TITLE:	Standard Operating Procedure (SOP) Delegated Review Procedure	**NUMBER:**	NSHA REB-SOP-4-003
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 processes for determining when research meets the criteria for delegated ethics review and the associated delegated review procedures.

2. POLICY:

Full board review is the default requirement for all research involving human participants; however, in some unique circumstances, research may be eligible for delegated review based primarily on the harms that are expected to arise from the research.

The NSHA REB has adopted a proportionate approach to research ethics review based on the general principle that the more invasive or harmful the proposed and ongoing research, the greater should be the care in assessing the research. While all research must be reviewed adequately, requirements for proportionate review allow the REB to provide an intensive level of scrutiny, and correspondingly more protection, for the most ethically challenging research.

In practice, the proportionate review implies different levels of REB review for different research projects. The NSHA REB utilizes two levels of review; Full Board review, or delegated review by one or more experienced REB members, as determined by the REB Chair or designee.

The REB Executive Chair or designee is responsible for determining if the research is eligible for delegated review. In some circumstances, the Executive Chair or designee may delegate this task to qualified REB Office Personnel; however, the responsibility for oversight remains with the Executive Chair or designee.

3. DEFINITIONS:

1) **Continuing Review:** Any review of ongoing research conducted by a research ethics board (REB) occurring after the date of initial REB approval and continuing throughout the life of the project to ensure that all stages of a research project are ethically acceptable in accordance with the principles in the Policy.

2) **Delegated review (also referred to as expedited review)**: the level of Research Ethics Board (REB) review assigned to minimal risk research studies, to minor changes in approved research and to continuing review applications that meet the delegated review criteria. Delegated reviewers are selected from among the REB membership to conduct the review.

3) **Minimal Risk:** Research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in the aspects of their everyday life that relate to the research.

4. PROCEDURES:

4.1. Determination of Qualification for Delegated Review

4.1.1. Full Board review is the default for most new research submissions involving human participants; however, some research may be eligible for delegated review based primarily on the limited potential for harm that could arise from the research;

4.1.2. Where it is clearly established that the research is of minimal risk, the Executive Chair or designee may authorize a delegated ethics review. Submissions that meet the following criteria may be eligible for delegated review. Any exceptions to those categories noted below are at the discretion of the executive chair or designee:

- Research projects that are expected to involve no more than minimal risk,
- Minor or minimal risk changes to previously approved research,
- Continuing review (annual renewals) of approved minimal risk research,
- Continuing review (annual renewals) of research that is no more than minimal risk for which enrolment is closed permanently and all research-related interventions for all participants are complete and the only remaining research activities are post-intervention activities or follow-up of participants; or, where the remaining research activities are limited to data analysis; or, where no participants have been enrolled and no additional risks have been identified,
- Continuing review of research that is more than minimal risk when there has been little or no modification of the research; and when there has been no increase in risk to or other ethical implications for

participants since the initial review by the full REB; if permissible under all applicable governing Regulations,

- Evidence that conditions or other requirements laid down by the NSHA REB in an initial review have been met,
- Changes to consent documents that do not affect the rights and welfare of research participants or involve increased risk, or affect data integrity, or require significant changes in research procedures,
- Reportable events, including adverse events and safety updates such as reports from Data and Safety Monitoring Boards (DSMB);

4.1.3. The REB Chair or designee may use delegated review procedures for the review of other types of minor changes including, but not limited to, the following:

- Participant materials such as: recruitment posters or scripts, diaries, validated questionnaires, clinical trial identification/wallet cards,
- Authorized translations of English versions of documents previously-approved by the REB;

4.1.4. The REB Chair or designee may be authorized by the Full Board to use delegated review procedures for the review of miscellaneous items such as changes to meeting minutes that previously received approval with conditions at a Full Board meeting;

4.1.5. When determining if initial review of research or modifications to previously approved research are eligible for delegated review, the REB Chair or designee will take into consideration the methods used to conduct the research, recruitment practices, participant population, confidentiality of data, and all regulatory and ethics guidance requirements as applicable.

