RS0300 – POPULATIONS FOR SPECIAL CONSIDERATION IN RESEARCH

Interior Health would like to recognize and acknowledge the traditional, ancestral, and unceded territories of the Dãkelh Dené, Ktunaxa, Nlaka'pamux, Secwépemc, St'át'imc, Syilx, and Tŝilhqot'in Nations, where we live, learn, collaborate and work together.

Interior Health recognizes that diversity in the workplace shapes values, attitudes, expectations, perception of self and others and in turn impacts behaviors in the workplace. The dimensions of a diverse workplace includes the protected characteristics under the human rights code of: race, color, ancestry, place of origin, political belief, religion, marital status, family status, physical disability, mental disability, sex, sexual orientation, gender identity or expression, age, criminal or summary conviction unrelated to employment.

1.0 PURPOSE

To describe the actions of the Interior Health (IH) Research Ethics Board (REB) required for the ethical review of research involving groups that are potentially vulnerable to Coercion concerning Autonomy or bearing unequal burden in research.

2.0 DEFINITIONS

TERM	DEFINITION
Authorized third party:	*Any person with the necessary legal authority to make decisions on behalf of a prospective participant who lacks the Capacity to Consent to participate, or to continue to participate, in a particular research project. An individual who is recognized by the institutional policy as acceptable for providing Consent in the non-research context to the procedures involved in the research will be considered an Authorized Third Party for the purposes of the research.*
Autonomy:	*The Capacity to understand information and to be able to act on it voluntarily; the ability of individuals to use their own judgment to make decisions about their own actions, such as whether to participate in research.*
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.*

Coercion:	*An extreme form of undue influence, involving a threat of harm or punishment for failure to participate in research.*
Consent:	*An indication of agreement by an individual to become a participant in a research project. Consent means "free (also referred to as voluntary), informed and ongoing Consent."*
Guardian:	*A person who has legal authority to make decisions on behalf of a person under 19 years of age and includes a parent of the person under 19 years of age.*
Vulnerability:	*A diminished ability to fully safeguard one's own interests in the context of a specific research project. This may be caused by limited Capacity or limited access to social goods, such as rights, opportunities and power. Individuals or groups may experience Vulnerability to different degrees and at different times, depending on their circumstances.*

3.0 POLICY

3.1 Vulnerable Populations

3.1.1 The REB shall apply additional protections as necessary to protect potentially vulnerable research participants. Not every human being is capable of self-determination. The Capacity for self-determination may change during an individual's life, and some individuals lose this Capacity wholly or in part because of illness, mental disability, or circumstances that severely restrict liberty or create a significant power differential (e.g. employer/employee, physician/patient, teacher/student relationships). The extent of additional protection afforded should depend upon the risk of harm and the likelihood of benefit.

3.1.2 The judgment that any individual lacks Autonomy or Capacity should be periodically reevaluated and will vary in different situations.

3.1.3 Individuals or groups whose circumstances may make them vulnerable in the context of research should not be inappropriately included or automatically excluded for participation in research. Researchers and the REB will determine appropriate protections for individuals and groups who might be vulnerable in the context of the research. For these individuals and groups the researcher and the REB will take into

account the risks and benefits of the research, and will consider protections afforded by IH policies and provincial and federal law.

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

3.1.4.1 Aboriginal individuals and communities;

3.1.4.2 Elderly persons;

3.1.4.3 Individuals with cognitive and/or physical impairment;

3.1.4.4 Individuals with limited language skills;

3.1.4.5 Individuals with mental illness and/or substance use issues;

3.1.4.6 Infants and children;

3.1.4.7 Women and pregnant women;

3.1.4.8 Prisoners;

3.1.4.9 Terminally ill individuals; or

3.1.4.10 Other groups (e.g. students, employees, members of the armed forces).

3.2 Children

3.2.1 The legal age of majority in British Columbia is 19.

3.2.2 For children under 19 years of age, the REB will require assent of the child and Consent to the research by at least one parent or guardian. If the parents share a joint custodial relationship, both will be required to Consent.

