Nova Scotia Health Research Ethics Board
Terms of Reference

AUTHORITY

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

PURPOSE AND RESPONSIBILITIES

The NS Health REB's primary mandate is to oversee that research conducted within the NS Health jurisdiction is scientifically valid and ethically acceptable. To fulfill this mandate, the NS Health REB reviews, approves, and conducts periodic reviews of research studies involving patients, affiliated physicians/scientists, staff, resources, and/or data to protect the rights, safety, and wellbeing of research participants within Nova Scotia (NS) Health's jurisdiction.

The NS Health REB is guided in decision-making by

- The Tri-Council Policy Statement 2, Ethical Conduct for Research Involving Humans,
- The ICH Good Clinical Practice: Consolidated Guideline,
- Canadian and Nova Scotia laws and regulations,
- Other national and international standards and guidelines as applicable.

The NS Health REB has the authority to:

- Approve, disapprove, propose modification(s), restrict, suspend, or terminate any proposed or ongoing human subject research involving staff (including medical staff), patients, resources, or data within the NS Health's jurisdiction.

- Solicit *ad hoc* independent external peer review and to seek external advice. The NS Health REB is accountable for any decision made based on this advice.

- Monitor research, including auditing documents and observing the consent process.

The NS Health REB delegates the review of clinical trial study budgets to Research Contracts.

MEMBERSHIP

The NS Health REB membership complies with:

- The Human Research Standards Organization: Ethical Review and Oversight of Human Research,
- 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),
- Other applicable national and international regulatory requirements.

REB members are volunteers who have responded to recruitment initiatives put forth by the NS Health REB. Members will be appointed by the REB Manager in consultation with the Executive Chair. Board members will be selected based on their qualifications and expertise with consideration of the NS Health REB needs. Details of membership requirements based on the above interpretations are outlined in NSH-REB-SOP-2-001.

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 NS Health and to the NS Health REB Executive Committee. Details regarding the Executive Chair's role and responsibilities are outlined in the Executive Chair's position description in the Research Ethics Office Manual.

The REB Manager submits monthly reports to the Senior Director, Research and VP, Research and Innovation. These reports contain metrics of ongoing research activity reported to the REB and major activities and accomplishments of the NS Health REB and office staff in reviewing, approving, and enhancing the ethical conduct of research within NS Health.

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

A 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 NS Health REB. If a 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 NS Health REB will strive to arrive at decisions by consensus, documented through anonymous voting. 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.

MEETINGS

Except when a delegated review procedure is used, the NS Health REB will review proposed research at convened meetings at which a quorum is present.

In the event a member will be or is absent at a meeting at which their assigned review will be discussed, they are asked to notify the Research Ethics Office as early as possible so that the office staff may find a replacement. On occasions, absent members may be asked to provide detailed written reviews prior to the meeting.

The NS Health REB is entitled to seek input from *ad hoc* advisors at its discretion. The NS Health 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

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

NS Health REB members must complete a conflict-of-interest disclosure form to be filed in their training binder by Research Ethics Office staff. The form asks members to list personal, monetary interests and arrangements that might constitute a conflict-of-interest. It also stipulates that those 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 NS Health REB member removed themselves from the deliberations.