TITLE:	Standard Operating Procedure (SOP) NSHA REB Submission Requirements & Administrative Review	**NUMBER:**	NSHA REB-SOP-3-001
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 Nova Scotia Health Authority Research Ethics Board (NSHA REB) submission requirements and the administrative review procedures. This SOP applies to all submissions including but not limited to: new research projects for initial review, amendments or modifications to approved research and consent forms, updated safety information, requests for annual approval, reports of unanticipated problems including serious adverse events, and protocol deviations.

2. POLICY:

REB members must rely on the documentation provided by the Principal Investigator (PI) and/or other parties for initial and continuing review. For that reason, the documents and materials submitted must provide adequate information to conduct the review and to make the required determinations.

The REB is supported by administrative procedures that ensure that REB members not only have adequate time for the assessment of the proposed research, but that the materials they receive allow them to adequately assess whether the research submission meets the criteria for REB approval. A new research submission will only be scheduled for REB review when it has been determined that the information and materials submitted provide an acceptable description of the proposed research.

The requirements for REB submissions are made available to all Researchers. The REB Office Personnel are responsible for maintaining and disseminating this information to Researchers.

For clinical trials, the PI must be a NSHA staff member (physician or dentist with an NSHA appointment, NSHA employee or other affiliated appointment with NSHA). External parties (outside of NSHA) and trainees (e.g., students, residents, fellows) may be Sub-Investigators but are not permitted to be the principal investigator. NSHA does not allow Co-Principal Investigators.

3. DEFINITIONS:

Researcher's Portal (ROMEO database): The ROMEO Researcher Portal is a web based system established to provide electronic submission, review and approval processes for the NSHA REB and grant/award applications. It may be accessed by research team members and supports collaborative editing and development of applications, REB submission, review and approval processes, and ongoing oversight of REB related activities.

4. PROCEDURES:

4.1 Submission Requirements

4.1.1 The required documents, checklists, format and submission procedures are outlined on the REB's website and on the appropriate REB submission forms and checklists found in the Romeo Researcher's Portal. A complete submission includes all of the documents listed on the researcher's checklist for submissions, as applicable;

4.1.2 The REB may request any additional documentation it deems necessary for the ethics review, or for ethics oversight;

4.1.3 The REB Office Personnel reserves the right to delay consideration of submissions that lack information critical to the deliberations of the REB review.

4.1.4 The REB requires that Extension Studies be submitted as a new submission when safety and supportive data from the main study are available; any exceptions to this must be authorized by the REB office and/or Executive Chair;

4.1.5 **Research Requirements**: The research question and methodology is written in sufficient detail to permit evaluation of the merit of the project. The research should include all of the required elements applicable to the research such as, but not limited to:

- Research rationale and objectives,
- Design and detailed description of methodology,
- Eligibility criteria, description of the population to be studied,
- Recruitment and consent process,
- Research interventions,
- Treatment allocation (if applicable),
- Primary and secondary outcome measures,
- Assessment of safety,
- Sample size justification,
- Data analysis,
- Data monitoring.

4.2 Administrative Review Procedures

4.2.1 A unique Romeo File number is automatically assigned to each submission at the time of the receipt of the application. REB Office Personnel screens the submission for overall completeness;

4.2.2 If the submission is incomplete (e.g. documents are missing or incorrect documents were uploaded), the REB Office Personnel will follow up with the Principal Investigator and/or study team member(s) to request the required information for inclusion with the submission;

4.2.3 Upon receipt of a complete submission (Full Board), the REB Office Personnel assigns the research application to the REB manager for initial review;

4.2.4 Upon receipt of a complete submission (delegated), the REB Office Personnel assigns the research application to the REB manager or a Research Ethics Coordinator for initial review;

4.2.5 For submissions requiring Full Board review, the REB Office Personnel posts the submission to the agenda of the next Full Board meeting. Primary, secondary and legal reviewers are assigned by the REB Manager once the agenda is complete;

4.2.6 For submissions reviewed via delegated review procedures, the REB Office Personnel assigns a reviewer(s) using a pre-determined order (Excel spreadsheet) and sends the research via Romeo.

4.3 NSHA REB Meeting Dates and Submission Deadlines

4.3.1 The NSHA REB meets weekly on Mondays, unless there is a holiday or insufficient business to warrant a meeting. The 'meeting dates' list located on the research ethics webpage. Meetings are scheduled one year in advance;

4.3.2 Studies requiring full board review must be submitted to the research ethics office via the Romeo Researcher's Portal at least 10 working days prior to the NSHA REB's meeting date. Complete submissions must be received in the office by 12 p.m. AST (noon) on the deadline date;

4.3.3 Submitted studies will be added to the REB meeting agenda by the responsible REB Office Personnel in the order in which they were submitted (tracked using the date and time stamp from the Romeo database). Once the agenda for the meeting has been filled, any remaining studies will be added to the agenda for the next scheduled REB meeting;

4.3.4 For studies requiring funding approval before they commence, it is recommended that an application for NSHA REB approval be submitted after funding is obtained. Otherwise, significant delays in start-up or changes to the protocol due to funding agency requirements may require a new submission to the NSHA REB.

4.4 Review Fees

4.4.1 Study sponsors are responsible for paying the review fee. Review fees are only charged for industry sponsored research.

5 REFERENCES

1) Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2014 (TCPS2 2014) Chapter 6;
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 46.108, 46.115;
4) US Food and Drug Administration (FDA) Code of Federal Regulations Title 21 Part 56.107, 56.108; 21 CFR 312, 812.

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