TITLE:	Standard Operating Procedure (SOP) Reporting New/Updated Safety Information	**NUMBER:**	NSHA REB-SOP-4-009
Effective Date:	April 2014	Revision:	September 29, 2017
Applies To:	Executive Chair, Co-Chairs, NSHA REB members, REB Office Personnel and Researchers.		

1. PURPOSE:

The purpose of this standard operating procedure (SOP) describes the procedures for submitting new and/or updated safety information to the Nova Scotia Health Authority Research Ethics Board (NSHA REB).

2. POLICY:

Researchers are to notify the NSHA REB of any new information that may adversely affect the safety of study participants or the conduct of the study. This information includes amended product information, data and safety monitoring committee/board reports (DSMB/DSMC), periodic safety update reports, safety alerts, sponsor safety information and/or reports of adverse reactions. These reports are to be submitted to the NSHA REB as soon as they are received by the Principal Investigator (PI) or research team.

It is the Principal Investigator's responsibility to notify the REB, in writing of any changes significantly affecting the conduct of the trial, and/or increasing the risk to participants.

3. DEFINITIONS:

Adverse event (AE): any untoward medical occurrence in a research participant, administered investigational product, including an occurrence which does not have a causal relationship with this product. An AE can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of an investigational product, whether or not related to the investigational product.

- **Local adverse event:** those adverse events experienced by research participants enrolled by the Investigator at the centre(s) under the jurisdiction of the Research Ethics Board (REB).

- **External (non-local) adverse event:** those adverse events experienced by research participants enrolled by Investigators at other centres/organizations outside the REB's jurisdiction.

Data safety monitoring board (DSMB): A multi-disciplinary, expert advisory group established by a research sponsor, that is responsible for safeguarding the interests of participants by reviewing emerging data**,** assessing the safety and efficacy of clinical trial procedures, and monitoring the overall conduct of a trial.

Local participant: A research participant enrolled by the investigator at one or more centers under the jurisdiction of the Nova Scotia Health Authority Research Ethics Board (NSHA REB).

Suspected Unexpected Serious Adverse Reaction (SUSAR): An adverse event that is serious (resulted in death, required hospitalization or prolonged an existing hospitalization, resulted in incapacity or disability, birth defect or jeopardized the participant or required intervention to prevent one of these criteria) and unexpected (not consistent with risks described in the study documents) and related or possibly related to participation in the research.

4. PROCEDURES:

4.1 Safety Related Events Reporting

4.1.1 Principal investigators are responsible for notifying the NSHA REB of safety related events, including updates to product information, reports from safety monitoring committees, periodic safety reports and/or safety alerts/updates from the study sponsor;

4.1.2 All safety updates are submitted via the Researcher's Portal using the Safety Update event form. All events are date and time stamped by the database;

4.1.3 The safety update will be reviewed and verified by the research ethics coordinator and sent to the Co-Chair for review;

4.1.4 If approved, the Co-Chair will update the review status to "approved" and a letter of approval will be sent to the principal investigator;

4.1.5 In the event the Co-Chair has a concern about the impact of this information on participant safety, he/she will document concerns in the comments box at the time of the review and will notify the ethics coordinator by changing the review status to "clarifications requested" or "more info required;"

4.1.6 The Ethics Coordinator will forward the clarifications to the research team and will liaise between the Co-Chair and research team until the issue has

been resolved. In the event the issue cannot be resolved, the Co-Chair may request to have the matter added to the agenda for the next scheduled Executive Committee meeting and if required, subsequent presentation to the Full Board;

4.1.7 As a result of the Executive Committee meeting or Full Board meeting, possible actions that could be taken include but are not limited to:

- Placing a hold on the study pending further information from the principal investigator,
- Requesting modifications to the protocol and/or consent form,
- Altering and/or increasing the frequency of continuing review,
- Requesting an internal audit of the study,
- Suspension or termination of the research.

4.1.8 If changes are required to the study protocol or the consent form, these revised documents must also be submitted to the NSHA REB using the applicable amendment form(s).

4.2 Adverse Reactions Involving Local Participants

4.2.1 Researchers are to record, assess, and report adverse events in accordance with the study protocol, and applicable sponsor and regulatory requirements;

4.2.2 All suspected, unexpected, serious adverse reactions (SUSAR) involving research participants enrolled by the investigator at one or more centers under the jurisdiction of the NSHA REB must be submitted to the NSHA REB using the Local Suspected Unexpected Serious Adverse Reaction: Initial Report event form;

4.2.3 All local SUSARs must be submitted to the NSHA REB within seven days of the research team's awareness of the event, even if full details are not yet known;

4.2.4 SUSARs should also be reported to the study sponsor, as sponsors are responsible for submitting safety information to applicable regulatory authorities (e.g., Health Canada) in accordance with regulatory requirements;

4.2.5 If the study is funded by a US Department of Health and Human Services agency (e.g., NIH, NCI), the sponsor is asked to report the SUAR to the applicable agency head (or designee) and the Office for Human Research Protections on behalf of NSHA;

4.2.6 Upon receipt of a SUSAR form, the ethics coordinator will review the SUSAR for completeness prior to sending a notification to the assigned

Co-Chair. Once reviewed and approved by the Co-Chair, an approval letter with the Executive Chair's electronic signature will be returned to the principal investigator and/or research team;

4.2.7 In the event the Co-Chair has a concern about the impact of this information on participant safety, he/she will document concerns in the comments box at the time of the review and will notify the ethics coordinator by changing the review status to "clarifications requested" or "more info required;"

4.2.8 The ethics coordinator will request that this item be added to the agenda for the next scheduled Executive Committee meeting and if required, subsequent presentation to the Full Board;

4.2.9 Investigators are required to submit new or modified information about the event until the event is resolved using the Local Suspected Unexpected Serious Adverse Reaction: Follow-up Report. Follow-up Reports are to be submitted until the event resolves.

4.3 Submitting External Safety Reports to the NSHA REB

4.3.1 The NSHA REB will only accept semi-annual or quarterly reports for external suspected unexpected serious adverse reactions (SUSAR) for clinical trials. External individual serious adverse events (SAE) reports will not be processed and will be returned to sender.

5 REFERENCES

I. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2014 (TCPS2 2014),Articles 6.15; 11.9;
II. The International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines, Sections 3, 4.4, 4.5, 4.10.2, 4.11, 4.12;
III. Health Canada Food and Drug Regulations, Division 5, C.05.014
IV. US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.103 (b)(4)(5);
V. US Department of Health and Human Services (HHS) CFR Title 45 Part 46.103, 46.109, 46.110, 46.111, 46.115;
VI. US Food and Drug Administration (FDA) Code of Federal Regulations (CFR), Title 21 Part 56.108, 56.109, 56.110, 56.111, 56.115;

6 RELATED DOCUMENTS: n/a

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