RR0800 – DOCUMENTATION OF CONSENT FOR 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 requirements for documentation of Consent for research activities involving human participants.

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 a legally authorized Representative for the purposes of the research.
Adult	A person who is 19 years of age or older.
Committee of the Person	Pronounced Kom'-ii-tee. A court appointed person under the Patient's Property Act to be the Personal Guardian of an Adult with the legal authority to make personal and health care decisions on behalf of the Adult.
Consent	An indication of agreement by an individual to become a participant in a research project. The term "Consent' means free (or voluntary), informed and ongoing Consent.

Implied Consent	Also known as "knowledgeable cooperation", this means informed Consent that is indirectly communicated by the Adult through their conduct such as: nodding their head; presenting their arm for an injection; cooperating with an examination, etc.
Personal Guardian	Is the name used in the *Health Care (Consent) and Care Facility (Admission) Act* (*HCCCFAA)* to describe a Committee of the Person for an Adult who is declared, under the *Patients Property Act* to be: a. Incapable of managing himself or herself; or b. Incapable of managing himself or herself and his or her affairs.
Representative	A person appointed by an Adult in a Representation Agreement under Section 7 (to help the Adult make decisions) or 9 of the Representation Agreement Act (to make decision on behalf of the Adult) and includes an alternate Representative.
Substitute Decision Maker	Includes a Personal Guardian (Committee of the Person), a Representative or a Temporary Substitute Decision Maker.
Temporary Substitute Decision Maker	A person chosen by a health care provider under the HCCCFAA and may include a person authorized by the Public Guardian and Trustee to make health care decisions on an Adult's behalf when the Adult is incapable and does not have a Personal Guardian (Committee of the Person), or authorized Representative.

3.0 POLICY

3.1 Documentation of Informed Consent

3.1.1 The REB will approve procedures for documentation of informed Consent that involve:

3.1.1.1 A written Consent form signed and dated by the participant or his/her legally Authorized Third Party, and by the person obtaining Consent; or

3.1.1.2 A short form written Consent form with oral presentation; or

3.1.1.3 A waiver of signed written Consent where it is culturally unacceptable, or where for reasons related to the safety or well-being of the research participant, documentation would not be appropriate. In such instances, the REB must approve the lack of retention of a written Consent form, and there must be a written, documented and REB approved description of the Consent procedures.

3.1.2 The REB is responsible for determining which procedure is appropriate for documenting informed Consent for each project that it reviews.

3.1.3 For clinical trial research the researcher must also sign and date the informed Consent form.

3.2 Written Consent Form Signed by Participant or Authorized Third Party

3.2.1 The REB typically requires that informed Consent is documented by the use of a written Consent form approved by the REB and signed and dated by the participant or the participant's Authorized Third Party.

3.2.2 The written informed Consent document should embody, in language understandable to the participants of the study, all the elements necessary for legally effective informed Consent.

3.2.3 The REB may request that a translation of the informed Consent form to a language understandable to the participant be provided to participants who do not understand English. A copy of the translated Consent with accompanying certification should be submitted to the REB for review and approval.

3.2.4 The researcher must allow the participant or Authorized Third Party adequate opportunity to read the Consent document before it is signed and dated.

3.2.5 A signed and dated copy of the Consent document must be given to the person signing the form.

3.3 Oral Presentation using a Short Form

3.3.1 In certain research projects, oral presentation of informed Consent may be used as an alternative to standard written informed Consent. In such cases, the participant must be provided with both:

3.3.1.1 A short form written informed Consent document stating that the elements of Consent have been presented orally to the participant or the participant's Authorized Third Party; and

3.3.1.2 A written summary of the information that is presented orally.

3.3.2 The participant or Authorized Third Party must sign the short form written Consent document.

3.3.3 A witness to the oral presentation is required. The witness must sign both the short form written informed Consent document and a copy of the written summary.

3.3.4 The person obtaining Consent must sign a copy of the written summary of the information that is presented orally. The person obtaining the Consent may not be the witness to the Consent.

3.3.5 Where informed Consent is documented using this short form procedure for non-English speaking participants, the written informed Consent document should embody, in language understandable to the participant, all the elements necessary for legally effective informed Consent. When this procedure is used with participants who do not speak English:

3.3.5.1 The oral presentation and the short form written informed Consent document should be in a language understandable to the participant;

3.3.5.2 The REB-approved English language informed Consent document may serve as the summary; and

3.3.5.3 The witness should be fluent in both English and the language of the participant.

3.3.5.4 The REB must receive all foreign language versions of the short form document as a condition of approval.

3.4 Other options for Consent

3.4.1 The REB may approve a process that allows the informed Consent document to be delivered by regular mail or email or other secure electronic platform (e.g. Qualtrics) to the potential participant, and to conduct a Consent interview by telephone or videoconference when the participant can read the Consent document as it is discussed. All

other applicable conditions for documentation of informed Consent must also be met when using this procedure.

3.4.2 In some types of research, and for some groups or individuals where written signed Consent may be felt by the participants as mistrust on the part of the researcher, the REB may approve the process of oral Consent, a verbal agreement or a handshake.

3.4.3 Where Consent is not documented in a signed Consent form, researchers may use a range of Consent procedures (e.g., oral Consent, field notes, Implied Consent through the return of a completed questionnaire). The procedures used to seek Consent must be documented by the researcher and approved by the REB.

3.4.4 Whenever possible, the research participant should have written documentation of participation in a research project, unless it may compromise their safety or confidentiality.

3.4.5 For research funded or supported by the U.S. Federal Government, in accordance with Health and Human Services regulations in 45 CFR 46.117(c), the REB may waive the requirement for the researcher to obtain a signed informed Consent form if it finds that either:

3.4.5.1 The only record linking the participant and the research would be the Consent document and the principal risk would be the potential harm resulting from a breach of confidentiality. The researcher shall ask each participant (or Authorized Third Party) whether the participant wants documentation linking them to the research, and the participant's wishes will govern; or

3.4.5.2 The research presents no more than minimal risk of harm to participants and involves no procedures for which written Consent is normally required outside of the research context.

3.4.5.3 If the participants or legally authorized Representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to participants and provided there is an appropriate alternative mechanism for documenting that informed Consent was obtained.

4.0 PROCEDURES

4.1 The REB includes review of documentation of Consent with each delegated or full board review to determine the procedures in this policy are followed.

4.2 The REB reviews Consent forms to ensure they are written in lay language at a level the participants can understand.

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

4. Interior Health. (2022). Research Policy Manual: *RR0700 - Obtaining Consent for Research*.

5. International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), ICH Harmonized Guideline, Integrated Addendum to ICH E6(R1); *Guideline for Good Clinical Practice*, E6(R2), November 9, 2016.

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

7. US Department of Health and Human Services, Code of Federal Regulations, Title 45, Part 46, Protection of Human Subjects (45CFR46) Section 46.117.

8. US Food and Drug Administration Code of Federal Regulations, Title 21, Volume 1:
    - Part 50, Protection of Human Subjects, Subpart B (21CFR50).
    - Part 56, Institutional Review Boards, (21CFR56) Section 56.109.