TITLE:	Standard Operating Procedure (SOP) Responsibilities of NSHA REB Members	**NUMBER:**	NSHA REB-SOP-2-003
Effective Date:	April 2014	Revision:	September 29, 2017
Applies To:	Executive Chair, Co-Chairs, REB members and REB Office Personnel.		

1. PURPOSE:

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

2. POLICY:

Each member's primary duty is the protection of the rights and welfare of the individual human beings who are serving as the participants of research. In order to fulfill his or her duties, REB members must be versed in regulations governing human participants' protection and biomedical research ethics, and policies relevant to human research participant protection.

The Executive Chair or designee is responsible for clearly articulating all required duties associated with membership to the REB to potential and current REB members.

3. DEFINITIONS:

Conflict of interest: circumstance of a person (e.g., Investigator or Research Ethics Board (REB) member) or organization in a real, perceived or potential conflict between their duties or responsibilities related to research and their personal, institutional or other (secondary) interests.

4. PROCEDURES:

4.1. Attendance

4.1.1. REB members are expected to attend their working groups regularly scheduled REB meetings. REB Members may be asked to step down if they consistently miss a specified percentage of their working groups scheduled REB meetings;

4.1.2. Members are expected to be available for the entire meeting, not just the sections for which they have been assigned as reviewers;

4.1.3. Members are expected to come to the meeting prepared to discuss each project and provide his/her input at convened meetings;

4.1.4. If a member is unable to attend a scheduled meeting, it is the member's responsibility to consult the detailed working group list and seek a comparable replacement (i.e. legal rep may substitute for another legal rep). REB members must notify the REB office if they will be absent for an REB meeting to ensure that quorum can still be met.

4.2. Terms of Duty

4.2.1. All members of the REB, including the REB Executive Chair and Co-Chairs, will be appointed for terms as specified in the REB's terms of reference.

4.3. Duties

4.3.1. All REB members attending an REB meeting are expected to review the relevant materials submitted for each item under review or consideration by the REB, to submit written comments to the Romeo Researcher's Portal prior to the commencement of the REB meeting, and to be prepared to discuss each agenda item and provide input at the Full Board meeting;

4.3.2. Each REB member is expected to fulfill specific duties based on their role(s) on the NSHA REB as outlined below. More than one member may fulfill each role.

4.3.3. **Scientific Members:** are expected to contribute to the evaluation of the research on its ethical, scientific and statistical merits, and standards of practice. These members should also advise the REB if additional expertise in a scientific or non-scientific area is required to assess whether the research protocol, consent document and other research materials adequately protect the rights and welfare of subjects;

4.3.4. **Non-Scientific Member(s):** are expected to provide input on areas relevant to his/her knowledge, expertise and experience, professional and otherwise. These members should advise the REB if additional expertise in a nonscientific area is required to assess if the research project adequately protects the rights and welfare of subjects and to comment on the comprehension of the consent document;

4.3.5. **Community Member(s):** are expected to provide input regarding their knowledge about the local community and be able to discuss issues and research from that perspective. Community members shall not have any affiliation with the institution nor be currently involved in research or legal work as their primary occupation.

4.3.6. **Member(s) knowledgeable in relevant law:** are expected to alert the REB to legal issues and their implications, but not to provide formal legal opinions nor to serve as legal counsel for the board.

4.3.7. **Member(s) knowledgeable in research ethics:** are expected to guide the REB in identifying and addressing ethics issues related to the research under review.

4.3.8. **Ad hoc advisors:** individuals with competence in special areas may be required to provide input on issues that require expertise beyond or in addition to that available on the REB. The ad hoc advisor may be required to submit a written report and to participate via teleconference or to attend the REB meeting to lend his/her expertise to the discussions;

4.3.9. **REB Executive Chair:** The REB Executive Chair or designee provides overall leadership to the REB;

