RR0700 – OBTAINING CONSENT FOR RESEARCH

Interior Health would like to recognize and acknowledge the traditional, ancestral, and unceded territories of the Dâkelh 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 processes necessary for obtaining informed Consent for research activities involving human participants required by the Interior Health (H) Research Ethics Board (REB).

2.0 DEFINITIONS[1]

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.*
Consent	*An indication of agreement by an individual to become a participant in a research project. The term "Consent' implies free (also referred to as voluntary), informed and ongoing Consent.*
Ethical Review	*The review of research involving human participants to ensure the value of human dignity is protected through the principles of respect for persons, concern for welfare and justice.*
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*

[1] All definitions in this section are from TCPS2.

	human reproduction, including embryos, fetuses, fetal tissues and human reproductive materials.
Impracticable	*As defined by the Tri Council Policy Statement, incapable of being put into practice due to a degree of hardship or onerousness that jeopardizes the conduct of the research; it does not mean mere inconvenience.*
Incidental Findings	*Unanticipated discoveries made in the course of research that are outside the scope of the research.*
Therapeutic misconception	*A misunderstanding, on the part of participants, of the purpose, benefits, and/or risks of clinical trials. Often participants do not understand that research is aimed primarily at producing knowledge and may not provide any therapeutic benefit to them.*

3.0 POLICY

3.1 Principles of Consent

3.1.1 *Respect for Persons* implies that individuals who participate in research should do so voluntarily, understanding the purpose of the research, its risks and potential benefits as fully as possible.

3.1.1.1 The voluntariness of Consent respects human dignity and means that individuals have chosen to participate in research according to their own values, preferences and wishes.

3.1.1.2 Participants shall be free to withdraw their Consent to participate at any time and need not offer any reason for doing so. The participant must not suffer any disadvantage or reprisal for withdrawing nor should any payment due prior to the point of withdrawal be withheld.

3.1.1.3 If a participant withdraws Consent, the participant can also request the withdrawal of their data or Human Biological Materials. The Consent form must set out any circumstances that do not allow for the withdrawal of data or Human Biological Materials once collected. Where the terms of the research do not allow for withdrawal of their data or Human Biological Materials, the identity of the participants shall be protected at all times during the project and after its completion.

3.1.1.4 The researcher must provide prospective participants, or Authorized Third Parties, full disclosure of all information necessary for making an informed decision to participate in a research project. This includes all of the information described in TCPS2, Article 3.2.

3.1.2 The Consent document should be in language understandable to the research participant or Authorized Third Party. When a research participant is non-English speaking, documentation of informed Consent can be by two methods:

3.1.2.1 Written Consent where the REB-approved English version of the Consent document is translated into the research participant's native tongue. The REB may require that translated Consent documents be accompanied by an attestation from a translator certifying that the translated Consent document accurately reflects the REB approved English Consent document. The participant will sign the translated version.

3.1.2.2 Oral Consent where a qualified, impartial interpreter fluent in both English and the research participant's language orally interprets the REB-approved English Consent form to the research participant. When the person obtaining Consent is assisted by an interpreter, the interpreter must sign and date the Consent document.

3.1.3 If a research participant is unable to read, an impartial witness must be present during the entire informed Consent discussion. Verbal Consent is obtained from the participant after the Consent form and any other written information is read and explained to the participant. Both the participant and the witness will sign the Consent document. The witness signature attests that the information was accurately explained to, and apparently understood by, the participant, and that informed Consent was freely given by the participant.

3.1.4 The REB may require researchers to provide additional information depending on the nature of the research. The REB encourages the use of the *BC Common Clinical Consent Form* template. The REB may require a separate Consent form for optional procedures of sub-studies (e.g. tissue, blood, or specimen banking or genetic testing).

3.1.5 The researcher must inform research participants promptly of any new information that might affect their willingness to continue their participation in the research project or that may affect their long term health, even if they have completed their participation in the research project. The researcher must obtain the currently enrolled participant's

Consent to continue to participate if there is a significant change to the research or risk.

