TITLE:	Standard Operating Procedure (SOP) Investigator Qualifications and Responsibilities	**NUMBER:**	NSHA REB-SOP-8-001
Effective Date:	April 2014	Revision:	September 29, 2017
Applies To:	Executive Chair, Co-Chairs, NSHA REB members and REB Office Personnel.		

1. PURPOSE:

The purpose of this standard operating procedure (SOP) is to describe the qualifications and responsibilities of the Principal Investigator who engages in research being conducted under the jurisdiction of the Nova Scotia Health Authority Research Ethics Board (NSHA REB).

2. POLICY:

Research involving human participants must be conducted by individuals appropriately qualified by education, training, and experience to assume responsibility for the proper conduct of the research and for the protection of human research participants. The Research Ethics Board (REB) must have assurance that the qualifications of new investigators, for the conduct of research studies, are appropriate.

Investigators are required to conduct the research in compliance with applicable regulations and guidelines, and to report serious or continuing non-compliance and the status of the research at time points stipulated by the REB. The Principal Investigator must promptly notify the REB of any unanticipated problems involving risks to participants or others, (including deviations from the approved research and serious, unexpected adverse events), and of any new information that might adversely affect the safety of research participants or the conduct of the research.

The Principal Investigator is responsible for all aspects of the study within the jurisdiction of the Nova Scotia Health Authority (NSHA). While individual tasks and study procedures may be delegated to other members of the research team, the Principal Investigator retains accountability for the proper clinical, ethical, scientific, financial, and administrative conduct of the study, and for the safety, rights, and well-being of research participants. There can only be one Principal Investigator, NSHA does not allow Co-Principal Investigators.

3. DEFINITIONS:

See Glossary of Terms

4. PROCEDURES:

4.1. Principal Investigator Qualifications

4.1.1. The Investigator must make available to the REB his/her current CV (within two years) and current medical/dental license (if applicable) and his/her relevant training and experience (i.e. TCPS 2 certificate), in sufficient detail for the REB to make an objective judgment regarding the Investigators qualifications, if necessary;

4.1.2. The Department/Division/Program Head, by signing the 'Letter of Support', confirms that he/she is aware of the proposal and supports its submission for ethics review; considers it to be feasible and appropriate and attests that the Investigator responsible for the conduct of the study, is qualified by education, training and experience to be the Principal Investigator for the study;

4.1.3. The Investigator must have completed appropriate training regarding the requirements of conducting and overseeing research (proof of training may be requested);

4.1.4. If applicable, the Investigator must be a physician with a specialty qualification in their field and with current professional qualifications entitling them to provide health care under the applicable laws;

4.1.5. For clinical trials regulated by Health Canada, there must be a Qualified Investigator (QI). NSHA uses the term Principal Investigator (PI) in place of Qualified Investigator (QI);

4.1.6. Any concerns raised in the REB review of the Researcher's qualifications will be communicated to the Researcher and must be satisfied prior to REB approval of the application.

4.2. Principal Investigator Responsibilities

4.2.1. The Principal Investigator is responsible for complying with the decisions and responsibilities set out by the REB. In addition, it is the Principal Investigator's responsibility to comply with all applicable regulations and ensure that (if applicable):

- He/she and his/her staff members are appropriately qualified by education, training, and experience to assume responsibility for the proper conduct of the research and for the protection of human research participants;

- The Principal Investigator is to provide the institution, the NSHA REB, sponsor and regulatory authorities with documentation of his/her credentials as requested
- He/she has adequate resources to properly conduct the research and conducts the research following written standard operating procedures;
- All real, potential or perceived conflicts of interest are declared to the REB at the time of the initial application, and as they arise;
- REB review and approval is obtained before engaging in research involving human participants;
- All necessary documentation is signed by the (local) Principal Investigator;
- Clinical trials are registered in a registry that is compliant with the criteria set by the World Health Organization (WHO) or international committee of medical journal editors (ICMJE) and that the number assigned to the trial upon registration is provided to the REB;
- Informed consent, when required, is obtained from participants prior to their enrolment into the research using the most current informed consent document approved by REB and in accordance with applicable regulations and guidelines;
- He/she personally conducts or supervises the described investigation(s);
- The research is conducted in compliance with the approved protocol and applicable regulations, guidelines and REB policies;
- Any unanticipated problems involving risks to participants or others are promptly reported to REB, including protocol deviations, serious, unexpected adverse events and privacy breaches;
- Any changes in the approved research are not initiated without REB review and approval, except where necessary to eliminate an immediate hazard(s) to the participant(s);
- Premature termination or suspension of the research is reported to the REB;
- Accurate and complete records are maintained according to applicable guidelines and regulatory requirements;
- An application for continuing review (annual renewal) is submitted to the REB prior to the expiration of REB approval;
- Any other unexpected findings or new research knowledge that could affect the risk/benefit ratio of the research are reported promptly to REB;

- The REB is notified if there is a change in Principal Investigator (e.g., temporarily on sabbatical or permanently);
- The REB is notified immediately if his/her medical license or hospital privileges are suspended, restricted or revoked or should his/her qualifications otherwise no longer be appropriate;
- The REB is notified when the study is completed.

Note (if applicable): The obligations of a Principal Investigator holding a Clinical Trial Application (CTA) with Health Canada (i.e., sponsor-Researcher) include both those of a sponsor and those of a Principal Investigator.

4.2.2. At NSHA, the Department is responsible for maintaining current CVs and medical licenses of each of its Principal Investigators. The Department is also responsible for immediately advising the REB should it become aware of any information that would indicate that the qualifications of the PI may no longer be appropriate.

5 REFERENCES

I. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2014 (TCPS2 2014), Article 11.3;
II. The International Conference on Harmonizati**on** (ICH) Guidelines for Good Clinical Practice (GCP), Section 1.56, 3.1.3 and Section 4;
III. Health Canada, Division 5, Part C.05.001 of the Food and Drug Act.

6 RELATED DOCUMENTS:

I. Policy & Procedure: CDHA RS 02-001 Research Ethics Board Jurisdiction

II. Policy & Procedure: CDHA RS 03-001 Responsibilities Of The Principal Investigator

III. Policy & Procedure: CDHA RS 03-002 Delegation Of Study Duties

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 PI's responsibilities harmonized with SOP RS-03-001