TITLE:	Standard Operating Procedure (SOP) NSHA REB Meeting Administration	**NUMBER:**	NSHA REB-SOP-3-002
Effective Date:	April 2014	Revision:	September 29, 2017
Applies To:	NSHA REB Executive Chair, Co-Chairs and REB Office Personnel.		

1. PURPOSE:

The purpose of this standard operating procedure (SOP) is to describe the required activities for the preparation, management and documentation of the Nova Scotia Health Authority Research Ethics Board (NSHA REB) Full Board meetings.

2. POLICY:

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 4 p.m., unless there is a statutory holiday or insufficient business to warrant a meeting.

The REB meeting agenda provides the meeting content, establishes a sequence of review, and includes a list of items that are pending review by the Full Board (i.e. Full Board request for annual renewal, old and new business) as well as the assigned reviewers for each of those items. An Excel spreadsheet of all items that have been reviewed and approved by delegated review procedures since the last convened REB meeting is also included with the agenda as an electronic attachment.

The meeting agenda provides the foundation for the meeting minutes. The REB meeting minutes document the actions that occur during the REB meeting and should provide the REB itself with sufficient detail to help it reconstruct its discussions at a later date, if necessary.

3. DEFINITIONS:

Quorum: a simple majority of Research Ethics Board (REB) members (50% + 1), who collectively have sufficient expertise in the scientific, methodological and clinical areas of the research under review and are knowledgeable about relevant ethical and legal matters. The quorum will include at least one community member and a member whose primary experience and expertise are in a non-scientific discipline. Quorum includes REB members participating by telephone or video conference.

4. PROCEDURES:

4.1. Agenda Preparation

4.1.1. Following an administrative review of the submission (e.g. new studies, amendments, requests for annual renewals, etc.) by the REB Officer Personnel and the determination of the review type by the REB Executive Chair or designee, the responsible REB Office Personnel, in consultation with the manager as necessary, adds any submissions requiring Full Board review to the next appropriate Full Board meeting agenda;

4.1.2. The REB Office Personnel will attach a report of all items that were previously reviewed and approved via delegated review procedures to the Full Board meeting agenda;

4.1.3. The REB Office Personnel attaches to the meeting agenda any previous REB meeting minutes for Full Board review and approval, and adds any other items for information or discussion at the REB meeting (e.g. SOP's, reports, etc.);

4.1.4. The REB Office Personnel, in consultation with the Executive Chair or designee as necessary, reviews the agenda, confirms meeting attendance, and assigns the reviewers for each project;

4.1.5. The meeting agenda, reviewer assignment and relevant supporting documents (e.g. reports, minutes) are sent by email from the REB Office Personnel five days prior to the meeting for the applicable working group.

4.1.6. Ad hoc advisors will receive copies of relevant submissions;

4.1.7. Any changes to the agenda are communicated to all REB members and REB Office Personnel. The REB Officer Personnel or designee may also issue an updated agenda notice depending on the nature of the changes.

4.2. Primary and Secondary Reviewers

4.2.1. Prior to the meeting, the REB Office Personnel, in consultation with the REB Chair or designee as necessary, will assign a primary and secondary reviewer for each new research study.

4.2.2. No REB member will be assigned as a reviewer on a submission in which he or she is a project team member or in which there is a declared conflict of interest;

4.2.3. The REB Office Personnel will issue the reviewer assignment via the Romeo Researcher's Portal. The assigned reviewers will receive an email notification from the Romeo Researcher's Portal. The meeting agenda and supporting documents will be sent in a separate email from the REB Office Personnel;

4.2.4. If any of the assigned reviewers declare a conflict, the submission is reassigned to another reviewer.

4.3. Prior to the REB Meeting

4.3.1. All REB members have access to each study that is listed on the meeting agenda via the Romeo Researcher's Portal. This includes:

- Submission checklist
- Ethics Application Form (EAF)
- Study protocol
- Surveys and questionnaires and patient information materials
- Product information (e.g., product monographs, investigator's brochures)
- Informed consent forms (ICF)
- Letter of support from the principal investigators dept./div./program/service
- Letter of support from the site investigators dept./div./program/service
- Letter(s) of support from collaborating CDHA departments
- Invoice request
- Letter of Authorization / Objection from Health Canada
- Radiological review application
- Peer review comments (both internal & external)
- Correspondence from another REB
- Copy of the PI's current license to practice in Nova Scotia
- PI's completion certificate for the online tutorial TCPS 2 CORE
- Site investigator's completion certificate for the online tutorial TCPS 2 CORE
- A current (within 2 years) signed and dated copy of the PI's CV
- A current (within 2 years) signed and dated copy of the site investigator's CV

4.3.2. The primary and secondary reviewers will conduct in-depth reviews of their assigned submissions and are expected to submit written reviewer comments via the Romeo Researcher's Portal prior to the REB meeting. The primary reviewer will focus on the research protocol and application form and is expected to lead the discussion at the meeting. The secondary reviewer will focus on the consent form and other supporting materials.

4.3.3. All REB members are expected to conduct a review of each agenda item prior to the Full Board meeting, including previous REB meeting minutes, and any attachments to the agenda for review or discussion;

4.3.4. All REB members should be prepared to present their comments and/or submit electronically to the Romeo Researcher's Portal and participate in

the discussion at the Full Board meeting.

