TITLE:	Standard Operating Procedure (SOP) Initial Review – Criteria for NSHA REB Approval	**NUMBER:**	NSHA REB-SOP-4-004
Effective Date:	April 2014	Revision:	September 29, 2017
Applies To:	Executive Chair, Co-Chairs, NSHA REB members and REB Office Personnel.		

1. PURPOSE:

The purpose of this standard operating procedure (SOP) is to describe the minimum requirements that all research proposals involving human participants must meet for approval under the auspices of the Nova Scotia Health Authority Research Ethics Board (NSHA REB).

2. POLICY:

All research proposals that intend to enroll human participants must meet certain criteria before study related procedures can be initiated. The approval criteria are based on the guiding ethical principles reflected in the TCPS 2 (Respect for Persons, Concern for Welfare, and Justice) and applicable regulations and guidelines.

Initial REB approval of the research is based on assessment of a complete submission to the REB. The NSHA REB may consult the Investigator for additional information as necessary.

Following initial review of the research submission, the REB should be prepared to make a determination as to the approvability of the research.

3. DEFINITIONS:

1) **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.

2) **Informed Consent:** The voluntary, knowledgeable agreement of the individual or, if the individual lacks capacity, their SDM with what is being done or proposed in relation to PHI. Consent can be express or implied. Express consent is given either verbally or in writing.

3) **Participant:** A person about whom a researcher obtains (1) data through intervention or interaction with the individual or the individual's cadaver, remains, tissues, biological fluids," embryos or fetuses, or (2) identifiable private information (e.g., health information). The term "subject" may also be used.

4) Personal Health Information (PHI): Individually identifiable information or information that could reasonably lead to identification or an individual and includes, but is not limited to: demographic information, health history, payment information, information related to provision of healthcare, donation of body parts/substances (see Glossary of Terms).

4. PROCEDURES:

4.1. Minimal Criteria for Approval of Research

In order for the research to receive REB approval, the REB will take the following into consideration:

4.1.1. A letter of support has been signed by the head of the Investigator's department; division; program; or service (as applicable), indicating that the Investigator has the qualifications to conduct the research;

4.1.2. Any potential conflicts of interest are declared and are managed appropriately to prevent any compromises to the safety or well-being of the participants or to the integrity of the data;

4.1.3. There is a state of clinical equipoise when there is a comparison of two or more treatment arms;

4.1.4. The research will generate knowledge that could be generalized and lead to improvements in health or well-being;

4.1.5. The methodology is scientifically sound and capable of answering the research question;

4.1.6. The risks to participants are minimized by:

- Using procedures that are consistent with sound research design and that do not unnecessarily expose participants to risk, and
- By using procedures already being performed on the participants for diagnostic or treatment purposes whenever appropriate;

4.1.7. The risks to participants are reasonable in relation to the anticipated benefits, if any, and the importance of the knowledge that will be generated. The REB should not consider long-range effects of applying the knowledge gained in the research;

4.1.8. The selection of participants is equitable. In making this assessment, the REB will take into account the purpose of the research and the research

setting. The REB will consider the scientific and ethical reasons for including vulnerable populations, if applicable;

4.1.9. There are sound scientific and ethical reasons for excluding classes of persons who might benefit from the research;

4.1.10. When some or all of the participants, such as children, prisoners, the elderly, pregnant women, those with mental health issues, and those with diminished capacity for self-determination are likely to be vulnerable to coercion or undue influence, additional safeguards have been included in the research, and in the REB review process to protect the rights and welfare of these participants;

4.1.11. The amount and method of payment to participants is appropriate to ensure that there is no coercion or undue influence and that information regarding payment to participants including method, amounts and schedule is provided to participants when applicable;

4.1.12. Informed consent will be sought from each prospective participant or from the participant's legally authorized representative, in accordance with and to the extent required, by applicable regulations and guidelines;

4.1.13. The informed consent form will accurately explain the research and contain the required elements of consent;

4.1.14. The informed consent process will be appropriately documented in either a departmental SOP approved by the REB or outlined in the application form, in accordance with the relevant regulations;

4.1.15. There will be provisions for on-going data and safety monitoring procedures that are appropriate to the size, complexity, phase, and level of risk of the research. The REB may recommend the use of a Data and Safety Monitoring Board (DSMB) to enhance participant protection;

4.1.16. There will be adequate provisions to protect the privacy of participants and to maintain the confidentiality of data;

4.1.17. There will be adequate provisions for continued access to the agent or device or adequate replacement of the test agent after the research is complete, when appropriate;

4.1.18. There will be adequate provisions for the timely publication and dissemination of the research results;

4.1.19. If the study is placebo controlled, use of placebo must be justified explicitly by the researcher;

4.1.20. The research has been submitted to Health Canada if applicable, and the Health Canada No Objection Letter has been issued;

4.1.21. Clinical trials must be registered with a recognized public registry and the registration number must be provided to the REB in the application form and on page 1 of the informed consent form(s). If the research is not registered at that time of initial review, the Investigator shall provide the REB with the registration number before final approval may be granted;

4.1.22. The resources required for successful completion of the study are secured (e.g., funding, space, personnel, etc.).

4.2. Additional Criteria

4.2.1. Studies proposing access to or collection of personal health information require consideration of additional items to protect the privacy of the personal health information and to determine whether the appropriate privacy legislation is adhered to. The REB must find that:

- Consent for study participation details access, use and disclosure of PHI and consent is obtained from participants or their legally authorized representative prior to access or;
- Consent is obtained from participants for the collection, use or disclosure of their personal health information or;
- The requirement for consent has been waived by the REB or;
- PHI will be contained in its most de-identified form and used in a manner that ensures confidentiality.

4.2.2. Additional criteria for research involving Aboriginal peoples in Canada, or research on materials related to human reproduction, or genetic research, or children, or prisoners, or pregnant women shall be applied when applicable in accordance with governing principles and/or regulations.

4.3. US Federally Funded Research

4.3.1. For research that is subject to the provisions of 45 CFR 46 or 21 CFR 56, the REB shall consider the listed criteria in the applicable regulations, to the extent that they differ from or vary the criteria noted in 4.1 above.

4.4. Length of Approval Period

4.4.1. The REB shall review research studies appropriate to the degree of risk, but not less than once a year;

4.4.2. The REB may require review more often than annually when there is a high degree of risk to participants relative to the population;

4.4.3. The REB may consider review of research more often than annually when any of the following are true:

- Proposed procedures have not been used in humans,
- The stage of the research is such that many of the risks are unknown,
- More than minimal risk exists to vulnerable populations with no prospect of direct benefit,
- There have been previously confirmed instances of serious or continuing non-compliance with the applicant principal investigator,
- The NSHA REB believes that more frequent review is required.

5 REFERENCES

1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2014 (TCPS2 2014);
2. The International Conference on Harmonization Guidelines for Good Clinical Practice, Sections 3, 4.1, 4.8;
3. Nova Scotia's Personal Health Information Act, Bill 89 (PHIA);
4. Personal Health Information Protection and Electronic Documents Act (PIPEDA);
5. US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.111 or 21 CFR 56.

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