- The REB Executive Chair can delegate any of his/her responsibilities, as appropriate to a Co-Chair or other qualified individual(s),
- Any responsibilities that are delegated by the REB Executive Chair must be documented,
- The REB Executive Chair or designee facilitates the review process based on organizational policies and procedures, SOPs and applicable regulations and guidelines. The REB Executive Chair or designee determines the level of risk of each research project. The REB Executive Chair or designee monitors the REB's decisions for consistency and ensures that decisions are recorded accurately and communicated to Researchers in writing in a timely fashion,
- The REB Executive Chair or designee ensures that all REB members are free to participate in discussions during the REB meetings. The REB Executive Chair or designee can ask a substitute REB member to attend an REB meeting in order to draw his/her expertise in an area that may be relevant to the REB's review and deliberations of the research,
- The REB Executive Chair or designee determines the appropriateness of a Full Board or delegated review of the research,
- The REB Executive Chair or designee performs or delegates authority to (an) REB member(s) to perform a delegated review,
- The REB Executive Chair or designee signs off on all REB decisions in writing,
- For REB approval of clinical trials approved by Health Canada, the REB approval letter which includes the REB attestation, is signed by the REB Executive Chair or designee,
- The REB Executive Chair can suspend the conduct of any research project deemed to place participants at unacceptable risk pending

discussion by the Executive Committee. The REB Executive Chair can suspend the conduct of the research if he/she determines that a Researcher is not adhering to the REB approved protocol or to the REB's policies and procedures,

- The REB Executive Chair or designee will report on the activities of the REB to the Quality Committee of the Board of Directors for NSHA on an annual basis,
- The REB Executive Chair or designee, in conjunction with the REB Office Personnel and other organizational representatives as applicable, ensures the REB members are informed of all new legislation, regulations, policies and guidelines pertaining to human participant research and shall advise the organization on policies and procedures related to research conduct,
- The REB Executive Chair, in conjunction with the REB Office Personnel, shall assess the educational and training needs of the REB members and Office Personnel, and will address any gaps identified.
- The REB Executive Chair or designee reviews and approves REB policies and procedures at set intervals, to ensure the REB SOPs meet all current standards.

4.4. REB Co-Chair(s)

4.4.1. The REB Co-Chair(s) are responsible for performing the responsibilities of the REB Executive Chair when the Executive Chair is unable to do:

- The REB Co-Chair(s) performs all responsibilities assigned by the Executive Chair,

- The REB Co-Chair(s) assists with the overall operation of the REB.

4.5. Primary and Secondary Reviewers

4.5.1. REB members may be appointed as either a primary or secondary reviewers for assigned research projects at Full Board meetings. The primary and secondary reviewers present their findings resulting from review of the REB submission materials and provide an assessment of the soundness and safety of the research and recommends specific action to the REB. They lead the discussion of the research project during the REB meeting. The primary and secondary reviewers review additional material(s) as requested by the REB for the purpose of approval of the research. Reviewers are assigned by the REB Manager or designee based upon the member's expertise and experience.

4.5.2. *The primary reviewer:*

- Conducts an in-depth review of the assigned research project with particular focus on the study protocol and ethics application form (EAF) form;
- Presents his/her assessment of the research at the convened meeting;
- Recommends a decision regarding approval or disapproval of the research.

4.5.3 *The secondary reviewer:*

- Conducts an in-depth review of the assigned research project, focusing on the EAF, informed consent form and any applicable patient materials and/or advertisements;
- Presents his/her assessment of the research study at the convened meeting and adds to the discussion initiated by the primary reviewer;
- Recommends a decision regarding the research, particularly patient-related materials.

4.5.4 All written comments are to be submitted to the Romeo Researcher's Portal prior to the commencement of the REB meeting.

4.5.5 In the event a primary reviewer is unable to present their assessment of the research, they are required to still submit their written review/comments to the Romeo Researcher's Portal prior to the commencement of the REB meeting. The presiding co-chair will present on their behalf;

4.5.6 Secondary reviewers who are not able to participate in a meeting are required to still submit their written review/comments to the Romeo Researcher's Portal prior to the commencement of the REB meeting.

4.6. Training & Continuing Education

4.6.1. REB members are expected to follow training and education procedures;

4.6.2. REB members are encouraged to participate in continuing education opportunities and events, including conferences, Advances, seminars, and/or reading pertinent articles/books.

4.7. Conflict of Interest

4.7.1. REB members are expected follow conflict of interest procedures.

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;

3) International Conference on Harmonization Good Clinical Practices, Section 3.
4) US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.107;
5) US Food and Drug Administration (FDA) CFR Title 21 Part 56.107.

6 RELATED DOCUMENTS:

1) NSHA Terms of Reference
2) NSHA REB-SOP-1-006A, Standard Operating Procedure (SOP) *Disclosure and Documentation of Conflict of Interest - REB Members & REB Office Personnel.*

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