TITLE:	Standard Operating Procedure (SOP) Noncompliance	**NUMBER:**	NSHA REB-SOP-9-003
Effective Date:	April 2014	Revision:	September 29, 2017
Applies To:	Executive Chair, Co-Chairs, NSHA REB members, REB Office Personnel and Researchers.		

1. PURPOSE:

This standard operating procedure (SOP) defines the actions the Nova Scotia Health Authority Research Ethics Board (NSHA REB) may take as a result of its review of complaints and reports of noncompliance. The purpose of this SOP is to describe the procedures for responding to complaints and reports of noncompliance.

2. POLICY:

Reports of noncompliance may come from any source including the REB members, Researchers, research participants, organizational personnel, the media or the public. The rights and welfare of research participants could be at risk if there were serious or repeated noncompliance on the part of a Researcher or any member of the research team. It is, therefore, the duty of the REB to be receptive to these reports and to act on credible allegations of noncompliance.

The REB Office Personnel and the REB members are responsible for acting on information or reports of noncompliance received from any source. The REB Chair or designee is responsible for the initial review of allegations of noncompliance.

Researchers are required to comply with all of the applicable guidelines and regulations governing the conduct of human research, as well as with the required conditions of approval of the REB.

The REB is responsible for reporting any incidents of serious or continuing noncompliance to the Researcher and to the appropriate Organizational Official(s), and has the authority to notify the regulatory authorities (as applicable), and the sponsor. The REB may delegate regulatory authority reporting (as applicable) to the organization

Allegations of research misconduct that have been proven by a preponderance of evidence, are handled in accordance with NSHA's policy *Responsible Conduct of Research (formerly Integrity in Research)* (RS-QI-003).

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.

Noncompliance: failure to follow applicable guidelines and regulations governing human participant research; failure to follow the protocol approved by the Research Ethics Board (REB), or failure to follow stipulations imposed by the REB as a condition of approval.

Research Misconduct: Actions that have been committed intentionally, knowingly, recklessly or without due consideration deemed reasonable in the circumstance and that have been proven by a preponderance of evidence. Research Misconduct includes any practice that seriously deviates from commonly accepted principles and standards for proposing, conducting or reporting Research, including:

- Deception
- Fabrication
- Falsification
- Destruction of Research records
- Plagiarism
- Redundant publications
- Invalid authorship
- Inadequate acknowledgement
- Mismanagement of Conflict of Interest
- Noncompliance with relevant policies, laws or regulations
- Failure to obtain appropriate approvals, permits, or certifications.

4. PROCEDURES:

4.1. Reporting Concerns of Noncompliance

4.1.1. Reports of noncompliance in human participant research may come from many sources including but not limited to: an Investigator (as a self-report) a study monitor, a sponsor; a research participant; a member of the research team; or a person not directly involved in the research;

4.1.2. Persons raising such concerns are encouraged to express them in writing. However, the REB office will receive and document oral reports of noncompliance;

4.1.3. Evidence of serious or repeated noncompliance may also arise from human protection-related Quality Assurance audits or inspections, sponsor audits or inspections, or regulatory agency audits or inspections.

4.2. Evaluating Allegations of Noncompliance

4.2.1. Investigators should be aware of the implications of engaging in research activities without prior REB approval. Research results may not be published, used to satisfy academic requirements, or submitted to regulatory authorities unless REB approval was obtained prior to collecting the data;

4.2.2. Investigators who conduct research without REB approval may also be subject to institutional sanctions and other consequences if the transgression is determined to constitute research misconduct;

4.2.3. When an allegation of research misconduct and/or noncompliance is reported to the REB, the REB Office Personnel will document the information and the contact details of the person reporting the allegation, and immediately refer the incident to the VP Research who will assess the allegation to determine its validity and will notify/discuss the allegation with the NSHA REB Executive Committee;

4.2.4. In most instances, the Executive Committee, lead by the Chair, will request a directed audit be performed by the Research Quality - Program Manager to obtain as much information as possible;

4.2.5. The Research Quality - Program Manager will conduct an audit and produce a written report of the findings to be presented to the Executive Committee;

4.2.6. Following review of the audit report, if the REB Chair or designee determines that there is evidence of noncompliance, he/she will then assess whether the noncompliance was intentional, serious and/or repeated;

4.2.7. If the REB Chair or designee determines that there is sufficient evidence to support the allegations, a confidential enquiry regarding Research Misconduct will be directed to the VP Research, Innovation and Knowledge Translation (VP Research) (or to NSHA's President & CEO if the enquiries relate to the VP Research and/or his/her staff);

4.2.8. If the REB Chair or designee determines that there is no or insufficient evidence to support the allegations, no further action will be required.

