TITLE:	Standard Operating Procedure (SOP) Annual Approval Process	**NUMBER:**	NSHA REB-SOP-4-006
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 procedures for the continuing review of research overseen by the Nova Scotia Health Authority Research Ethics Board (NSHA REB) and the criteria for continued (renewed) approval.

2. POLICY:

Research is subject to continuing research ethics review from the date of initial NSHA REB approval throughout the life of the project. At the time of the initial review, the NSHA REB has the authority to determine the term of approval and the level at which continuing ethics review occurs (delegated or full board) in accordance with proportionate approach to research ethics review. The level of research ethics review may be adjusted over the life of the project based on the level of risk. For research projects lasting longer than one year, researchers shall submit, at minimum, a request for annual approval at least once per year, prior to the anniversary date, with sufficient details to enable the NSHA REB to make an informed judgment about the continued ethical acceptability of the research. For research lasting less than one year, a study closure reporting form is required.

The Principal Investigator cannot continue with the study after the initial approval period without submitting a request for annual approval to the NSHA REB. Failure by the investigator to ensure timely submission of requests for annual approval is a serious matter that may lead to expiration of NSHA REB approval, suspension or termination of the research project.

It is the responsibility of the Principal Investigator to immediately notify the REB in writing, of any changes significantly affecting the conduct of the study and/or increasing the risk to participants.

If any new information is received through continuing review that might affect the rights and welfare of research participants, the NSHA REB may require that the research be modified, suspended or terminated. The NSHA REB will also consider if this new information should be communicated to research participants.

3. DEFINITIONS:

See Glossary of Terms

4. PROCEDURES:

4.1. Level of NSHA REB Review for Annual Approvals

4.1.1. The Executive Chair may delegate the authority to approve requests for annual approval to the Co-Chair(s) when there has been no change or minimal change to the research project. Under these conditions, the request for annual approval will follow the Board's delegated review procedure.

4.1.2. If the Executive Chair or Co-Chair feels that a request for annual approval warrants review by the Full Board, they may make this request at any time.

4.1.3. Annual renewals will be reviewed by the Full Board if required by the study sponsor, funding agency, or regulatory agency.

4.1.4. Review of annual approval of studies funded by the US Federal Government or regulated by the US Food and Drug Administration must be reviewed by the Full Board unless they clearly meet the following criteria:

- The research is (i) permanently closed to the enrollment of new participants; (ii) all participants have completed all research-related interventions; and (iii) the research remains active only for long term follow up of participants; OR
- Where no participants have been enrolled and no additional risks have been identified; OR
- Where the remaining research activities are limited to data analysis.

4.2. Request for Annual Approval by the Full Board

4.2.1. Researchers are to submit their request for annual approval at least 30 days prior to the anniversary date as indicated in the NSHA REB initial letter to the Principal Investigator. This interval is required in order to ensure that the research ethics office has sufficient time to review the request;

4.2.2. Requests for annual renewal will be scheduled for the NSHA REB meeting that occurs immediately prior to the end of the approval period, to preserve the expiry date each year;

4.2.3. Annual renewal applications are due by the deadline for the applicable REB meeting (i.e., the expiry date must be on or before the scheduled REB meeting date). Where possible, the request for annual renewal will be assigned to the original working group's meeting (e.g. if group 1 originally reviewed the study, the request for annual approval will go to group 1's next scheduled meeting, provided it is prior to the study's anniversary date);

4.2.4. It is the Investigator's responsibility to submit requests for annual renewal on time. To assist the researchers in submitting on time, a courtesy reminder(s) approximately six to eight weeks prior to the expiry date may be generated. The Romeo database also has a "reminders" quick link that researchers can check to track any upcoming anniversary dates;

4.2.5. The responsible REB Office Personnel reviews the application for completeness, and requests any clarifications, missing documents or other information from the researchers, as applicable;

4.2.6. The REB may request verification from sources other than the investigator that no material changes have occurred since previous REB review. For example:

- Based on the results of a previous audit or inspection (internal or external),
- Suspected non-compliance,
- Studies involving vulnerable populations,
- Studies involving a potentially high risk to participants,
- Suspected or reported protocol deviations,
- Participant or Research Staff complaints,
- Any other situation that the REB deems appropriate;

4.2.7. The responsible REB Office Personnel will assign the application to the agenda of the next REB meeting if the research meets the criteria for Full Board review;

4.2.8. For research that meets the criteria for Full Board review, the REB will discuss the research at the Full Board meeting and will make a decision regarding the continued approval of the research, as well as any other additional determinations regarding the conduct of the research, as applicable.

