TITLE:	Standard Operating Procedure (SOP) NSHA REB Document Management, Archiving and Retention	**NUMBER:**	NSHA REB-SOP-3-003
Effective Date:	April 2014	Revision:	September 29, 2017
Applies To:	Executive Chair, Co-Chair(s), REB Members and REB Office Personnel		

1. PURPOSE:

The purpose of this standard operating procedure (SOP) is to describe the requirements for document management, including document retention and document archiving. The Nova Scotia Health Authority Research Ethics Board (NSHA REB) files (both paper and electronic) must be maintained in a manner that contains a complete history of all actions related to a research study.

This SOP applies to all documents, including but not limited to initial and continuing review documents submitted to and reviewed by the REB, as well as REB administrative documents.

2. POLICY:

In order to provide a complete history of all actions related to the REB review and approval of submitted research, the REB office must retain all relevant records regarding NSHA REB activities. This includes but is not limited to, documents reviewed and approved or disapproved, meeting minutes, correspondence with investigators, written SOPs, and REB membership lists. Such records must be stored 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/organizations, researchers and funding agencies within a reasonable time upon request.

REB Office Personnel are responsible for maintaining complete files on all research submitted to and reviewed by the NSHA REB, and for maintaining administrative documents related to such research (e.g., agendas, minutes, correspondence) as per ICH GCP 3.4.

The Executive Chair or designee is responsible for retention and archiving of the NSHA REB files.

The NSHA REB Executive Chair, Co-Chair(s), and REB Officer Personnel, as well as other research services staff (e.g. auditor) all maintain responsibility for the confidentiality of REB files.

Process Pathways, Calgary Alberta is responsible for the back-up and security of the Romeo database.

3. DEFINITIONS:

See Glossary of Terms

4. PROCEDURES:

4.1. Research Related Documents

4.1.1. The REB office retains the submission materials for all research that has been submitted for REB review regardless of whether the research has been approved, acknowledged or disapproved;

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

- Signed REB initial application form and all associated attachments;
- Correspondence between the REB and the Researcher, including REB 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 REB and regulatory agencies;
- Reports of any complaints received by the REB and their resolution.

4.2. REB Administrative Documents

4.2.1. The REB office retains all administrative records related to the REB review activities.

4.2.2. REB administrative documents include, but are not limited to, the following:

- Agendas and minutes of all NSHA REB meetings;
- Submitted REB member reviews;
- NSHA REB member records:
    - Current and archived membership lists,
    - Curriculum Vitae and training records of current and past NSHA REB members;
- Signed conflict of interest and confidentiality agreements;
- Current and archived standard operating procedures;
- Current and archived documentation of the NSHA REB Executive Chair's delegation of authority, responsibilities or specific functions;
- Records of registration of the REB with the US Office of Human Research Protection, if applicable, and REB membership updates.

4.3. Document Access

4.3.1. 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;

4.3.2. The research community will be granted supervised access to relevant/applicable files upon request. Paper files can only be removed from the REB office by authorized Research Services personnel. In the event, a file needs to be taken out of the office, it must be signed out by writing their name and the file number on the white board in either the REB office or the research ethics coordinator office (depending on the office in which the file was removed from);

4.3.3. Process Pathways shall access the REB research data only for the purposes of providing assistance, training, and support (including system maintenance).

4.4. Document Storage & Archiving

4.4.1. The REB records are housed in a physically secure onsite location with back-up, disaster and recovery systems in place;

4.4.2. Prior to July 1, 2015, all research related documents received in the REB office are filed in the paper master file. The file number is in the format of either CDHA-RS/20YY-01 or NSHA-RS (after 2016/04/01), with the year being the fiscal year the study was submitted and the number being a sequential number in order of submission. All paper files are stored in the REB offices. The offices are locked when unattended and are accessible by key to authorized persons only;

4.4.3. All Master files (paper) for clinical trials will be archived in accordance with applicable regulatory requirements (currently 25 years from the date of study closure for drug trials, device trials and natural health products

studies) while other (paper) master files will be archived for three years from the date of study closure;

4.4.4. The Romeo electronic database will store all electronic files indefinitely;

4.4.5. All research related documents are to be managed in accordance with applicable NSHA policies on document archiving, PHIA, PIIDPA and other applicable standards.

4.5. Document Retention

4.5.1. 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;

4.5.2. Documents that are retained include, but are not limited to the following (as applicable):

- REB application forms,
- Research protocol,
- Scientific evaluations,
- Investigator brochures and/or product monographs,
- Participant recruitment materials, survey instruments and questionnaires,
- Approved consent form/addendums,
- Research budgets,
- Health Canada No Objection Letters (NOL),
- All correspondence between the REB and the Investigator/research team,
- 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 to the research protocol,
  - significant deviations from the research protocol,
  - significant new findings provided to participants,
- Progress reports and study completion reports;
- Copies of correspondence between the REB and regulatory agencies;
- Reports of any complaints received from research participants or regulatory agencies, and their resolution.

4.6. Confidentiality of Documents

4.6.1. All materials received by the NSHA REB are considered confidential and are accessible only to NSHA REB members (including the Executive Chair and Co-Chairs), consultants/ad hoc advisors (as appropriate), as well as to the organizational official(s) (Director of Research Services) and the REB Office Personnel;

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

4.6.3. 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.

4.7. Destruction of Materials/Documents

4.7.1. At the end of the retention period, all required material which is considered to be confidential and surplus will be securely disposed of in accordance with policy CH 90-015 Confidential Waste Management, and other applicable standards. NSHA REB members without access to secure disposal must return their NSHA REB materials to the office for disposal;

4.7.2. If required, all computer hardware, software and application media will be disposed of in accordance with Nova Scotia Health Authority policy 50-066 Disposition of Surplus Obsolete NSHA IT Hardware and Software – Application Assets.

5 REFERENCES

1) Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2014 (TCPS2 2014), Article 6.17;
2) The International Conference on Harmonization Guidelines for Good Clinical Practice, Section 3.4
3) Health Canada Food and Drug Act Regulations Part C – Division 5
4) Natural Health Products Regulations – Part 4 Clinical Trials involving human subjects
5) US Food and Drug Administration (FDA) Code of Federal Regulations (CFR) Title 21 Part 56.115;
6) US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.103, 46.115;

6 RELATED DOCUMENTS:

1) Nova Scotia Health Authority policy CH 90-015 Confidential Waste Management

2) Nova Scotia Health Authority policy 50-066 Disposition of Surplus Obsolete Capital Health IT Hardware and Software – Application Assets.

Version History

Effective Date	Major Revisions (e.g. Standard 4 year review)	Minor Revisions (e.g. spelling correction, wording changes, etc.)
June 3, 2016		Reflect the change from nine DHA's to one
Nov. 15, 2016	**Deleted:** The NSHA REB uses two electronic databases, ACCESS (2010 and previous file numbers) and Romeo (2011 and onward file numbers). All study related information pertaining to amendments, safety reports, etc. are logged into the databases. The exception is the ACCESS database does not log or track submissions of "Supporting Materials" documents. *All files in the Access database were successfully transferred to the Romeo database.* **Deleted:** Research records are to be managed in accordance with the Department of Research Services Records Management Guide for Research records, Nova Scotia Health Authority policies RS 01-011 Retention of Research Records and CH 100-055 Retention of Records, PHIA, PIIDPA and other applicable standards. *These policies refer to requirements of the Investigator and/or sponsor, not the REB.*	
September 29, 2017		Harmonize with CAREB/N2 SOP's