TITLE:	Standard Operating Procedure (SOP) Suspension or Termination of NSHA REB Approval	**NUMBER:**	NSHA REB-SOP-4-007
Effective Date:	April 2014	Revision:	September 29, 2017
Applies To:	Executive Chair, Co-Chairs, NSHA REB members and Office Personnel.		

1. PURPOSE:

The purpose of this standard operating procedure (SOP) describes the procedures associated with suspension or termination of research previously approved by the Nova Scotia Health Research Ethics Board (NSHA REB). Suspensions and terminations represent an action by the NSHA REB to temporarily or permanently withdraw approval for some or all research procedures.

2. POLICY:

The REB is responsible for determining whether any information received throughout the course of the research requires the suspension or termination of REB approval for the research being considered.

If it is determined that research is not being conducted in accordance with REB, institutional or regulatory requirements, the REB has the authority to suspend or terminate approval.

As a result of ongoing review activities, the REB may require that research be modified, or may suspend or terminate REB approval if the risks to the research participants are considered to be unreasonably high (e.g. excessive numbers of unexpected serious adverse events). The REB also has the authority to suspend new enrolment pending additional information from the Principal Investigator.

A decision to suspend or terminate REB approval must include consideration of the safety, rights and well-being of participants already enrolled in the study, whether and how to continue the care of enrolled participants, and how and when the notification of research participants will take place.

The REB Executive Chair and/or designated Co-Chair have the authority to suspend approval; however only the Executive Committee has the authority to terminate REB approval. If a research study is suspended or terminated, the Board will be notified at the next scheduled board meeting.

Any requests to lift a suspension or to re-approve the research must be reviewed by the Executive Committee and subsequently reported to the Full Board.

The Principal Investigator is responsible for notifying the REB and the organization of any suspensions or terminations of the research by the Sponsor and for providing a detailed explanation for the action.

The Principal Investigator may decide to voluntarily suspend or terminate some or all research activities; however, this is not considered a suspension or termination of REB approval.

The REB Executive Chair or Co-Chair shall notify the Principal Investigator, and the Organizational Official(s), of any suspension or termination of REB approval of the research and has the authority to notify the regulatory authorities (as applicable) and the Sponsor. The REB may delegate regulatory authority reporting to the organization.

3. DEFINITIONS:

Suspension: A temporary or permanent halt to all research activities pending future action by the Research Ethics Board (REB), by the sponsor and/or by the Investigator or his/her research team.

Termination: A permanent halt by the Research Ethics Board (REB), by the sponsor and/or by the Investigator to all or some research activities.

4. PROCEDURES:

4.1. Suspension or Terminations of Research by the Sponsor

4.1.1. The sponsor of the research may suspend or terminate the research (e.g., following results of interim analyses, due to inadequate drug availability, in response to a Data and Safety Monitoring Board (DSMB) recommendation, due to pre-planned stopping criteria, etc.);

4.1.2. It is the responsibility of the Principal Investigator to immediately inform the REB of any suspensions or terminations and the reasons for such action;

4.1.3. Reports of suspensions or terminations by the sponsor should be forwarded by the Principal Investigator to the research ethics office immediately, in turn reports will be forwarded to the Executive Chair and/or Co-Chair, as applicable;

4.1.4. If the REB Executive Chair or Co-Chair decides to suspend REB approval of the research, he/she must notify the REB at its next Full Board meeting;

4.1.5. If REB approval is suspended, a subsequent review by the Executive Committee will be conducted to determine if a Full Board review is required.

4.1.6. A sponsor may voluntarily suspend a study for administrative or other reasons. The Principal Investigator is to notify the REB in writing of the suspension and any relevant information/documents regarding the suspension. to the research ethics office. The Principal Investigator is responsible for notifying the REB when study related activities resume.

