TITLE:	Standard Operating Procedure (SOP) Communication: Investigators and Research Staff	**NUMBER:**	NSHA REB-SOP-6-001
Effective Date:	April 2014	Revision:	September 29, 2017
Applies To:	Executive Chair, Co-Chairs, NSHA REB members, REB Office Personnel, and Researchers.		

1. PURPOSE:

The purpose of this standard operating procedure (SOP) is to describe the Nova Scotia Health Authority Research Ethics Board (NSHA REB) communications with the Principal Investigator and with his/her research staff.

2. POLICY:

In the interest of enhancing human research participant protection, it is important for the REB to foster collaboration and open communication between and among the REB, Principal Investigator, research staff, and organizational representatives. This applies not only to communication related to a specific research project, but also to communication related to ethical issues and REB processes, policies and procedures.

All Investigators' participating in REB approved research shall be informed, in writing, of all determinations made by the REB regarding specific research.

Feedback from Investigators and research staff is encouraged and should be considered an opportunity to review and to improve the function of the REB and of the REB office procedures.

In order to facilitate clear and accurate communication with Investigator's and research staff, the REB will follow standardized notification and documentation procedures.

The REB Office Personnel is responsible for drafting correspondence on behalf of the REB following a convened meeting or delegated review procedure. The REB Office Personnel is responsible for distributing the REB correspondence to appropriate parties and for day-to-day operational communication with the Investigator and research staff, as applicable.

The Executive Chair or designee is responsible for overseeing all communications with Investigators conducted on behalf of the REB and for the content of all initial review and approval letters issued on behalf of the REB.

3. DEFINITIONS:

See Glossary of Terms

4. PROCEDURES:

4.1. Notification of REB Decisions

4.1.1. The responsible REB Office Personnel will notify Investigators in writing of the REB's decision as soon as possible following review of new studies, modifications to currently approved studies, or applications for continuing review;

4.1.2. Notification of REB decisions regarding new studies will be prioritized over amendments and requests for annual approval, unless the anniversary date is imminent;

4.1.3. If the research is not approved or re-approved (for continuing review), the responsible REB Executive Chair or designee will notify the Investigator of the REB's decision following the REB determination;

4.1.4. The responsible REB Office Personnel will summarize the determinations of the REB noting any concerns or requests for clarification including recommended changes to the consent form, and clarifying the reasons for the disapproval of the submission (when appropriate);

4.1.5. The Co-Chair will review the draft initial letter, request revisions as necessary, and when satisfied with the content of the letter, will email the responsible REB Office Personnel his/her agreement;

4.1.6. The responsible REB Office Personnel will send an email via the Romeo database with the REB initial review letter as an attachment to the Investigator and/or research staff, as applicable;

4.1.7. The Investigator is allotted a maximum of three months to respond to the REB initial review letter, unless otherwise determined by the REB;

4.1.8. Upon receipt of the Investigator response to the REB initial review letter, the responsible REB Office Personnel will verify the responses, request additional clarifications if required or needed, and notify the Co-Chair that the response is pending their review/approval;

4.1.9. Once all of the REB conditions are satisfied and the Co-Chair has reviewed and approved the submission, the responsible REB Office Personnel will prepare the final approval letter using the final approval letter template. The approval letter is sent as an attachment to an email through the Romeo database to the Principal Investigator and research team, as applicable;

4.1.10. If the REB has not received a response to the initial REB review letter within the three month time frame, the responsible REB Office Personnel will email the standardized *"three month window to respond has expired"* reminder to the Principal Investigator or research team requesting a response to the REB initial review letter or update on the status within seven days;

4.1.11. If no correspondence is received within seven days, the responsible REB Office Personnel will update the research file to *'closed'* and a formal study closure notification will be sent from the REB Office to the Principal Investigator, applicable research team members, and Research Services. Once the file is closed, if the Investigator wishes to re-apply, the REB requires a new submission (and fees as applicable).

4.2. Reconsideration of REB Decisions

4.2.1. Investigators have the right to request, and the REB has an obligation to provide, prompt reconsideration of decisions affecting a research project;

4.2.2. It is the responsibility of the Investigator to contact the REB Executive Chair or designee to confirm that the customary submission and review processes have been undertaken, and to explore whether a mutually satisfactory resolution can be achieved without the need for a formal appeal;

4.2.3. If a disagreement between the Investigator and the REB cannot be resolved through reconsideration, the Investigator has the option of appealing the REB decisions through the NSHA REB appeal process.

4.3. Investigator Appeal of REB Decision

4.3.1. Investigators have the right to request an appeal of the decision of the REB and/or any of the revisions to the research requested by the REB, when after reconsideration, the REB has refused ethics approval of the research;

4.3.2. Appeals are conducted in accordance with the applicable REB and institutional policies and meet the requirements of the TCPS 2.

4.3.3. The appeal Board for the NSHA REB is the Horizons Health Research Ethics Board in St. John, New Brunswick;

4.3.4. The entire research submission that was reviewed by the NSHA REB will be sent to the next scheduled meeting of the Horizons Health REB for review and comment;

4.3.5. The decision of the appeal Board will be presented to the NSHA REB Executive Committee, followed by the REB members and lastly the Investigator;

4.3.6. The decision of the appeal board on behalf of the NSHA REB shall be final.

4.4. Other Communication with the Investigator or Research Staff

4.4.1. The responsible REB Office Personnel will respond to queries from Investigators and research staff in a timely and professional manner;

4.4.2. Any letters, memos, or emails between the REB and Researchers that provide information concerning the review of research (e.g., requests for amendments (i.e. consent form changes, requests for additional information) and that do not imply or appear to imply approval of the research, may be issued as per delegated signing authority.

5 REFERENCES

I. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2014 (TCPS2 2014), Articles 6.18, 6.19;
II. International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines as adopted by Health Canada, Section 3.3.9;
III. US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.103, 46.109, 46.115.
IV. US Food and Drug Administration (FDA) CFR Title 21 Part 56.115.

6 RELATED DOCUMENTS:

I. NSHA REB-SOP-1-007

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