3.1.6 The researcher has an obligation to disclose to the participant any material Incidental findings discovered in the course of the research. Material Incidental findings are findings that have been interpreted as having significant welfare implications for the participant, whether health-related, psychological or social. The researcher's plan to identify and to disclose Incidental findings must be submitted to the REB and approved prior to implementation.

3.1.7 Research shall begin only after the participants, or their Authorized Third Parties, have provided their Consent. Participants shall provide their Consent prior to engaging in research, thus demonstrating that they have considered the risks and potential benefits of the research project.

3.2 Recruitment

3.2.1 Researcher's patients: If the patient is under the care of the researcher, the researcher may approach the patient directly, but in such a manner that the patient does not feel pressured or obligated in any way. In this instance, the patient's Consent should be obtained by an individual other than the researcher. Any exceptions to this procedure must be appropriately justified and submitted to the REB for review.

3.2.2 In circumstances where the researchers will obtain Consent, the researcher must ensure that the Consent has been obtained without undue coercion or influence and that there is no likelihood of Therapeutic Misconception, if applicable.

3.2.3 Referrals: The researcher may send a letter to colleagues asking for referrals of potential patients. The researcher may provide colleagues with an REB-approved Consent form or research information sheet to give to their patients. The patient will then be asked to contact the researcher directly, or, with documented permission from the patient, the researcher may initiate the call.

3.2.4 Health Records Department: The researcher may ask the Health Records Department to identify patients who appear to meet the research project's eligibility criteria. The researcher should supply Health Records with a standard letter describing the research.

3.2.5 Patient Personal Information: Clinical Research Coordinators (CRCs) employed by IH may access patient records in IH custody for the purpose of recruiting patients for research, provided that:

3.2.5.1 The research has been approved by the IH REB;

3.2.5.2 The CRCs approach only those patients that meet study criteria, in order to introduce the study and to request the patient's Consent to participate in that study.

3.2.5.3 The CRC ensures that accessing patient records is clearly documented in the research ethics application.

3.2.5.4 Only CRCs who are listed on the research ethics application will approach eligible patients for recruitment purposes.

3.2.5.5 The patient information obtained for recruiting patients is not disclosed outside of the Health Authority or for any unauthorized purpose.

3.2.5.6 CRCs will cease to access or review an individual patient record as soon as it is apparent that the patient will not meet eligibility criteria.

3.2.6 Registries: If the REB has previously approved a patient research registry and the patient has provided permission to be contacted for potential research, the researcher or his/her research team may contact these patients directly. The person contacting the patient should identify him/herself as associated with the patient's clinical caregiver, and remind the patient that s/he has agreed to be contacted. The patient must be offered the option of having his/her name removed from the database at any point after the patient has given permission for his/her name to be added.

3.2.7 Advertising: The REB must first review and approve the text and the use of any advertisements, notices or media messages.

3.2.8 All recruitment materials must be approved by the REB prior to implementation.

3.3 Alteration of Consent

3.3.1 The REB may approve research that involves an alteration to the requirements for Consent if the researcher can adequately explain why their research question cannot be answered without an exception to the requirement to seek prior Consent. The REB must be satisfied that:

3.3.1.1 The research involves no more than minimal risk to the participants;

3.3.1.2 The alteration to Consent requirements is unlikely to adversely affect the welfare of participants;

3.3.1.3 It is impossible or Impracticable to carry out the research and to answer the research question properly, given the research design, if the prior Consent of the participants is required;

3.3.1.4 In the case of a proposed alteration, the precise nature and extent of any proposed alteration is defined; and

3.3.1.5 The plan to provide a debriefing, which may also offer participants the possibility of refusing Consent and/or withdrawing data and/or Human Biological Materials, shall be in accordance with Article 3.7.B of the TCPS2.

3.3.2 The REB will not approve an alteration to Consent for research that involves a therapeutic intervention, or other clinical or diagnostic intervention.

