SOP Title	Informed Consent Requirements and Documentation

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5. SPECIFIC POLICIES AND PROCEDURES.

5.1 Required Elements of Informed Consent

5.1.1 All informed consent documents are available in the online system to all HSREB members (in the case of full HSREB review), or to the applicable reviewers (under the delegated HSREB review process);

5.1.2 The HSREB members will review the proposed consent process for appropriateness, and the proposed consent form(s) for general readability, for appropriateness of the language and content, and for the inclusion of the applicable elements per the HSREB Consent Form Template and Guidance document;

5.1.3 The HSREB often requires a separate consent form for optional procedures such as studies (e.g., tissue, blood, genetic testing or specimen banking); the HSREB will decide at its discretion whether consent forms can be used for optional procedures such as studies.

5.1.4 Following the review, the HSREB may approve the consent form(s) as submitted, or require changes;

5.1.5 When changes are required by the HSREB and are made by the Investigator, the Ethics Officer (EO) reviews the revised consent form(s) to confirm that the required changes have been made

5.5.5 The nature of the provision of the new information to currently enrolled participants and the documentation required will be determined by the HSREB;

5.5.6 The Investigator must inform former research participants of any new information that may be relevant to their long-term health by contacting them via phone or mail.

5.6 Recruitment Methods

5.6.1 Investigator's Patients: If the patient is under the care of the Investigator, the Investigator 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 Investigator. Any exceptions to this procedure must be appropriately justified and submitted to the HSREB for review;

5.6.2 In circumstances where the Investigator will obtain consent, the Investigator must ensure that the consent has been obtained without undue coercion or influence (actual, apparent, perceived or potential) and that there is no likelihood of therapeutic misconception;

5.6.3 Timing of Consent: The amount of time required for a participant to consider whether or not they wish to participate in research is contextual. For most low to moderate-risk studies, participants can provide consent in a limited time, including on the same day as an intervention. However, for high-risk studies, more time is usually required for participants to weigh the advantages and potential disadvantages of participating in the research. Generally, Investigators should endeavour to provide as much time as is feasible for participants to make a decision about participation in research.

5.6.4 Referrals: The Investigator may send an HSREB-approved letter to colleagues asking for referrals of potential patients. The Investigator may provide colleagues with an HSREB-approved consent form or study information sheet to give to their patients. The patient will then be asked to contact the Investigator directly, or, with documented perp.3 (t)-4.(f)-2 (p.3 (e.)-7 (u m)-2 (a)9 1g.6 (s)-2.3(.)

5.8.6 The HSREB may approve a process that allows the informed consent document to be delivered by regular mail, email or facsimile to the potential participant, and to conduct the consent interview by telephone 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.

5.8.7

6. Incidental Findings

6.9. Within the limits of consent provided by the participant, researchers shall disclose any material incidental findings discovered in the course of research. The Researcher's plan to identify and disclose incidental findings must be submitted to the REB and approved prior to implementation.

7. REFERENCES

6.1. Health Canada, Division 5 of the Food and Drugs Act
6.2. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2)
6.3.