

Nova Scotia Health Authority Research Ethics Board (NSHA REB)

Terms of Reference

AUTHORITY

The Nova Scotia Health Authority Research Ethics Board (NSHA REB) reports to the Quality Committee of the Board of Directors for the Nova Scotia Health Authority.

PURPOSE AND RESPONSIBILITIES

The NSHA 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 in order to protect the rights, safety, and wellbeing of research participants within the Nova Scotia (NS) Health Authority. The NSHA REB reviews and oversees this research to verify that it is scientifically valid and ethically acceptable.

The NSHA REB is guided in decision-making regarding research protocols by (a) the Tri-Council Policy Statement 2, Ethical Conduct for Research Involving Humans, (b) the ICH Good Clinical Practice: Consolidated Guideline, (c) Canadian and Nova Scotia laws and regulations and (d) other national and international standards and guidelines as applicable.

In brief, the NSHA REB has the authority to:

- Approve, disapprove, propose modification to, restrict, suspend, or terminate any proposed or ongoing human subjects research involving staff (including medical staff), patients, resources or data within the NS Health Authority (TCPS 2);
- Solicit ad hoc independent external peer review and to seek external advice. The NSHA REB is accountable for any decision made on the basis of this advice;
- Monitor research, including auditing documents and observing the consent process.

The NSHA REB delegates the review of clinical trial study budgets to Research Services.

MEMBERSHIP

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 (TCPS2) on Ethical Conduct of Research Involving Humans (Article 6.4), The International Conference on Harmonization Good Clinical Practices (ICH GCP 3.2.1) and applicable national and international regulatory requirements.

Medical representatives are designated by their respective departments/divisions. Legal, general and community representatives are volunteers who have responded to recruitment initiatives put forth by the NSHA REB. Members will be appointed by the REB Manager in consultation with the Executive Chair. Board members will be selected on the basis of their qualifications and expertise and consideration of the NSHA REB needs (Article 6.7).

The REB Executive Chair is appointed by the Vice President, Research and Innovation and is accountable to the Quality Committee of the Board of Directors for the Nova Scotia Health Authority (NSHA) and to the NSHA REB executive committee. Details regarding the executive chair's role and responsibilities are outlined in the executive chair's position description;

The Executive Chair submits annual reports to the Quality Committee of the Board of Directors for NSHA and the NSHA REB executive committee summarizing the activities and accomplishments of the NSHA REB in reviewing, approving, and enhancing the ethical conduct of research being conducted within NSHA;

The Executive Chair and Co-Chairs will be appointed for a 3-year term with the possibility for re-appointment. Chairs have the option of remaining in their capacity on a year-to-year basis after their term has expired.

QUORUM

Quorum consists of at least 50% + 1 of the board members and must include a co-chair and the minimum membership requirements outlined in the section on composition of the NSHA REB. If quorum cannot be achieved after 30 minutes, the meeting is to be rescheduled.

Decisions made at a convened meeting require a quorum to be present. The NSHA REB will strive to arrive at decisions by consensus; if consensus cannot be reached there shall be a vote. The results of the vote, including objections and abstentions will be documented in the minutes. If quorum is lost during a meeting, no further decisions will be made until quorum is restored (CGBS, 2012).

MEETINGS

Except when a delegated review procedure is used, the NSHA REB will review proposed research at convened meetings at which a quorum is present. The NSHA REB (one working group per week) meets every Monday at 4pm, unless there is a statutory holiday or insufficient business to warrant a meeting.

In the event a member will be absent from a meeting at which his/her assigned submission will be discussed, he/she must notify the research ethics office and must find an appropriate replacement (selected from members of their respective role on the NSHA REB (i.e. legal representative may replace another legal representative) to complete the assigned reviews and attend the meeting. On rare occasions, absent members may be asked to provide written reviews prior to the meeting and/or participate in meetings via conference call.

Decisions made at a convened meeting require a quorum to be present. The NSHA REB will strive to arrive at decisions by consensus; if consensus cannot be reached there shall be a vote. The results of the vote, including objections and abstentions will be documented in the minutes.

The NSHA REB is entitled to seek input from ad hoc advisors at its discretion. The NSHA REB is entitled to have observers attend REB meetings at the discretion of the Chair. All observers are required to sign a confidentiality statement.

CONFLICT OF INTEREST

NSHA REB members are in a conflict of interest when their own research projects are under review by the NSHA REB, when they are a co-investigator, or when they are in a supervisory or mentoring relationship with a graduate student applicant. NSHA REB members may also be in a conflict of interest situation when they have interpersonal or financial relationships with the researchers, or personal or financial interests in a company, labor union or not-for-profit organization that may be the sponsor of the research project, or that may be substantially affected by the research.

NSHA REB members must complete a conflict of interest disclosure form to be filed in their training binder. The form asks members to list personal, financial interests and arrangements that might constitute a conflict of interest, and stipulates that members must exclude themselves from the review of studies for which they may have a conflict of interest.

The minutes will reflect that a Conflict of Interest was declared and that the NSHA REB member removed him or herself from the deliberations.