

<b>TITLE:</b>	Standard Operating Procedure (SOP) Management of NSHA REB Membership	<b>NUMBER:</b>	NSHA REB-SOP-2-002
Effective Date:	April 2014	Revision:	November 15, 2017
Applies To:	REB Executive Chair, Co-Chairs, REB Office Personnel and REB members		

## 1. PURPOSE:

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

## 2. POLICY:

REB membership (e.g., appointment, terms) must be adequately managed to continue to meet applicable regulatory composition requirements and to maintain the appropriate diversity, experience and expertise for the type and volume of research reviewed.

## 3. DEFINITIONS:

See Glossary of Terms

## 4. PROCEDURES:

### 4.1. Appointments – Regular 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. Members will be selected based on the needs of the NSHA REB as per applicable regulations, guidelines and standards;
- 4.1.3. REB medical and general members are appointed as per the REB terms of reference;
- 4.1.4. Community members (meeting membership requirements) are solicited from the greater local and provincial community;
- 4.1.5. Each REB member selected is approved by the Executive Chair or designee;

- 4.1.6. Candidates selected to serve on the REB will be asked to sign a Confidentiality of Information and Conflict of Interest Agreement.

## **4.2. Appointments – REB Executive Chair and Co-Chair(s)**

- 4.2.1. The Executive Chair is appointed as per the NSHA's terms of reference;
- 4.2.2. The Co-Chairs are appointed as per the NSHA's terms of reference;
- 4.2.3. To qualify as a Co-Chair, the individual must have served on an REB for at least two years;
- 4.2.4. The REB Executive Chair and Co-Chair(s) will be asked to sign a *Confidentiality of Information and Conflict of Interest Agreement*.

## **4.3. Ad Hoc Advisors**

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

## **4.4. Terms of Appointment**

- 4.4.1. Each REB member will be asked to serve for a three year term;
- 4.4.2. Re-appointment of an REB member for (an) additional term(s) is allowed, by mutual agreement of the REB member and the REB Executive Chair or designee;
- 4.4.3. The Executive Chair and Co-Chairs will be appointed for a 3-year term with the possibility for re-appointment. Both have the option of remaining in this capacity on a year-to-year basis after their term has expired.
- 4.4.4. Whenever possible, to preserve the experience level, expertise, and continuity of the REB appointments will be staggered so that not more than one-third of the members will be appointed each year;

## **4.5. Qualifications and Training of REB Members**

- 4.5.1. Each member of the REB will follow qualification and training procedures as per the REB policies and procedures.

## **4.6 Resignations and Removals**

- 4.6.1 All REB members may resign before the conclusion of his/her term upon provision of notice to the Executive Chair or REB Manager;
- 4.6.2 REB members are expected to attend at least 80% of their assigned groups scheduled meetings. A member may be asked to step down if they

consistently miss 50% of their scheduled Full Board meetings during their term;

- 4.6.3 Frequent unexplained absences will be construed as notice of resignation. For medical representatives, the Executive Chair will notify the respective department head concerning their representative's resignation and a replacement will be expected. For legal, community and general representatives, a letter will be sent from the Executive Chair or designee to the member acknowledging their resignation from the board.
- 4.6.4 The REB Executive Chair or designee may otherwise remove an REB member at any time, if they are not fulfilling their designated REB duties in a timely, competent and ethical manner. A letter will be sent to the individual board member or the respective department head (if applicable) acknowledging their termination from the board and thanking that individual for their participation;
- 4.6.5 An REB member should resign immediately upon determination of research misconduct, mismanaged conflict of interest or any other relevant behavior that could be perceived as compromising his/her ethical judgment;
- 4.6.6 Every effort will be made to recruit a similarly qualified replacement prior to the departure of a member to preserve experience and continuity of function of the NSHA REB.

#### **4.7 Compensation**

- 4.7.1 REB members do not receive compensation for their role. Membership is strictly voluntary;
- 4.7.2 Community and legal members may be reimbursed for parking expenses associated with meeting attendance.

#### **4.8 Liability Insurance**

- 4.8.1 All REB members are insured for their research ethics review-related work in their role as REB members under the insurance policy of NSHA, subject to the terms and conditions of that policy.

#### **4.9 NSHA REB Membership List**

- 4.9.1 The REB Office Personnel will maintain an updated electronic REB membership list;
- 4.9.2 The REB membership list is reviewed and updated as required or with the initiation of new or conclusion/termination of existing terms;

- 4.9.3 The current and archived REB membership lists are maintained and available in a binder in the REB office;
- 4.9.4 CVs, other supporting documents related to education and expertise, and confidentiality agreements for all current and past REB members will be maintained in each member's training binders stored in the REB office;
- 4.9.5 A detailed membership list will be stored and locked in the REB office. This list will contain REB member contact information and additional information on areas of expertise for the purposes of communication and reviewer assignments. It will be kept confidential for access by the REB Office Personnel, and by request may be distributed to REB members for the purposes of REB related communications;
- 4.9.6 The REB Chair or designee will update the REB registration with the US Office for Human Research Protection (OHRP) 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.

### 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
November 15, 2017		A member may be asked to step down if they consistently miss <del>20%</del> 50% of their scheduled Full Board meetings during their term.