3.2.3 Exceptions may be made if the child is an emancipated minor, is capable of giving Consent pursuant to the provisions of the BC Infants Act relating to Consent to health care, or is considered competent to Consent in accordance with applicable common law (Infants Act, 1996, Part 2).

3.2.4 If the research proposal involves a child who is legally incompetent to give Consent pursuant to applicable BC legislation or applicable common law, then the REB may not approve their involvement in the research unless provisions for obtaining Consent for an individual lacking Capacity (TCPS2 Articles 3.9 and 3.10) have been met, as well as the following:

3.2.4.1 The research question can be addressed only with participants as defined by the protocol; and

3.2.4.2 The research does not expose the participants to more than minimal risk without the prospect of direct benefits for them; or

3.2.4.3 Where the research entails only minimal risk, it should at least have the prospect of providing benefits to participants or to a group that is the focus of the research and to which the participants belong (TCPS2 Articles 4.4 and 4.6).

3.2.5 If a research study involves children and is funded or supported by the US federal government, the REB shall apply the requirements of 45 CFR 46, Sub-Part D, to the extent that they vary from the protections set out above and elsewhere in the TCPS2.

3.2.6 If during the course of the research, the child first signed an assent form for children aged 7-13, and is now over the age of 13, s/he should be re-assented with a form suitable for children aged 14-18. If a child signed an assent form for children aged 14-18 and turns 19 prior to ending his/her participation in the research, s/he shall be re-Consented with the adult Consent form.

3.3 Participants with Cognitive Impairment

3.3.1 Studies involving participants with impaired decision-making Capacity may take place over extended periods. The REB may require that researchers periodically re-Consent participants after taking into account the study's anticipated length and the condition of the individuals to be included (e.g. participants with progressive neurological disorders). Additionally, the REB will consider whether and when a reassessment of decision-making Capacity is required.

3.3.2 Studies involving participants with impaired decision-making Capacity warrant special attention and careful consideration by researchers and the REB. Researchers must be aware of all applicable legal and

regulatory requirements with respect to decision-making Capacity and/or Consent.

3.3.3 For research involving individuals who lack the Capacity, either permanently or temporarily, to decide for themselves whether to participate, the REB shall ensure that, as a minimum, the following conditions are met:

3.3.3.1 The researcher involves participants who lack the Capacity to Consent on their own behalf to the greatest extent possible in the decision-making process;

3.3.3.2 The researcher seeks and maintains Consent from Authorized Third Parties in accordance with the best interests of the persons concerned;

3.3.3.3 The Authorized Third Party is not the researcher or any other member of the research team;

3.3.3.4 The researcher 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 but only for the benefit of the other persons in the same category, the researcher shall demonstrate that the research will expose the participant to only a minimal risk and minimal burden, and demonstrate how the participant's welfare will be protected throughout the participation in research; and

3.3.3.5 When authorization for participation was granted by an Authorized Third Party, and a participant acquires or regains Capacity during the course of the research, the researcher shall promptly seek the participant's Consent as a condition of continuing participation.

If these criteria are met, the REB may approve the inclusion of participants with impaired decision-making Capacity in research on the basis of informed Consent from Authorized Representatives.

3.3.4 Although a participant may lack Capacity to provide informed Consent, some persons may resist participating in a research protocol approved

by their representatives. Under no circumstances may participants be forced or coerced to participate.

3.3.5 Where an Authorized Third Party has Consented on behalf of an individual who lacks legal Capacity, but that person has some ability to understand the significance of the research, the researcher shall ascertain the wishes of that individual with respect to participation (e.g. assent or dissent). Prospective participants' dissent will preclude their participation.

3.4 Pregnant Women, Infants and Fetuses

3.4.1 Women shall not be automatically excluded from research solely on the basis of gender, sex or reproductive capacity. In considering research on pregnant or breastfeeding women, researchers and REBs must take into account potential harms and benefits for the woman and her embryo, fetus or infant.

