TITLE:	Standard Operating Procedure (SOP) Composition of the NSHA REB	**NUMBER:**	NSHA REB-SOP-2-001
Effective Date:	April 2014	Revision:	September 29, 2017
Applies To:	REB Office Personnel and REB members		

1. PURPOSE:

The purpose of this standard operating procedure (SOP) is to describe the membership composition requirements of the Nova Scotia Health Authority Research Ethics Board (NSHA REB).

2. POLICY:

To promote complete and adequate review of the type of research commonly reviewed by the REB, the REB must include appropriate diversity, multi-discipline backgrounds, scientific and non-scientific expertise, and sensitivity to such issues as community attitudes to assess the research submitted for review. Important consideration are also race, sex, cultural backgrounds, clinical and research experience, organizational affiliation, and sensitivity to such issues as broad representation from organizations served by the REB.

Individual members of the NSHA REB will be qualified through training, experience and expertise to ascertain the acceptability of proposed research in terms of ethical principles; and applicable regulations, guidelines and standards pertaining to human participants or human materials protection. The majority of NSHA REB members are to be Canadian citizens or permanent residents under the *Immigration Act.*

3. DEFINITIONS:

Ad hoc advisor: a person with relevant and competent knowledge and expertise consulted by an Research Ethics Board (REB) for a specific research ethics review, and for the duration of that review, in the event that the REB members lack specific expertise or knowledge to review with competence the ethical acceptability of a research proposal. The ad hoc advisor is not a member of the REB and is not counted in the quorum or allowed to vote on REB decisions.

4. PROCEDURES:

4.1. Selection of NSHA REB Members

4.1.1. No appointment shall be made solely on the basis of gender; qualified individuals will be given equal consideration regardless of gender;

4.1.2. The REB will strive to include cultural and ethnic diversity to represent the participant population from which research participants are recruited, within the scope of available expertise needed to conduct its functions;

4.1.3. REB membership will not consist entirely of members of one profession;

4.1.4. REB members will be selected based on the needs of the NSHA REB as outlined below and per applicable regulations, guidelines and standards.

4.2. Composition of the NSHA REB

4.2.1. The NSHA REB membership is in compliance with Health Canada (Division 5, Part C.05.001 of the Food and Drug Act), the Tri-Council Policy Statement (TCPS 2) on Ethical Conduct of Research Involving Humans (Article 6.4), The International Conference on Harmonization Good Clinical Practices (ICH GCP 3.2.1), Research ethics oversight of biomedical clinical trials (CAN/CGSB-191.1-2013), and the US Code of Federal Regulations;

4.2.2. The REB Executive Chair or designee monitors the REB membership composition for appropriate membership in relation to the nature and volume of research submissions;

4.2.3. The NSHA REB consists of members divided into four working groups. Each group meets face-to-face once per month for a total of four monthly meetings. Each of the four working groups shall have at least five members, and shall represent both medical and non-medical departments of NSHA who are actively involved in health related research and /or knowledgeable and interested in research ethics. In compliance with the TCPS 2 the composition of the NSHA REB shall include the following members;

a. At least two members whose primary experience and expertise are in a scientific discipline, who have broad experience in the methods and areas of research to be approved and one of whom is from a medical discipline;
b. At least one member is knowledgeable in ethics;
c. At least one member is knowledgeable in the relevant law (but that member should not be the institution's legal counsel or risk manager).
d. At least one member knowledgeable in complementary or alternative health care.
e. At least one member whose primary experience and expertise are in a non scientific discipline; and
f. At least one community member who has no affiliation with NSHA;

g. When possible, one member who is from an identifiable Aboriginal community or Native centre, when the REB reviews research that recruits participants from that community;

4.2.4. REB membership consists of broad representation from across therapeutic areas and include physicians, nurses/health care professionals with clinical and/or research experience, community members, and members with expertise in research ethics, relevant law, privacy legislation and may consist of other related disciplines such as pharmacy, epidemiology, and biostatistics;

4.2.5. Membership, when required, should include at least one member who has expertise in complementary or alternative care;

4.2.6. In order to ensure its ability to conduct timely and competent ethics reviews, NSHA REB members of comparable qualifications (a general representative may not substitute for a medical representative) may substitute for one another within the four working groups to ensure that the appropriate membership is present for decisions requiring full board review ;

