TITLE:	Standard Operating Procedure (SOP) Statement of Authority and Purpose	**NUMBER:**	NSHA REB-SOP-1-001
Effective Date:	April 2014	Revision:	September 29, 2017
Applies To:	All REB members and Office Personnel associated with the Nova Scotia Health Authority Research Ethics Board		

1. PURPOSE:

The purpose of this standard operating procedure (SOP) is to:

i. State the institutional authority under which the Nova Scotia Health Authority Research Ethics Board (NSHA REB) is established and empowered;
ii. Define the purpose of the NSHA REB;
iii. State the principles governing the NSHA REB to assure that the rights and welfare of participants are protected;
iv. State the authority of the NSHA REB;
v. Define the relationship of the NSHA REB to other committees and to officials within NSHA and/or the IWK Health Center.

2. POLICY:

2.1 Statement of Authority and Purpose

2.1.1 The Nova Scotia Health Authority Research Ethics Board reports to the Quality Committee of the Board of Directors for the Nova Scotia Health Authority. The NSHA REB requires that all projects conducted under the auspices of the NSHA REB and defined as research by the Tri-Council Policy Statement Ethical Conduct for Research Involving Humans (TCPS2, 2014), involving humans as participants or human materials be reviewed and approved by the NSHA REB prior to initiation of any research related activities. Activities intended to discuss the feasibility of the research, establish research partnerships or discuss the design of the research project may begin before research ethics approval is granted.

2.2 Purpose of the NSHA REB

2.2.1 The REB's primary mandate is to review and approve the initiation of, and conduct periodic reviews of, research studies involving patients, staff, resources, and/or data involving Nova Scotia Health Authority patients, staff, resources, and/or data in order to protect the rights, safety, and wellbeing of research participants. The REB reviews and oversees such research to verify that it is scientifically valid and to assure that it meets ethical principles and complies with all applicable regulations and standards pertaining to human participant protection. These include but are not limited to Health Canada's Food and Drugs Act, the International Conference on Harmonization Good Clinical Practice: Consolidated Guidelines, the Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects, the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, and where and to the extent applicable, US Federal Regulations.

2.3 NSHA REB Authority

2.3.1 The REB is established to review research involving human participants that is conducted by faculty, staff and students, or anyone conducting research that has an affiliation with the Nova Scotia Health Authority. This policy applies to funded and non-funded research involving human participants.

In brief, the REB has the authority to:

- Approve, disapprove, propose modification to, restrict, suspend, or terminate any proposed or ongoing human subjects research involving NSHA staff (including medical staff), patients, resources or data;
- Conduct continuing ethical review to protect the rights and welfare and privacy of research participants;
- Ensure that the researcher has policies and procedures to protect the rights, safety and welfare of research participants;
- Solicit *ad hoc* independent external peer review and to seek external advice. The REB is accountable for any decision made on the basis of this advice;
- Monitor research, including auditing documents and observing the consent process;
- Take any actions considered reasonably necessary, and consistent with policies and procedures, to ensure the protection of the rights, safety, and well-being of participants in research conducted under the jurisdiction of NSHA;
- The REB reviews clinical trial study budgets to ensure that conflicts of interest are identified and minimized, or otherwise managed.

Research Services reviews the budget and reports to the Executive Chair.

2.4 NSHA REB Autonomy

2.4.1 It is understood that the REB operates with no undue influence by senior institutional administrators.

3 DEFINITIONS:

Standard Operating Procedure (SOP): document used to standardize the format of all standard operating procedures. Written statements that typically describe a series of steps required to complete various tasks.

4 GUIDING PRINCIPLES AND VALUES:

The REB is guided by the three core principles – Respect for Persons, Concern for Welfare, and Justice as set forth in the TCPS2 regarding all research involving humans as participants including:

- Respect for a person's right for self-determination and autonomy,
- Not harming others and not violating a person's fundamental rights of liberty and privacy,
- Doing good to others, including society, research participants, researchers, sponsors and institutions,
- Recognizing the duty of researchers to disseminate the analysis and interpretation of any significant results to the research community, since silence on negative outcomes may foster potentially harmful clinical practices or wasteful supplication.
- Equitable distribution of the benefits and burdens of research.

5 RESEARCH SUBJECT TO US REGULATIONS

The REB shall apply the requirements of the applicable US regulations to the extent that they vary from the protections set out in the applicable Canadian regulations and guidelines.

6 REFERENCES

1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2014 (TCPS 2)
2. International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) 3.3;
3. Health Canada Therapeutic Products Directorate Food and Drug Regulations for Clinical Trials, Division 5;

4. US Food and Drug Administration (FDA) Code of Federal Regulations (CFR), Title 21 CFR 56.108(a);
5 US Department of Health and Human Services (HHS) CFR Title 45 CFR 46.103(4).

7 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		Harmonized with CAREB/N2 SOP's