the HSREB that is confidential in nature and that can personally identify an individual (i.e. name and contact information of a complainant) will be kept securely on hard copy in the Office of Research Ethics. Any electronic copies of personally identifying information will be de-identified and stored electronically in a secure network drive with restricted access. In addition, a copy of the de-identified information will be attached to the ROMEO file within the secure electronic system.

6.0 REFERENCES

See References.

7.0 APPENDICES

None.

8.0 REVISION HISTORY

SOP Title	Version	Updates
Document Management	v.303.001 2015MAY25	Original: Adoption of standardized SOPs developed by CAREB/N2 with an effective date of 2014SEP15. Minor modifications were made to the CAREB/N2 SOPs to reflect institutional policies.