4.2.7. Institutional senior administrators are not permitted to be members of the NSHA REB.

4.3. NSHA REB Executive Chair

4.3.1. Whenever possible and practicable, the Executive Chair will be selected from experienced REB members who have served on the NSHA REB for at least two years and who are familiar with the applicable regulations and guidance documents;

4.3.2. The REB Office Personnel updates the REB membership list to reflect changes in membership as they occur.

4.4. NSHA REB Co-Chairs

4.4.1. The NSHA REB has two co-chairs per working group who are responsible for the conduct of proceedings for REB meetings. The co-chair(s) provide overall leadership for the board and facilitate the ethics review process based on the requirements of applicable regulations, standards, and applicable policies and procedures;

4.4.2. In conjunction with the Executive Chair, the Co-Chair(s) are directly responsible for overseeing the protection of research participants by ensuring the proper review, approval, or disapproval of research protocol submissions to the NSHA REB. Additionally, the Co-Chairs are responsible for the review of:

- Ongoing activity of annual research projects (annual approval form);
- Any proposed changes to REB approved documents and processes before implementing such changes for approval;
- Review of any new participant recruitment materials;
- Review any new safety information, including amended product information;
- Review of any serious unexpected adverse reactions involving local study participants;
- Review any study violations initiated by the research team and/or study sponsor;
- Review any unanticipated problems related to the research and;
- Sign off on study closure reports.

4.5. NSHA REB Executive Committee

4.5.1. The NSHA REB Executive Committee is comprised of the REB Executive Chair, Co-Chairs, and representation from Zone 1 (Western), Zone 2 (Northern) and Zone 3 (Eastern);

4.5.2. Executive meetings are chaired by the Executive Chair;

4.5.3. Meetings will be held every two weeks, or at the discretion of the Executive Chair;

4.5.4. Quorum consists of 50% +1 of the committee's membership. If quorum is not achieved, the meeting is cancelled and agenda items brought forward to the next meeting.

4.5.5. The NSHA REB executive committee:

- Is authorized to sign documents pertaining to the approval and ongoing review of specific research studies;
- Approves additions, deletions, and modifications to REB policies and procedures;
- Advises on nomination and selection of members of the working groups;
- Reviews terms of reference for the REB annually, and revise if necessary;
- Reviews REB practice to ensure consistency in the review process and compliance with applicable policies and standards;
- Ensures smooth operation of the REB and solicits input from investigators on the performance of the REB;
- Reviews concerns and other matters of interest regarding proposed and ongoing research studies;
- Oversees the internal quality audit program;
- Liaises with other bodies within Nova Scotia and across Canada as applicable.

4.6 Ad Hoc Advisors

4.6.1 At his/her discretion, the REB Chair or designee may invite individuals with expertise and competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the REB;

4.6.2 The ad hoc advisor may be asked to participate in the REB meeting to lend his/her expertise to the discussions;

4.6.3 All ad hoc advisors shall sign a *Confidentiality of Information and Conflict of Interest Agreement;*

4.6.4 The ad hoc advisor may not contribute directly to the REB's decision and their presence or absence shall not be used in establishing a quorum;

4.6.5 Documentation of key information provided by the ad hoc advisor shall be summarized in the REB minutes and if available, the written report shall be placed in the REB files.

4.7 Observers at REB Meetings

4.7.1 The REB may allow observers to attend its meetings;

4.7.2 Observers will sign a *Confidentiality of Information and Conflict of Interest Agreement* agreeing to abide by the REB conflict of interest and confidentiality policies;

4.7.3 Where the REB finds that an observer qualifies as an expert in relation to the research under consideration, the observer may be allowed to contribute input if it is relevant and significant to the discussion;

4.7.4 Observers shall not participate when the REB discusses its decision, reaches consensus or votes on the application;

4.7.5 The minutes will reflect the presence of any observers as well as his/her expertise and contributions, when applicable.

5 REFERENCES

1) Health Canada (Division 5, Part C.05.001 of the Food and Drug Act);
2) Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2014 (TCPS2 2014); Article 6.4, 6.5, 6.6, 6.7, 6.8;
3) The Canadian General Standards Board (CGSB), National Standard of Canada for Research Ethics Oversight of Biomedical Clinical Trials, CAN/CGSB-191.1-2013.
4) US Office for Human Research Protections 45 Code of Federal Regulations Title 46.107;

5) US Food and Drug Administration Code of Federal Regulations Title 21 Part 56.107;
6) The International Conference on Harmonization Good Clinical Practices, Section 3.2.1.

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