3.4.2 Research may be undertaken on methods to treat, in utero, a fetus that is suffering from genetic or congenital disorders. Because the fetus and the woman cannot be treated separately, any intervention on one involves an intervention on the other. Accordingly, and consistent with the requirements of informed Consent, research involving a human fetus requires the free and informed Consent of the woman.

3.4.3 If a research study involves pregnant women, human fetuses, or neonates and is funded or supported by the US federal government, the REB shall apply the requirements of 45 CFR 46, Sub-Part B, to the extent that they vary from the protections set out above and elsewhere in the TCPS2.

3.5 Research Involving Aboriginal People

3.5.1 Research studies involving Aboriginal Peoples will receive special consideration from the REB. The REB shall use TCPS2 Chapter 9 as a framework for the review of research involving Aboriginal Peoples. In addition, the REB will engage the First Nations Health Authority (FNHA) Research Review Committee as appropriate for all research studies involving Aboriginal Peoples.

3.5.2 Where the research is likely to affect the welfare of an Indigenous community, or communities, to which prospective participants belong, researchers shall seek engagement with the relevant community. The conditions under which engagement is required include, but are not limited to:

3.5.2.1 Research conducted on First Nations, Inuit, or Metis lands;

3.5.2.2 Recruitment criteria that include Indigenous identity as a factor for the entire study or for a subgroup in the study;

3.5.2.3 Research that seeks input from participants regarding a community's cultural heritage, artefacts, traditional knowledge or unique characteristics;

3.5.2.4 Research in which Indigenous identity or membership in an Indigenous community is used as a variable for the purpose of analysis of the research data; and

3.5.2.5 Interpretation of research results that will refer to Indigenous communities, peoples, language, history or culture.

3.5.3 The nature and extent of community engagement in a project shall be determined jointly by the researcher and the relevant community and shall be appropriate to community characteristics and the nature of the research.

3.5.4 The researcher must submit evidence to the REB that research involving First Nations will follow the First Nations principles of Ownership, Control, Access and Possession known as OCAP®. A copy of the research agreement between the researcher and the First Nation must be submitted with the application to the IH REB.

3.6 Prisoners

3.6.1 If a research study involves prisoners and is funded or supported by the US federal government, the REB shall apply the requirements of 45 CFR

46, Sub-Part C, to the extent that they vary from the protections set out above and elsewhere in the TCPS2.

4.0 PROCEDURES

4.1 The REB will follow procedures for the ethical review of any research involving participants identified as vulnerable per policy RR0300 Initial Review of Research and as described above.

5.0 REFERENCES

1. Canadian Association of Research Ethics Boards and N2 Network of Networks. (2023). Standard Operating Procedure 403.003 *Initial Review – Criteria for REB Approval*.

2. Canadian Institutes of Health Research, *Guidelines for Health Research Involving Aboriginal People* (2007-2010). Retrieved from the Canadian Institute of Health Research website: http://www.cihr-irsc.gc.ca/e/29134.html

3. Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, December 2022.

4. Infants Act, R.S.B.C. 1996, c. 223. Retrieved from the BC Laws Website: http://www.bclaws.ca/EPLibraries/bclaws_new/document/ID/freeside/00_96223_01

5. Interior Health (2021). Administrative Policy Manual: AL0100 Consent - Adults.

6. Interior Health (2021). Administrative Policy Manual: AL0200 Consent - Persons Under 19 Years of Age.

7. Interior Health. (2021). Research Policy Manual: RR0300 Initial Review of Research.

8. The First Nations Information Governance Centre. (May 2014). *Ownership, Control, Access and Possession (OCAP™): The Path to First Nations Information Governance*. (Ottawa: The First Nations Information Governance Centre, May 2014).

9. US Department of Health and Human Services, Code of Federal Regulations, Title 45, Part 46, Protection of Human Subjects (45CFR46).

10. US Food and Drug Administration Code of Federal Regulations, Title 21, Volume 1:
Part 50, Protection of Human Subjects, (21CFR50).
Part 56, Institutional Review Boards, (21CFR56).