TITLE:	Standard Operating Procedure (SOP) NSHA REB Review Decisions	**NUMBER:**	NSHA REB-SOP-4-002
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 decisions that the Nova Scotia Health Authority Research Ethics Board (NSHA REB) may make resulting from its review of proposed research.

2. POLICY:

As a result of its review, the NSHA REB has the authority to approve, disapprove, or require modifications/clarifications to submitted research projects. If there are questions that must be addressed prior to a determination, the NSHA REB may defer its decision. When the Full Board review procedure is used, decisions will be made by consensus of the REB members in attendance at a convened meeting with a quorum present. If consensus cannot be achieved, a vote will be taken.

The REB Chair or designee is responsible for ensuring that a decision is made for every submission that is reviewed by the REB, that the decision is clearly understood, and that the delegation of responsibility for considering any further information prior to issuing approval is clearly agreed.

NSHA REB members with a conflict of interest regarding the research under review must not participate in the deliberations or the decision, in accordance with the REB's and organization's conflict of interest policies.

When the delegated review procedure is used, the REB Chair and/or REB member(s) who are assigned to review the research can decide to approve or to request revisions to the research; the decision to disapprove the research can only be made by the Full Board. A delegated review is "Not Approved" only if the submission it is incomplete or has ethical issues.

No research participant is to be recruited to participate in any research study prior to receiving the REB's written approval.

Researchers have the right to request reconsideration of the REB's decisions and to appeal the decision of the REB.

3. DEFINITIONS:

Appeal: A process that allows a researcher to request a review of a research ethics board (REB) decision when, after reconsideration, the REB has refused ethics approval of the research (TCPS 2).

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. NSHA REB Decisions

4.1.1 REB decisions are made either by consensus or a majority vote of the REB members present at a Full Board meeting, with the exception of those who have recused themselves in accordance with the conflict of interest policies. The REB Co-Chair abstains from voting except to break a tie vote;

4.1.2 The NSHA REB should reach one of the following decisions as a result of its review and deliberation of research submitted for initial or for continuing review:

- ***Full Approval*** *(approve the application as submitted, including the consent form)*:
  - When an acceptable risk/benefit ratio exists and the regulatory criteria required for approval are satisfied, the research may be approved as submitted;
  - The decision is made by a consensus of the members present, excluding those who have a conflict of interest;
  - If consensus cannot be achieved, a vote will be taken;
  - The approval date is defined as the date of this letter confirming that the research was reviewed and approved at a convened NSHA REB meeting. The expiration date is calculated from this letter date. Notwithstanding rare circumstances, this date is the day following the convened NSHA REB meeting.

- ***Clarifications Requested***

  - When an acceptable risk/benefit ratio exists, the regulatory criteria required for approval are satisfied, but the REB members require modifications to any aspect of the application or clarification or further

information to secure approval, the REB may recommend the research be “approved with clarifications”;

- When the REB recommends “approved with clarifications,” the REB Chair or designee should ensure that the additional information, modifications, or clarifications required are identified at the REB meeting and that the procedures for reviewing the additional information and issuing the approval are clear. The responsibilities for additional review and the decision regarding approval conditions should be delegated to one of the following:
  - The Co-Chair alone,
  - The Co-Chair and one or more named REB members that were present at the REB meeting or who submitted written comments on the application,
  - A sub-group of the REB members designated by the Co-Chair,
  - A designated REB member or members with sufficient knowledge and experience regarding the research and the regulations.
- In deciding the procedures to be followed, the REB will consider the significance of the requested additional information or modifications and the expertise necessary to assess it. Where the information or modifications are straightforward, it is acceptable to delegate the consideration of that materials to the Co-Chair alone,
- Where the additional information/modification is technical (e.g. statistical clarifications), the Co-Chair should review the information with consideration given to involving other REB members, such as the lead reviewer(s) or relevant expert member(s),
- A “clarifications requested” letter addressed to the Principal Investigator (PI) is composed by the assigned REB Ethics Coordinator and reviewed by the presiding Co-Chair (or designee), typically the day after the Full Board meeting, outlining the requested clarifications/modifications and/or explanations;
- The PI is permitted a maximum of three months (unless an extension is requested) to respond to the REB regarding the requested clarifications/modification and/or explanations;
- If the Investigator’s response to the “clarifications requested” letter is deemed complete and satisfactory by the assigned Co-Chair (with input from the reviewers as applicable), approval can be issued by the Co-Chair;
- If the PI’s response to the “clarifications requested” letter is incomplete and does not fully address the matters raised, requests for further information, modifications or clarification will be sent to the Investigator and/or research team,
- The reviewers may decide upon reviewing the Researcher’s response that the decision should be deferred and that the application and the Researcher’s response materials should be reviewed at a subsequent Full Board meeting (see ‘Deferral’ process below),

- The approval date is defined by the date of the initial Full Board meeting. The expiry date of the REB approval is calculated from this date; however, the approval letter is not issued until all of the conditions for approval have been met.

