TITLE:	Standard Operating Procedure (SOP) Review of Research Involving Human Genetic Research and Research Concerning Human Reproduction	**NUMBER:**	NSHA REB-SOP-5-002
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) describes the procedures undertaken by the Nova Scotia Health Authority Research Ethics Board (NSHA REB) concerning review of research that involves human genetic research and research involving human reproduction.

2. POLICY:

Issues of privacy and confidentiality in research involving genetic material may affect the individual, the family and the group to which the individual belongs. Given the present inability to know the limits or effects of such research, or the context in which genetic information is interpreted and used, the NSHA REB will adhere to the guidelines provided in the TCPS 2 and will seek to ensure that researchers satisfy all of the relevant requirements.

3. DEFINITIONS:

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.

Human Genetic Research: The study of genetic factors responsible for human traits and interaction of those factors with each other, and with the environment.

4. PROCEDURES:

4.1. Consent in Genetic Research

4.1.1. Guidance regarding a proportionate approach to research ethics review, consent, privacy, confidentiality, research with human biological materials and other ethical guidance described in other SOPs apply equally to human genetic research.

4.1.2. The REB requires that the research protocol include a full explanation of the rationale for taking genetic samples and their planned usage; the source of the samples and their subsequent storage or long term banking must be clearly articulated as well as specifying the length of storage time; how samples will be de-identified, and how samples will be ultimately destroyed.

4.1.3. The genetic portion of the consent form may be included in the main study consent form or it may be a separate consent form, depending on sponsor requirements. Researchers should consult the NSHA REB's consent form template and consent form preparation and use document for required consent form wording regarding human biological materials.

4.2. Managing Information Revealed through Genetic Research

4.2.1. Where researchers plan to share results of genetic research with participants, the researchers should make a plan to have genetic counseling available at that time, where appropriate.

4.3. Incidental Findings

4.3.1. Investigators have an obligation to disclose to the participant any material incidental findings discovered in the course of research. The Investigator's plan to identify and to disclose incidental findings must be submitted to the REB and approved prior to implementation.

5 REFERENCES

I. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2014 (TCPS2 2014), Chapter 13;
II. US Office for Human Research Protections (OHRP) Code of Federal Regulations (CFR) Title 45 Part 46 Sub-Part B.

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