TITLE:	Standard Operating Procedure (SOP) Study Completion	**NUMBER:**	NSHA REB-SOP-4-008
Effective Date:	April 2014	Revision:	September 29, 2017
Applies To:	Executive Chair, Co-Chairs, NSHA REB members and Office Personnel.		

1. PURPOSE:

The purpose of this standard operating procedure (SOP) describes the procedures for the closure of a research study with the Nova Scotia Health Authority Research Ethics Board (NSHA REB).

2. POLICY:

The completion of a research study is a change in activity that must be reported to the REB. Although research participants will no longer be at risk under the research, a final report allows the REB to close its files in addition to providing the REB with information that may be used in the evaluation and approval of related studies.

A Study Closure reporting form is to be submitted to the REB when there is no further participant involvement and all data collection, clarification and transfer is complete (including access to the participants' health record). Submission of the closure form indicates that these activities have ceased, the study does not require continuing ethics approval, and the REB study file can be closed.

3. DEFINITIONS:

See Glossary of Terms

4. PROCEDURES:

4.1. Criteria for Closing a Research Study with the REB

4.1.1. Subject to US regulatory requirements, for studies that involve direct human participation, no further participant contact is contemplated and all data collection procedures as per the approved protocol have been completed;

4.1.2. Subject to US regulatory requirements, for studies that do not involve direct human participation (i.e., secondary use of data), the acquisition of

data is complete (i.e., no new cases are being added to the study dataset);

4.1.3. For studies that analyze human tissue, no additional tissue samples are being withdrawn from or deposited to the tissue bank or being acquired from another research group;

4.1.4. The Principal Investigator must have received notification from the study sponsor and/or monitoring group before a study closure form is submitted to the REB;

4.1.5. In studies where it is contemplated that researchers will report back to participants or to the community or group from whom they collected data, a Study Closure reporting form should not be submitted until after data analysis, interpretation of findings and dissemination.

4.2. Premature Termination

4.2.1. If a study has been terminated prematurely by any party (sponsor, PI, regulatory body), the Principal Investigator or appropriate research team member is to submit the premature termination form to the REB as soon as the decision to prematurely terminate the study has been made;

4.2.2. The research team must promptly inform participants of the reason for the premature termination and any impact on their care or wellbeing. Information for participants must be approved by the REB prior to its use;

4.2.3. After all study activities are complete at all sites, the research team must follow-up with the submission of the Study Closure reporting form.

4.3. Completion of the Study Closure Form

4.3.1. The Principal Investigator may submit a Study Closure reporting form to the REB when there is no further participant involvement at the site, all new data collection is complete, and the sponsor closeout activities, if applicable, have been completed;

4.3.2. The responsible REB Office Personnel will review the research closure application and request any outstanding information, clarification or documentation from the Principal Investigator, if needed;

4.3.3. The REB Co-Chair will review the submission, and if satisfied will grant approval of the closure form. The responsible REB Office Personnel will change the status of the research to "*Closed*," enter the closure date in the Romeo database;

4.3.4. The responsible REB Office Personnel will send an electronic approval letter of the study closure to the PI and Research Services;

4.3.5. Once a research project is "*Closed*" with the REB, no further submissions for that research will be permitted; however, if required, the Principal Investigator may still submit relevant documents for acknowledgement and, if applicable, further investigation and/or action may be undertaken by the REB;

4.3.6. If the sponsor requests additional data following the closure of the research, a request for approval shall be made to the REB and the conditions of this request will be determined at the time of the review;

4.3.7. The responsible REB Office Personnel coordinates storage of closed studies for archiving as per applicable Health Canada regulations (as it pertains to any paper ethics files).

5 REFERENCES

I. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2014 (TCPS2 2014), Article 6.14.
II. The International Conference on Harmonization Good Clinical Practices, Section 4.13;
III. US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.103; 46.109;
IV. US Food and Drug Administration (FDA) CFR Title 21 Part 56.108, 56.109.

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