TITLE:	Standard Operating Procedure (SOP) Reviews Requiring Special Consideration	**NUMBER:**	NSHA REB-SOP-5-001
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) describes the policy concerning review of research that involves groups that could be potentially vulnerable to coercion in regard to autonomy or bearing unequal burden in research, as well as review of specific types of research (e.g. research in emergency situations, genetic research, etc.) some of which may require additional considerations by the Nova Scotia Health Authority Research Ethics Board (NSHA REB).

2. POLICY:

The REB shall apply special protections as necessary to protect potentially vulnerable research participants, whist satisfying the ethical requirement for research in the context of the safeguards expressed in the TCPS 2. Additionally, certain categories of research may involve methodologies that might require additional considerations or for which there are federally mandated determinations that the REB is required to make and document.

3. DEFINITIONS:

Aboriginal peoples: Persons of Indian (First Nations), Inuit, or Métis descent, regardless of where they reside and whether or not their names appear on an official register. In the international context, the term comparable to Aboriginal peoples is Indigenous peoples.

Capacity: The ability of prospective or actual participants to understand relevant information presented (e.g. purpose of the research, foreseeable risks, and potential benefits), and to appreciate the potential consequences of any decision they make based upon this information.

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.

Human reproductive materials: A sperm, ovum, or other human cell, or a human gene, including a part of any of them.

4. PROCEDURES:

4.1. Consent for Research Involving Participants who Lack Capacity

4.1.1. For research involving individuals who lack capacity, either permanently or temporarily, to decide for themselves whether to participate, the REB must ensure that at a minimum the following conditions are met:

- The Principal Investigator involves participants who lack the capacity to consent on their own behalf to the greatest extent possible in the decision-making process,
- The Principal Investigator seeks and maintains consent from authorized third parties,
- The authorized third party is not the Principal Investigator or any other member of the research team,
- The Principal Investigator demonstrates that the research is being carried out for the participant's direct benefit or for the benefit of other persons in the same category. If the research does not have the potential for direct benefit to the participant, the Principal Investigator shall demonstrate how the research will expose the participant to only a minimal risk and how the participant's welfare will be protected during participation in the research;

4.1.2. If an authorized third party has consented on behalf of a person who lacks legal capacity but that person has some ability to understand the significance of the research, the Principal Investigator ascertains the wishes of that individual with respect to participation;

4.1.3. Assent from a participant is not sufficient to permit them to participate in a research project in the absence of consent by an authorized third party; however, their expression of dissent is respected;

4.1.4. Prospective participants who may be capable of verbally or physically assenting to, or dissenting from, participation in research include:

- Those whose capacity is in the process of development, such as children whose capacity for judgment and self-direction is maturing,
- Those who were once capable for making an autonomous decision regarding consent but whose capacity is diminishing or fluctuating, and
- Those whose capacity remains only partially developed, such as those living with permanent cognitive impairment;

4.1.5. If assent for research is required, the Principal Investigator must submit to the REB the proposed procedures for obtaining consent from the capable substitute decision maker and assent from the research participant. The Principal Investigator must submit an assent form or summary of the assent process to the REB for approval as per the organization's guidelines;

4.1.6. When authorization for participation was granted by an authorized third party, and the participant acquires or regains capacity during the research, the Principal Investigator will seek the participant's consent as a condition of continuing participation;

4.1.7. Studies involving participants with impaired decision making capacity may take place over extended periods. The REB will consider if and at what interval(s) periodic re-consenting of individuals should be required to ensure that a participant's continued involvement is voluntary;

4.1.8. The REB has the right to request that Investigators re-consent participants after taking into account the study's anticipated length, the condition of the individuals to be included (e.g. participants with progressive neurological disorders), and the estimated probability, severity, average duration, and reversibility of potential harm;

4.1.9. If an individual signed a research directive indicating their preference for ongoing and/or future participation in research, in the event that the individual loses capacity or upon their death, an authorized third party may be guided by these directives during the consent process.

4.2. Research Involving Children

4.2.1. There is no legal age of consent in Nova Scotia. Nova Scotia law provides that a minor may give valid consent if he/she is capable of appreciating fully the nature and consequences of the treatment or procedures. Where children have not yet attained the capacity to consent for themselves to participate in research, researchers shall seek consent from an authorize third party while ascertaining the child's assent or dissent;

4.2.2. For research involving children being conducted at NSHA, it will be done so in consultation with the IWK REB;

4.2.3. If the study involves both institutions, the NSHA REB office must receive a copy of the IWK approval letter before the study can be initiated at NSHA.

4.3. Research Involving Other Vulnerable Groups

4.3.1. The REB will determine appropriate protections for individuals and groups who might be inappropriately excluded from research on the basis of

attributes such as culture, language, sex, race, ethnicity, age and disability, and who require additional protections. For these individuals and groups the REB will take into account the risks and benefits of the research, and will consider protections afforded by organizational policies, and provincial and federal law;

4.3.2. In addition, when the REB regularly reviews research involving a vulnerable population, consideration shall be given to the inclusion of one or more individuals who are knowledgeable and experienced in working with these participants this population.

Potentially vulnerable groups may include, but are not limited to:

- The Elderly,
- Individuals with mental illness,
- Pregnant women,
- Individuals with limited language skills,
- Aboriginal individuals and communities,
- Prisoners;

4.3.3. Studies involving vulnerable groups will be given special consideration in accordance with the framework and appropriate guidelines for ethical conduct of research as outlined in the TCPS2 2014;

4.3.4. If research involves prisoners, children, pregnant women, fetuses and/or neonates, and is funded or supported by the US Federal Government, the REB shall apply the requirements of 45 CFR 46, including as appropriate, Sub-Parts, B, C and D.

4.4. Research Involving Human Embryos

4.4.1. The *Assisted Human Reproduction Act* prohibits the creation of a human embryo specifically for research purposes, with the limited exception of creating an embryo for the purpose of improving, or providing instruction in, assisted reproduction procedures;

4.4.2. The REB respects and adheres to the guidelines to research involving materials related to human reproduction as described in the TCPS2 2014.

5 REFERENCES

I. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2014 (TCPS2 2014), Articles 3.10, 4.6, Chapter 9, Chapter 12;
II. US Food and Drug Administration (FDA) CFR Title 21 CFR 50.24, 21 CFR 56.111(b), 45 CFR 46, Sub-Part C

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