- ***Deferral (defer decision making on the application and continue deliberation of the application at a future Full Board meeting)***
  - The REB may defer its decision to a subsequent Full Board meeting when significant questions are raised during its review of the research;
  - The research and the PI's response materials shall be reviewed at a Full Board meeting,
  - The PI or a member his/her research team may be invited to attend the Full Board meeting to respond to questions and provide clarification around the issues raised at the initial meeting;
  - Upon consideration of the research along with the response from the PI, at the Full Board meeting, the REB should issue its final decision (approval, approval with clarifications, deferral or disapproval),
  - The review decision is made by a consensus or a vote of the members present, excluding those who have conflict of interest
  - The approval date is defined by the date of the initial Full Board meeting. The expiry date of the REB approval is calculated from this date; however, the approval letter is not issued until all of the conditions for approval have been met.

- ***Disapproval***
  - The REB may disapprove the research when it fails to meet the ethical or scientific standards for approval and where revision is unlikely to enable the REB to reach a positive determination;
  - Disapproval cannot be decided through the delegated review procedure. If the recommendation under delegated review is to disapprove the research, a final decision must be made by the REB at a Full Board meeting;
  - The decision to disapprove the research is made by a consensus or vote of the members present, excluding those who have a conflict of interest;
  - The Co-Chair should ensure that the reasons for disapproval are clearly identified at the Full Board meeting for communication to the PI;
  - When the research is disapproved, the reasons for disapproval will be communicated to the PI and he/she will be given an opportunity to respond in person or in writing.

4.2. Delegated Reviews

- When the research qualifies for delegated review, the reviewer(s) has the authority to approve the application, to require modifications

to any aspect of the application, or to request clarification or further information before considering it eligible for ethics approval. The reviewer(s) may also refer the applications as submitted for a review at a Full Board meeting;

- When delegated review procedures are followed, approval is considered as the day the research is approved by the REB Chair or designee as well as all other designated reviewer(s), if applicable. The expiry date of the REB approval is calculated from this date; however, the approval letter is not issued until all of the conditions for approval have been met;

- The research cannot be disapproved through the delegated review procedure; the decision to disapprove the research can only be made by the Full Board following review of the research at a Full Board meeting. A delegated review study is "Not Approved" only if the submission it is incomplete or has ethical issues.

4.3. Reconsideration and Appeal of REB Decisions

4.3.1 Researcher's may appeal the decision of the REB if the disagreement between the Principal Investigator/applicant and the REB cannot be resolved through a reconsideration process at a Full Board meeting at which the Principal Investigator / applicant shall have the right to be heard;

4.3.2 The Principal Investigator must justify the grounds on which a reconsideration of the decision is requested. An appeal may be launched only for procedural or substantive reasons, and a final decision after reconsideration must be issued by the REB prior to the initiation of an appeal process;

4.3.3 St. Michael's Hospital in Toronto, Ontario, is the organization at which the appeal will take place in consultation with the Researcher (and his/her affiliated organization);

4.3.4 The appeal committee shall have the authority to review negative decisions made by the REB and in so doing it may approve, disapprove or request modifications to the research proposal. Its decision shall be final and shall be communicated to the Researcher and the REB in writing.

4.4 Documenting REB Decisions

4.4.1 For each study, the responsible REB Officer Personnel will ensure that the meeting minutes will satisfy the applicable requirements and includes the following:

- The REB's decision,

- If a consensus is not achieved, the outcome of a vote (i.e., the number of members in agreement, opposed, abstained),
- Any members not present due to conflicts of interest,
- Any modifications/clarifications requested by the REB,
- Additional information requested from the investigator (if applicable);

4.4.2 The REB shall notify the Principal Investigator in writing of its decision to approve or not approve the proposed research, or of modifications/clarifications required to secure approval of the research;

4.4.3 The initial review letter will contain the following: date of review, a list of all reviewed material, requests for any clarifications/revisions, contact information for the REB and references to compliance with regulations, and the assigned co-chair's electronic signature;

4.4.4 The final approval letter will contain the following: a list of all received materials, confirmation of official NSHA REB approval, a list of all approved documents, standard conditions of approval to which the Principal Investigator must adhere to, the period for which the approval is granted, instructions for the Principal Investigator to maintain ongoing correspondence with the REB, and the electronic signature of the co-chair;

4.4.5 If the REB defers its decision, the letter to the Principal Investigator will include the issues of concern, what further information is required, and notification that the information will be discussed at a subsequent Full Board meeting, with the Principal Investigator invited to attend;

4.4.6 When the decision to approve a submission is recorded on behalf of the Full Board, or by delegated review procedures, the notification or correspondence to the Principal Investigator may be issued by the responsible REB Office Personnel;

4.4.7 All official correspondence between the REB and investigators must contain a version number and/or date. This allows for proper auditing and efficient administration of the study.

4.5 Additional Criteria

4.5.1 Clinical trials that require a regulatory submission (initial submission/review) are issued provisional approval to allow for submission to Health Canada. Following evidence of no objection from Health Canada, the NSHA REB will issue final approval.

5 REFERENCES

1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2014 (TCPS 2 2014), Chapter 1, 2 and 6;

2. International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines as adopted by Health Canada, Section 3.0;
3. US Food and Drug Administration (FDA) Code of Federal Regulations (CFR), Title 21 CFR 50 and 56;
4. US Department of Health and Human Services (HHS) Title 45 CFR 46.109, 46.111.

6 RELATED DOCUMENTS:

1. Appeals policy
2. NSHA REB-SOP-4-003-Delegated Review Procedure

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