4.3. Request for Annual Approval by Delegated Review Procedures

4.3.1. Researchers are to submit their request for annual approval at least 30 days prior to the anniversary date as indicated in the NSHA REB initial letter to the Principal Investigator. This interval is required in order to

ensure that the research ethics office has sufficient time to review the request;

4.3.2. It is the Investigator's responsibility to submit requests for annual renewal on time. To assist the researchers in submitting on time, a courtesy reminder(s) approximately six to eight weeks prior to the expiry date may be generated. The Romeo database also has a "reminders" quick link that researchers can check to track any upcoming anniversary dates;

4.3.3. When the research received initial approval via delegated review it may undergo delegated review at the time of continuing review;

4.3.4. Research that was previously reviewed by the Full Board may also be reviewed at the time of continuing review using delegated review procedures if the conditions are met;

4.3.5. The responsible REB Office Personnel reviews the continuing review application for completeness, including verification of the currently approved informed consent form(s), and requests any clarifications, missing documents or other information as applicable;

4.3.6. The responsible REB Office Personnel will forward the application to the appropriate REB Co-Chair;

4.3.7. The REB Co-Chair may request additional information or clarification, as necessary, and will make a decision regarding the continued approval of the research and the continued conduct of the research;

4.3.8. Upon reviewing an application that was sent for delegated review, if the reviewer determines that the risks are now greater than minimal, the reviewer will refer the application for review by the Full Board.

4.4. NSHA REB determinations for annual approval

4.4.1. To grant continuation of approval of the research, the REB must determine that:

- There have been no material changes to the research or to the informed consent form that have not been previously submitted and approved,
- There is no new conflict of interest or new information that has emerged that might adversely affect the safety or well-being of study participants,
- Risks to study participants are minimized and reasonable in relation to the anticipated benefits,
- Selection of research participants is equitable,

- Informed consent processes continue to be appropriate and documented,
- Adequate provisions are in place for monitoring and data protection to ensure the safety and privacy of participants and confidentiality and integrity of the data,
- Any complaints from research participants have been followed-up appropriately;

4.4.2. The REB may also make additional determinations, such as:

- Request changes to the informed consent form(s);
- Request changes for the continuing review interval (based on risks);
- Impose special precautions (e.g., frequency of monitoring, the requirement for interim reports or duration of approval period);
- Require modifications to the research;
- Suspending or terminate REB approval.

4.5. Annual Renewal Applications not Received by the Expiry Date

4.5.1. If the application for annual renewal is not submitted by the expiry date, an "Expired REB Approval" email will be sent from the research ethics office notifying the Principal Investigator and applicable research team members that a request for renewal must be submitted within seven days or the study will be closed immediately. Once closed, the Investigator must cease all research activities as specified by the REB;

4.5.2. In the event of a lapse in approval, the Principal Investigator is responsible for notifying the REB if there is a need to continue research-related medical treatment of current research participants for their safety and well-being (e.g. when the research interventions hold out the prospect of direct benefit to the subjects or when withholding those interventions poses increased risk to the subjects). The Principal Investigator should provide as much detail as possible about the proposed continued activities. The REB Chair or designee will review the request as quickly as possible and discuss the proposed continued activities with the Principal Investigator;

4.5.3. Enrollment to new participants is suspended during the period of expired renewal;

4.5.4. The NSHA REB executive chair or designee will decide whether prospective research data collection (except safety data) will be allowed and whether procedures that are being performed only for the purposes of the study should be undertaken until NSHA REB approval is reinstated;

4.5.5. If a renewal request is not received, the REB will send a Study Closure letter to the Principal Investigator and research services;

4.5.6. If the REB closes an expired study but the Principal Investigator wishes to continue the study, he/she must re-submit the proposal as a new submission, including a new submission fee, if applicable. After REB approval has been granted, the research team may recommence study activities and accounts will be re-activated.

4.6. Documentation and Communication

4.6.1. REB notice of annual approval or changes required to obtain annual approval will be distributed to investigators and/or research team members in a timely manner;

4.6.2. All REB continuing review activities will be documented, filed and retained per research ethics office operational procedures.

5 REFERENCES

I. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2014 (TCPS2 2014), Article 2.8, and 6.12.
II. The International Conference on Harmonization Good Clinical Practices, Sections 3, 4.4, 4.5, 4.10, 4.11, 4.12;
III. US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.109, 46.111, 46.113, 46.115;
IV. US Food and Drug Administration (FDA) CFR Title 21 Part 56.108, 56.109, 56.110, 56.111, 56.115.

6 RELATED DOCUMENTS:

I. NSHA REB-SOP-3-003: Document Management, Archiving and Retention
II. 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