TITLE:	Standard Operating Procedure (SOP) Review of Research	**NUMBER:**	NSHA REB-SOP-4-001
Effective Date:	April 2014	Revision:	September 29, 2017
Applies To:	NSHA REB members and staff.		

1. PURPOSE:

The purpose of this standard operating procedure (SOP) is to describe specific research activities that require review by the Nova Scotia Health Authority Research Ethics Board (NSHA REB) and, conversely, those activities that do not.

2. POLICY:

All research submitted to the NSHA REB will undergo initial review by the NSHA REB Manager and/or designee to determine that the research requires ethics approval (e.g. does not meet the criteria of research exempt from REB review as described below).

No intervention or interaction with human participants in research, including recruitment, may begin until the NSHA REB has reviewed and approved the research protocol, consent documents and recruitment materials.

3. DEFINITIONS:

Embryo: A human organism during the first 56 days of its development following fertilization or creation, excluding any time during which its development has been suspended. It also includes any cell derived from such an organism that is used for the purpose of creating a human being.

Fetus: A human organism during the period of its development beginning on the 57th day following fertilization or creation, excluding any time during which its development has been suspended, and ending at birth.

Full research ethics board (REB) review: The level of REB review assigned to above minimal risk research projects. Conducted by the full membership of the research ethics board, it is the default requirement for the ethics review of research involving human participants.

Human biological materials: Tissues, organs, blood, plasma, skin, serum, DNA, RNA, proteins, cells, hair, nail clippings, urine, saliva, and other body fluids. The term

also includes materials related to human reproduction, including embryos, fetuses, fetal tissues and human reproductive materials.

Publicly available information: Any existing stored documentary material, records or publications, which may or may not include identifiable information, and that has no restrictions on its use or distribution, or that may be released under certain legal conditions.

Research: An undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation.

Secondary use: The use in research of information or human biological materials originally collected for a purpose other than the current research purpose.

4. PROCEDURES:

4.1. Research that requires NSHA REB Review

4.1.1. The following requires ethics review and approval by the NSHA REB before the research commences:

a) All research involving living human participants (faculty, patients, staff, students or members of the community),
b) All research involving human biological materials, biological fluids, cadaveric remains, embryos or fetuses, fetal tissue, reproductive materials and stem cells. This applies to materials derived from both living and deceased individuals,
c) All research in which access to human participants involves any records maintained by the Nova Scotia Health Authority;
d) All research involving data collected from human participants that are to be carried out by faculty, staff or students affiliated with the NSHA shall be reviewed and approved in advance by the NSHA REB.

4.2. Research Exempt from NSHA REB Review

4.2.1. Research that relies exclusively on publicly available information does not require NSHA REB review when:

a) The information is legally accessible to the public and appropriately protected by law; or
b) The information is publicly accessible and there is no reasonable expectation of privacy.

4.2.2. NSHA REB review is not required for research involving the observation of people in public places where:

a) It does not involve any intervention staged by the researcher, or direct interaction with the individuals or groups;

b) Individuals or groups targeted for observation have no reasonable expectation of privacy; and

c) Any dissemination of research results does not allow identification of specific individuals.

4.2.3. NSHA REB review is not required for research that relies exclusively on secondary use of anonymous information, or anonymous human biological materials, so long as the process of data linkage or recording or dissemination of results does not generate identifiable information.

4.2.4. The opinion of the REB should be sought whenever there is any doubt about the applicability of the guidelines and regulations.

4.3. Activities Not Requiring NSHA REB Review

4.3.1. Quality assurance (QA) and quality improvement (QI) studies, program evaluation activities, and performance reviews, or testing within normal educational requirements when used exclusively for assessment, management or improvement purposes, do not require NSHA REB review unless they contain an element of research;

4.3.2. Clinical use of drugs through Health Canada's Emergency Drug Release Program does not require NSHA REB review. Innovative (experimental) practices should be developed into a research protocol as soon as is feasible so that meaningful information can be collected;

4.3.3. Activities outside the scope of research subject to REB review may still raise ethical issues that would benefit from careful consideration by an individual or a body capable of providing some independent guidance, other than the NSHA REB;

4.3.4. Creative practice activities, in and of themselves, do not require REB review. However, research that employs creative practice to obtain responses from participants that will be analyzed to answer a research question is subject to REB review;

4.3.5. The NSHA REB does not grant *post hoc* approval. If the investigator intends to publish study results in a journal that requires proof of NSHA REB approval, this approval must be obtained prior to conducting the study.

5 REFERENCES

1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2014 (TCPS2 2014).

2. US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46.102(d)(f).

3. US Food and Drug Administration (FDA) CFR Title 21 Part 50.3(c)(g).

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