4.3. Managing Noncompliance

4.3.1. The REB will attempt to resolve apparent instances of noncompliance without interrupting the conduct of the research, especially if the rights and welfare of participants may be jeopardized by interrupting the research;

4.3.2. If the REB Chair or designee determines that the noncompliance was not serious or repeated, and the research team recognized the

noncompliance and took appropriate corrective actions, no further action may be required;

4.3.3. If the REB Chair or designee determines that the noncompliance was not serious or repeated, but the research team did not recognize the noncompliance or take appropriate corrective actions, the REB Chair or designee may discuss the matter directly with the Principal Investigator, recommend corrective action, request a Quality Assurance audit, and/or refer the matter to the REB Executive Committee;

4.3.4. If it appears that a Principal Investigator was intentionally non-compliant, the REB Chair or designee may suspend the conduct of the research immediately and refer the matter to the REB Executive Committee, and will inform the VP Research, Innovation and Knowledge Translation (VP Research) (or to NSHA's President & CEO if the enquiries relate to the VP Research and/or his/her staff) as appropriate;

4.3.5. The REB Executive Committee will review the information at the next meeting and determine the appropriate corrective actions;

4.3.6. Corrective actions are based upon the nature and the degree of the noncompliance. In evaluating the noncompliance, the REB may consider one or more of the following actions:

- Request modification of the protocol,
- Request modification of the informed consent document,
- Require that additional information be provided to past participants,
- Require that current participants be notified,
- Require that current participants re-consent to participation,
- Modify the continuing review schedule,
- Require onsite observation of the consent process,
- Suspend the new enrollment of participants,
- Suspend REB approval of the research,
- Suspend Investigator involvement in the research,
- Terminate REB approval of the research,
- Require the Investigator and/or staff to complete a training program,
- Notify organizational entities (e.g., legal counsel, risk management),
- Ensure that all other regulatory reporting requirements are met, as required,
- Any other action deemed appropriate by the REB.

4.4. REB Response to Reports of Noncompliance

4.4.1. The REB Chair will notify the Principal Investigator in writing of the results of the investigation and of any remedial actions required by the REB;

4.4.2. The REB Chair or designee will report any serious or continuing noncompliance to the Principal Investigator as well as to the VP Research, Innovation and Knowledge Translation (VP Research) (or to NSHA's President & CEO if the enquiries relate to the VP Research and/or his/her staff), and has the authority to report to the regulatory authorities (as applicable) and the Sponsor. The REB may delegate regulatory authority reporting to the organization;

4.4.3. The REB will submit an allegation of research misconduct to the VP Research, Innovation and Knowledge Translation (VP Research) (or to NSHA's President & CEO if the enquiries relate to the VP Research and/or his/her staff) as appropriate;

4.4.4. The REB will request a time-sensitive response in writing from the Principal Investigator to the Research Quality - Program Manager, including the corrective action plan;

4.4.5. The Research Quality - Program Manager and the REB Executive Committee will review the response to determine its acceptability. A copy of the letter will be forwarded to the Principal Investigator's department/division head.

4.4.6. The Research Quality - Program Manager or designee will follow-up to assess any corrective measures implemented by the Principal Investigator.

4.5. Complaints to the NSHA REB

4.5.1. Other complaints received by the REB (determined not to be issues of noncompliance) shall have a preliminary investigation completed by the Chair. The Principal Investigator will be informed of the complaint before the investigation begins. Once the preliminary findings are documented the issue will be brought before the REB Executive Committee for review;

4.5.2. If there is sufficient evidence to warrant a full investigation, the Executive Committee will order an internal audit. The results of the audit will be disseminated to the Principal Investigator, the Principal Investigator's supervisor and the REB Executive Committee.

4.6. Documenting Noncompliance

4.6.1. The REB Chair or designee will document the findings of reports of noncompliance. The report will include the allegations, the information obtained during the initial assessment, whether allegations of

noncompliance were verified, the Executive Committee's decision and actions taken, and the Investigator's response;

4.6.2. For those incidents of noncompliance referred to the Executive Committee, the REB Office Personnel will document the following in the meeting minutes: a description of the incident and findings, verification of the noncompliance, the Executive Committee's decision, the remedial action required by the Executive Committee, the Investigator's response and actions implemented and plans for further follow-up.

4.7. Communication of Findings

4.7.1. Depending on the severity of the audit findings, the Executive Chair will convey the issue and decision of the Executive Committee to the Quality Committee of the Board of Directors for NSHA within 48 hours or as part of the yearly report presented to the Quality Committee.

4.7.2. The VP Research, Innovation and Knowledge Translation (VP Research) and the Principal Investigator will receive copies of the decision of the Executive Committee.

5 REFERENCES

I. The International Conference on Harmonization Good Clinical Practices, Section 5.20;
II. US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.103 (b)(4)(5);
III. US Food and Drug Administration (FDA) CFR Title 21 Part 56.108 (b).

6 RELATED DOCUMENTS:

I. SOP Internal Quality Assurance Audits
II. NSHA REB-SOP-4-007 Suspension or Termination of REB Approval
III. Policy & Procedure: RS-QI-003 Responsible Conduct of Research (formerly Integrity in Research (RS 04-001)

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