3.3.3 If the research project is funded by or supported by the U.S. federal government, waiver of informed Consent or some or all of the required elements of informed Consent may only be permitted in accordance with applicable regulations, including a consideration of whether the study would qualify as exempt research under the applicable U.S. regulation(s).
For FDA regulated research, the REB may not waive informed Consent except under the specific provisions in 21 CFR 50.24 governing emergency research.

3.4 Consent for Research in Individual Medical Emergencies

Subject to all applicable legal and regulatory requirements, research involving medical emergencies shall be conducted only if it addresses the emergency needs of the individuals involved, and then only in accordance with applicable policies, including IH policy RS0400 Research in Emergency Health Situations.

3.5 Capacity

3.5.1 For research involving individuals who lack the 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:

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

3.5.1.2 The researcher seeks and maintains Consent from Authorized Third Parties in accordance with the best interests of the person(s) concerned;

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

3.5.1.4 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, the researcher shall demonstrate how the research will expose the participant to only a minimal risk and minimal burden, and how the participant's welfare will be protected during participation in the research; and

3.5.1.5 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.

3.5.2 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.

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

3.5.3.1 Those whose capacity is in the process of development, such as children whose capacity for judgment and self-direction is maturing;

3.5.3.2 Those who once were capable of making an autonomous decision regarding Consent but whose capacity is diminishing or fluctuating; and

3.5.3.3 Those whose capacity remains only partially developed, such as those living with permanent cognitive impairment.

In the case of children assenting to participate in research, age-appropriate assent forms should be used, e.g. one assent form for children aged 7-13, one for children aged 14-18. If a child ages into the next group, e.g. turns 14 or reaches the age of majority (19 in BC) during the time s/he is a research participant, the child shall be re-Consented/assented with the age-appropriate form.

While their assent would not be sufficient to permit them to participate in the absence of Consent by an Authorized Third Party, their expression of dissent or signs suggesting they do not wish to participate must be respected.

3.5.4 If assent is required for research, the researcher must submit the proposed procedures for obtaining the Consent of the Authorized Third Party and the assent from the research participant.

3.6 Research Directives

3.6.1 Where an individual has signed a research directive indicating his/her preference about future participation in research in the event that they lose capacity or upon death, the Authorized Third Party should be guided by these directives during the Consent process.

3.6.2 Evidence of Consent shall be contained either in a signed Consent form or in documentation by the researcher of another appropriate means of Consent.

4.0 PROCEDURES

4.1 REB members will review the proposed Consent process for appropriateness, and the proposed forms for general readability, for appropriateness of language and content, and for the inclusion of the applicable elements of informed Consent per TCPS2.

4.2 The REB is responsible for determining whether informed Consent exemptions or waivers are applicable and appropriate.

4.3 The REB will review all recruitment materials and procedures for appropriateness with the proposed research and target research participants.

4.4 In considering the adequacy of informed Consent procedures, the REB may require monitoring of the Consent process by an impartial observer.

4.5 Such monitoring may be particularly warranted when the research presents significant risks to participants, or if participants are likely to have difficulty understanding the information to be provided.

5.0 REFERENCES

1. Canadian Association of Research Ethics Boards and N2 Network of Networks. (2023). Standard Operating Procedure 701.003: *Informed Consent Form Requirements and Documentation.*

2. 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.

3. Health Canada, Food and Drug Regulations, Part C, Division 5, C05.005. *Drugs for Clinical Trials Involving Human Subjects*, (GUI-0100), March 14, 2023, version 2.

4. Interior Health Privacy Office. (April 25, 2022). SBAR: *Access to Patient Records – Clinical Research Coordinators*.

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. (2022). Research Policy Manual: RS0400 Research in Medical Emergencies.

8. Research Ethics BC. (July 2020). *BC Common Clinical Informed Consent Template Guidance.*

9. UBC Office of Research Ethics. (2018). Standard Operating Procedure 701: *Informed Form Requirements and Documentation.*

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

11. 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).

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