TITLE:	Standard Operating Procedure (SOP) Internal Quality Audit	**NUMBER:**	NSHA REB-SOP-9-001
Effective Date:	April 2014	Revision:	September 29, 2017
Applies To:	Executive Chair, Co-Chairs, REB Members, REB Office Personnel, Researchers.		

1. PURPOSE:

The purpose of this standard operating procedure (SOP) is to describe the processes for monitoring, evaluating and improving the effectiveness of the human research protection enterprise at the Nova Scotia Health Authority (NSHA).

2. POLICY:

Quality Management programs, Quality Assurance (QA), and Quality Control (QC) activities, such as audits of the REB and of Investigators, allow for a continuous evaluation and subsequent assurance of the human research protection enterprise.

Findings are measured against established policies and procedures and all of the applicable, ethical, legal, and regulatory requirements. When areas for improvement are identified, corrective action is taken including training, education, and the revision of SOPs.

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) or the IWK Research Ethics Board.

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:

I. REB Internal Quality Audits

4.I.1. The Program Manager-Research Quality will develop a schedule for routine quality audits or initiate ad hoc inspections in response to complaints or other concerns;

4.I.2. Quality audits may include the REB and the REB office;

4.I.3. When the Program Manager-Research Quality conducts a quality audit of the REB and the REB office the audit may including the following:

- An assessment of the SOPs and compliance with applicable regulations and guidance,
- A review of research files, REB membership rosters, REB attendance records, and REB agendas and minutes,
- A review of workload, performance metrics and annual reports,
- A review of stakeholder satisfaction surveys,
- An assessment of quality control procedures for compliance with the SOPs,
- A review of checklists, forms, and templates,
- Interviews with REB members, REB Office Personnel, Researchers, sponsors, and regulators,
- A review of training/education records,
- A review of all continuous improvement activities,
- An assessment of whether any new requirements (ethical, legal, or regulatory) were incorporated into the policies and procedures,
- A review of the status of any corrective action items from previous reviews,
- A review of any deviations from ethical, legal, or regulatory requirements, or deviations from the organization's policies, and whether the deviations require remediation,
- An assessment of compliance with all applicable requirements;

4.I.4. The Program Manager-Research Quality compares the findings against established policies, SOPs and applicable ethical, legal, and regulatory requirements;

4.I.5. The Program Manager-Research Quality prepares a written report of the inspection, including areas requiring improvement;

4.I.6. The Program Manager-Research Quality reports the findings to the REB Chair or designee, and to the REB and/or to the appropriate Organizational Official as required;

4.I.7. The Program Manager-Research Quality may recommend corrective action based on the findings. This may include a recommendation for the provision of additional resources, training, or education, the development of, or revisions to the SOPs, and changes to forms, checklists or templates;

4.I.8. The Program Manager-Research Quality works with the REB Executive Chair or designee to implement improvements (e.g. new or revised SOPs or forms, training, education, additional resources or modifications to existing resources).

II. Researcher Quality Assurance Inspections

4.II.1. The Program Manager-Research Quality will develop a schedule for routine QA inspections and implement inspections in response to Principal Investigator requests;

4.II.2. The Program Manager-Research Quality will work with the REB and the organization at which the research is being conducted to determine if and when a for-cause inspection of a Principal Investigator is warranted;

4.II.3. The REB may direct the Program Manager-Research Quality to conduct for-cause inspections;

4.II.4. The Program Manager-Research Quality or designee may request copies of the sponsor's monitoring reports for a designated research project or that a questionnaire from the REB is completed;

4.II.5. The criteria for selecting Principal Investigator or research projects for inspection may include:

- The results of a previous external audit or inspection,
- The results of a sponsor audit,
- Investigator-initiated studies (i.e., where the Principal Investigator is also the sponsor),
- Studies that involve a potentially high risk to participants,
- Studies that involve vulnerable populations,
- Studies in which Principal Investigator are enrolling large numbers of participants,
- Suspected noncompliance,
- Unanticipated problems involving risks to participants or others,
- Suspected or reported protocol deviations,
- Participant complaints,
- Research Staff complaints,
- Any other situation that the REB deems appropriate;

4.2.6 The Program Manager-Research Quality or designee will notify the Principal Investigator of the inspection and a mutually acceptable time will be scheduled. It may be necessary to schedule an inspection without first obtaining the formal consent of a Principal Investigator (e.g., participant safety or suspected non-compliance);

4.2.7 The Program Manager-Research Quality or designee will conduct the inspection using designated/ appropriate evaluation tools;

4.2.8 When the Program Manager-Research Quality conducts an inspection of the Principal Investigator, the inspection may include some or all of the following (as applicable):

- An assessment of the SOPs and compliance with applicable regulations and guidance,
- A review of all regulatory binders including the REB approval documentation, REB approved consent documents, signed consent documents, correspondence between the Principal Investigator and sponsor, etc.,
- Interviews with the research staff and/or the Principal Investigator,
- A review of test article accountability,
- A review of specimens and associated collection processes,
- A review of computer hardware and/or software associated with the research,
- A review of the consent form(s) and associated processes including eligibility requirements,
- A review of the completed case report forms (CRFs) or other data collection mechanisms,
- A review of appropriate source material (participant medical records),and
- A review of other documentation, as relevant and available;

4.2.9 The REB or the Program Manager-Research Quality may choose to have a qualified impartial observer to monitor the consent process or to interview research participants;

4.2.10 At the conclusion of the evaluation, the Program Manager-Research Quality or designee will discuss the findings with the Principal Investigator;

4.2.11 The Program Manager-Research Quality or designee will draft a report or provide a summary of the inspection including: positive findings, areas for improvement and recommendations for corrective action, and submit the report to the REB Chair or designee for review;

4.2.12 The Principal Investigator will be given an opportunity to respond to the report with responses and/or corrective action plans within a time specified by the REB;

4.2.13 The Program Manager-Research Quality or designee will send a copy of the final report to the Principal Investigator and the REB. When applicable, the REB Chair or designee will provide the findings to the local Organizational Official.

4.3 Corrective Action

4.3.1 The Program Manager-Research Quality may recommend corrective action based on the findings. This may include a recommendation for the provision of additional resources, training, or education, the development of, or revisions to the SOPs, and changes to forms, checklists or templates;

4.3.2 The Program Manager-Research Quality may evaluate the effectiveness of the implemented improvements and adjust processes accordingly;

4.3.3 The Program Manager-Research Quality may follow-up with the Principal Investigator in a timely manner to determine if the corrective actions have been implemented by the Investigator following an Investigator audit or inspection.

4.4 Documentation

4.4.1 The Program Manager-Research Quality files all reports and correspondence concerning QA inspections in the appropriate QA Files.

5. REFERENCES

I. The International Conference on Harmonization (ICH) Guidelines for Good Clinical Practice (GCP), Section 5.19.2(b);
II. US Food and Drug Administration (FDA) CFR Title 45 Part 46.103(b)(4)(5);
III. US Food and Drug Administration (FDA) CFR Title 45 Part 46.112;
IV. US Food and Drug Administration (FDA) CFR Title 21 Part 56.108(b).

6. RELATED DOCUMENTS

I. Policy & Procedure RS 04-002 Regulatory Inspections and Investigations of Research Studies;
II. NSHA REB SOP-9-003 – Non Compliance;
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