4.2. Procedure for Conducting Delegated Review

4.2.1. The REB Executive Chair or designee will make the determination of whether the submission meets the criteria for delegated review;

4.2.2. For research that meets the criteria, delegated review may be conducted by the REB Executive Chair, designee or by qualified REB Office Personnel, in addition to one or more qualified REB members;

4.2.3. Using the Excel spreadsheet located on the shared drive, REB Office Personnel will select the REB member who is next to conduct a delegated review. REB Office Personnel will send an email notification to the assigned reviewer which includes a link to the Romeo Researcher's Portal where all study related documents can be accessed;

4.2.4. The assigned reviewer is requested to review the study and to submit their electronic comments via the portal within five days;

4.2.5. Once the delegated review has been completed by the assigned reviewer, the submission is assigned to the responsible REB Office Personnel and a Co-Chair;

4.2.6. The REB Office Personnel prepares the initial letter based on reviewer comments and then sends an email notification to the assigned Co-Chair;

4.2.7. The Co-Chair will review the submission and the letter, and may request revisions as necessary;

4.2.8. Upon approval of the letter by the Co-Chair, the responsible REB Office Personnel will email the letter to the Principal Investigator and/or research team via the researcher's portal;

4.2.9. A copy of the current membership list is NOT sent to the Principal Investigator and/or research team for reviews conducted using delegated review procedures. The current membership list is only provided for research that undergoes Full Board review.

4.3. Authority of Delegated Reviewer(s)

4.3.1. The reviewer may exercise all of the authorities of the NSHA REB, except that they may not disapprove the research; the research may only be disapproved after it has been reviewed at a Full Board meeting;

4.3.2. The REB Executive Chair or designee or REB member reviewing research under delegated review procedures must not have a conflict of interest in the research.

4.4. Continuing Review: Amendments to the Protocol and/or Informed Consent Form, and Annual Approvals

4.4.1. Research that was previously reviewed by delegated review procedures may be reviewed at the time of annual approval using delegated review procedures;

4.4.2. Research that was previously reviewed by the full NSHA REB may be reviewed at the time of annual approval using delegated review procedures when there are minimal-risk changes, or no changes to previously approved research;

4.4.3. If the NSHA REB Executive Chair, Co-Chair, or designate, determines that the risks are now more than minimal, the study will be deferred for Full Board review at the next NSHA REB meeting;

4.4.4. The PI will be sent a notification from the REB Office Personnel notifying them of the Full Board meeting date, as well the research team will be

advised to ensure that the information provided to the REB is in lay terms for presentation to the Full Board;

4.4.5. Delegated review procedures may be used for changes proposed to study related documents that do not affect the rights, safety and welfare of study participants and do not involve increased risk or significant changes in study procedures;

4.4.6. A copy of the current membership list is NOT sent to the Principal Investigator and/or research team for continuing review (review of already approved research) conducted using delegated review procedures. The current membership list is only provided for continuing review that requires Full Board review.

4.5. Serious Adverse Events and Safety Updates

4.5.1. Delegated review procedures may be used for reports of unanticipated problems (including serious adverse events) and safety updates such as reports from Data Safety Monitoring Committees;

4.5.2. If the Co-Chair, subsequently considers that action is needed to protect the safety of research participants, he/she may take such action and/or request that the NSHA REB Executive Committee review reports of unanticipated problems or safety updates to determine what further action, if any, is required.

4.6. Notification of Delegated Review Decisions to the NSHA REB

4.6.1. At its next Full Board meeting, the NSHA REB will be informed of research that was reviewed and approved using delegated review procedures, including full approvals, amendments, and annual approvals.

5 REFERENCES

1) Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2014 (TCPS2 2014),Chapter 1 section C; Chapter 2 section B; Article 6.12;
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 46.102, 46.110;
4) US Food and Drug Administration (FDA) Code of Federal Regulations Title 21 Part 56.102, 56.110;

6 RELATED DOCUMENTS: n/a

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