4.4. During the NSHA REB Meeting

4.4.1. A quorum must be present to conduct a convened meeting;

4.4.2. Should quorum fail during a Full Board meeting (e.g., through recusal of members with conflicts of interest or early departures), the REB may not make further decisions unless quorum can be restored;

4.4.3. Should a REB member not be physically present during a Full Board meeting, he/she may participate via videoconference or teleconference. REB members participating by videoconference or teleconference will count towards quorum;

4.4.4. *Ad hoc* advisors, consultant(s) and those members recusing themselves due to conflicts of interest will not be used to establish a quorum;

4.4.5. Under unusual circumstances (e.g. public health alerts and quarantines) the REB Chair or designee may, at his/her discretion, conduct an REB meeting with all REB members attending via simultaneous videoconference or teleconference, provided everyone has access to the review materials and quorum is met;

4.4.6. Only those REB members present (i.e., in person, or via videoconference or teleconference) at the Full Board meeting may participate in the deliberation and final decision regarding approval;

4.4.7. Observers may be invited or permitted to attend REB meetings, subject to the agreement of the REB and execution of a *Confidentiality Agreement*. Observers must disclose any vested interest in, or scientific or management responsibility for, any applications being considered at the REB meeting;

4.4.8. If requested, the Principal Investigator (PI) or their designate, may attend the REB meeting to present their study and respond directly to any comments or questions raised by the REB, subject to agreement by the REB. The PI/designate may not be present for REB discussions, deliberations and decisions;

4.4.9. Any individual not listed on the current NSHA REB membership list may not participate in the decisions of the NSHA REB;

4.4.10. The REB Office Personnel will record attendance and recusal of members in conflict.

4.5. Minute Meeting Preparation

4.5.1. The REB Office Personnel will draft the REB meeting minutes including key discussions, decisions, votes, recusals due to conflict of interest and/or early departures;

4.5.2. The key REB discussions and decisions for submissions are recorded;

4.5.3. The REB's concerns, clarifications and recommendations to the PI as discussed at the REB meeting are included in the REB review letter that is sent to the PI. The information documented in the letter is included in the REB minutes, with the exception of changes requested to the informed consent form(s), which are summarized with the number of changes rather an exhaustive list;

4.5.4. The meeting may be audio tape recorded (on an encrypted device) for reference purposes and to provide additional reference information for the generation of the final draft minutes;

4.5.5. The minutes are intended to reflect what the REB decided, how it resolved controverted issues, and any determinations required by the regulations;

4.5.6. The draft minutes should be completed and prepared for distribution prior to the next REB meeting.

4.6. Meeting Minute Approval

4.6.1. The minutes are included in the REB meeting package sent by email from the REB Office Personnel, five days prior to the scheduled Full Board meeting where the minutes are presented for review and approval;

4.6.2. It is the responsibility of the REB members to review and recommend changes (as necessary) to the meeting minutes;

4.6.3. The REB motion and votes on the previous meeting minutes noting any required revisions are recorded in the current meeting minutes;

4.6.4. If the previous REB meeting minutes are approved pending modifications, the REB Office Personnel makes the required changes, and unless the REB requests further review of the minutes prior to approval, the REB Office Personnel records the minutes as "approved by the REB."

4.7. Documentation

4.7.1. The REB meeting minutes include the following items:

- Date, place, and time the REB meeting commenced and adjourned,
- Names of REB members in attendance (present, teleconference, videoconference),
- Names of REB members absent,

- Names of REB Office Personnel present at the meeting,
- Presence of observers,
- Use of ad hoc advisors, or consultants and their specialty,
- List of declared conflicts of interest or a note that none were declared,
- A summary of key discussions and issues and their resolution for each submission, as applicable,
- The decisions taken by the REB regarding approval for each submission, as applicable,
- The basis for requiring changes or for disapproving submissions,
- REB member(s) recused related to conflicts of interest for each submission requiring a decision,
- Number(s) voting for, against or abstaining in the event of a vote for each submission requiring a decision,
- Reference to any attachments to the agenda;

4.7.2. Reviewer comments are stored electronically in the Romeo database as part of the meeting review;

4.7.3. The REB membership listed is completed and a copy is sent to each Investigator/research team whose studies were reviewed at the meeting;

4.7.4. Meeting agendas, and meeting minutes are retained in the REB records and are stored as per Part C Division 5 of the Food and Drug Regulations of Health Canada;

4.7.5. The meeting agenda and meeting minutes are confidential documents not released outside the research ethics office unless required by law. They may be inspected by authorized regulatory personnel (e.g., Health Canada, FDA).

5 REFERENCES

1) Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2014 (TCPS2 2014) Article 6.10; 7.3;
2) The International Conference on Harmonization Guidelines for Good Clinical Practice, Section 3;
3) US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.103; 46.107; 46.108, 46.109, 46.115;
4) US Food and Drug Administration (FDA) Code of Federal Regulations Title 21 Part 56.107, 56.108, 56.109, 56.115.

6 RELATED DOCUMENTS:

1) Confidentially agreement for NSHA REB Members

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