TITLE:	Standard Operating Procedure (SOP) External Inspections or Audits	**NUMBER:**	NSHA REB-SOP-9-002
Effective Date:	April 2014	Revision:	September 29, 2017
Applies To:	Executive Chair, Co-Chairs, NSHA REB Members, REB Office Personnel, Researchers.		

1. PURPOSE:

The purpose of this standard operating procedure (SOP) is to describe the procedures to be followed before, during and following an external inspection or audit.

2. POLICY:

Health Canada has the authority to inspect Investigator sites conducting clinical trials that fall under the *Regulations* to assess compliance with relevant regulations and guidelines.

The US Food and Drug Administration (FDA) has the authority to audit Investigator sites involved in studies conducted under a US Investigated New Drug Application (IND) or Investigational Device Exemption (IDE) to assess compliance with relevant regulations and guidelines. The US Office for Human Research Protection (OHRP) has the authority to audit Canadian Research Ethics Boards (REB's) that oversee studies that are supported by the US federal government.

Sponsors, funding entities, or others authorized by regulations or agreements with the organizations may have the authority to audit or inspect research-related documents and procedures.

These audits or inspections may involve the REB; therefore, the REB must have policies in place for dealing with external audits or inspections. The Principal Investigator is responsible for notifying the REB of any planned audits or inspections of research projects overseen by the REB.

3. DEFINITIONS:

Audit: A systematic and independent examination of study-related activities and documents, to determine whether the evaluated activities were conducted, and the data were recorded, analyzed, and accurately reported according to the protocol and all applicable standards.

External Audit: An audit performed by an external party such as the study sponsor (or its agents).

Informed Consent Form (ICF): A document confirming the research participant's willingness to participate in a particular research study.

Inspection: The act by a regulatory authority of conducting an official review of documents, facilities, records, and any other resources that are deemed by the authority to be related to the research study.

4. PROCEDURES:

4.1. Preparing for an Inspection or Audit

4.1.1. The REB Chair or designee will confirm with the Sponsor and/or the Principal Investigator (or inspector/auditor, as applicable) regarding the agreed dates and times of the inspection/audit, and verify the purpose of the inspection/audit, the applicable project(s) undergoing inspection/audit and the inspection/audit plan and procedures;

4.1.2. The REB Chair or designee will notify the REB Executive Committee and the REB Office Personnel of the inspection/audit;

4.1.3. The REB Chair or designee will review the inspection/audit procedures with the Executive Committee and REB Office Personnel and conduct a thorough review of the required documentation;

4.1.4. The REB Chair or designee will arrange for access to the appropriate documents for the inspector/auditor;

4.1.5. The REB Chair or designee will confirm that the Executive Committee and REB Office Personnel are available for interviews or to assist the inspector/auditor;

4.1.6. The REB Chair or designee will arrange for a suitable work area (e.g. private and with sufficient space, with access to a computer and in close proximity to a photocopier and telephone) for the inspector/auditor.

4.2. Participating in an Inspection or an Audit

4.2.1. The REB Chair or designee will meet with the inspector/auditor as scheduled. Prior to being granted access to the research-specific REB documentation, the inspector/auditor must exhibit proof of authority or authorization to conduct the inspection/audit;

4.2.2. The REB Chair or designee will record the name, contact information and title of the inspector/auditor and retain any written notices of inspection/audit for the REB files;

4.2.3. The REB Chair or designee will provide a brief orientation to the inspector/auditor of REB procedures;

4.2.4. The REB Chair or designee will provide access to the research-specific documents requested by the inspector/auditor and maintain a list of the documents reviewed;

4.2.5. The REB Chair or designee will accompany the inspector/auditor at all times while in confidential areas of the REB office and/or the organization;

4.2.6. The REB Chair or designee will ensure that the inspector/auditor's questions are answered by the most appropriate personnel. The REB Chair or designee, REB Office Personnel and REB members must make every reasonable effort to be available and to accommodate the requests of the inspector/auditor;

4.2.7. The REB Chair or designee will request meetings with the inspector/auditor at the end of each day, as needed, to discuss any observations. If questions are asked or observations are made during the daily meetings, the REB Chair or designee will research the issues and provide the inspector/auditor with clarification as soon as possible once the information is available;

4.2.8. The REB Chair or designee will ensure that the required personnel are present at the exit interview

4.2.9. The REB Chair or designee will record any observations of the inspector/auditor and any discussion and ascertain when/if a written response is required.

4.3. Follow-up after an Inspection or Audit

4.3.1. The REB Chair or designee will request a copy of the report from the Researcher;

4.3.2. The REB Chair or designee and any other designated individuals will review any findings relevant to the REB and prepare a written response to each item or observation, including any clarification or corrective action that will be taken. The response to the inspector/auditor should be coordinated through the appropriate channels (e.g., the sponsor via the Investigator);

4.3.3. The REB Chair or designee and any other designated individuals will institute any correction actions as applicable and revise the REB SOPs as needed;

4.3.4. The REB Chair or designee will file the inspection/audit and response documents in the appropriate files (e.g. quality assurance).

5. REFERENCES:

I. The International Conference on Harmonization (ICH) Guidelines for Good Clinical Practice (GCP), Section 5.19.1, 5.19.2(b), 5.19.3(b)(c).
II. US Food and Drug Administration (FDA) Code of Federal Regulations (CFR) Title 45 Part 46.115(b)
III. US Food and Drug Administration (FDA) Code of Federal Regulations (CFR) Title 21 Part 56.115(b)

6. RELATED DOCUMENTS:

I. Policy & Procedure RS 04-002 Regulatory Inspections and Investigations of Research Studies;
II. Policy & Procedure RS 04-003 External Audits of Research Studies;
III. http://policy.nshealth.ca/Site_Published/dha9/document_render.aspx?documentRender.IdType=6&documentRender.GenericField=&documentRender.Id=43305

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
September 29, 2017		Harmonize with CAREB/N2 SOP's