4.2. Suspension or Termination of REB Approval

4.2.1. If any concerns are raised during the REB's ongoing review of the research that are related to new information or to the conduct of the research, the REB may suspend or terminate its approval of the research as appropriate. These concerns may include:

- The research not being conducted in accordance with the REB-approved protocol or REB requirements,
- The research is associated with unexpected serious harm to participants (i.e., as may be determined following REB review of reportable events or DSMB reports),
- Falsification of research records or data,
- Failure to comply with prior conditions imposed by the REB (i.e., under a suspension or approval with modifications),
- Repeated or deliberate failure to properly obtain or document consent from research participants,
- Repeated or deliberate failure to limit administration of the investigational drug or device to those research participants under the Researcher's supervision,
- Repeated or deliberate failure to comply with conditions placed on the research by the REB, by the sponsor, or by regulatory agencies,
- Repeated or deliberate failure to obtain prior REB review and approval of amendments or modifications to the research, or
- Repeated or deliberate failure to maintain accurate research records or submit required reportable event reports to the REB;

4.2.2. The REB designated Co-Chair is authorized to suspend REB approval of research after an audit. If the designated Co-Chair suspends approval of the research, the Executive Committee will be notified at its next scheduled meeting;

4.2.3. The REB is authorized to recommend terminating its approval of the research following a safety report review at a Full Board or Executive Committee meeting;

4.2.4. Prior to suspending or terminating a REB approval, the Executive Chair and/or Co-Chair must consider:

- Risks to current participants,
- Actions to protect the safety, rights and well-being of currently enrolled participants,
- The appropriate care and monitoring of research participants,
- Whether withdrawal of enrolled participants is warranted and the specific procedures for their safe withdrawal,
- Whether participants should be informed of the termination or suspension,
- Whether adverse events or outcomes should be reported to the REB,
- Identification of a time frame in which the corrective measures are to be implemented;

4.2.5. The REB Executive Chair or Co-Chair will notify the Principal Investigator or an suspensions or terminations of REB approval, and the reasons for the decision;

4.2.6. Unless otherwise stated by the REB, when the REB Executive Chair or Co-Chair suspends or terminates ethics approval of the research, no further activities can take place other than the submission of an amendment or reportable events;

4.2.7. If the research is suspended or terminated, the REB Executive Chair or Co-Chair will issue a formal letter to the Principal Investigator with the reason(s) for the REB action and the corrective measures proposed by the REB;

4.2.8. If the research has been suspended, the suspension may be lifted after corrective actions are completed to the REB's satisfaction;

4.2.9. In the event of a suspension or termination of research the REB will ensure appropriate action is taken to protect the rights, safety and welfare of currently enrolled participants; this includes ensuring appropriate follow up care and/or monitoring is in place.

4.3. Reporting Suspensions or Terminations

4.3.1. The REB Executive Chair or Co-Chair will report any suspension, termination of REB approval, or reinstated approval of research within seven days to the appropriate Organizational Official(s) and has the authority to notify the regulatory authorities (OHRP, CIHR as applicable), and the sponsor. The REB may delegate regulatory authority reporting to the organization.

4.3.2. Reports of suspensions or terminations will be noted on the monthly activity report and shared with the Full Board at the next scheduled meeting.

4.4. Reporting to US Federal Authorities

4.4.1. In accordance with US federal regulations, the NSHA REB shall report any suspensions (excluding administrative holds) or terminations and any serious or continuing non-compliance to the requirements of the NSHA REB by an investigator in relation to a study funded or supported by the US Federal Government to the appropriate federal regulatory authorities.

5 REFERENCES

I. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2014 (TCPS2 2014), Article 2.8, and 11.9
II. The International Conference on Harmonization Good Clinical Practices, Sections 4.4, 4.5, 4.10, 4.11, 4.12, and 5.21;
III. US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.109, 46.111, 46.113, 46.115;
IV. US Food and Drug Administration (FDA) CFR Title 21 Part 56.108, 56.113

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