

SOP Title	Informed Consent Requirements and Documentation
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Approvals

Name and Title of Signatories	Signature	Date mm/dd/yyyy
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1. PURPOSE

This standard operating policy and procedure (SOP) describes the requirements for obtaining and documenting initial and ongoing informed consent.

2. GENERAL POLICY STATEMENT

Free, continuous, and informed consent lies at the heart of ethical research involving human research participants. The Research Ethics Board (REB) must review all consent documents and procedures, including recruitment methods. Investigators must obtain informed consent from the potential research participant or from his/her substitute decision maker prior to conducting any study-related procedures, unless a waiver of informed consent has been granted by the REB.

3. RESPONSIBILITY

This SOP applies to all Health Sciences Research Ethics Board (HSREB) members including the Chair and Vice-Chair(s) and to all Office of Human Research Ethics (OHRE) staff.

The Investigator is responsible for providing the HSREB with a detailed description of the consent documents, the consent process and recruitment methods.

The Investigator, the sponsor and the HSREB are jointly responsible for ensuring that the consent form contains all of the basic elements and the applicable additional elements. The HSREB is responsible for verifying that the consent documents contains the required elements.

The Investigator is responsible for providing appropriately translated consent documents if applicable.

The HSREB is responsible for determining whether informed consent exemptions or waivers are applicable and appropriate.

The HSREB Chair or designee is responsible for reviewing consent forms or changes to consent forms if the changes meet the criteria for expedited review.

4. DEFINITIONS

See glossary of terms.

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 or sub-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 or sub-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 and that the version date has been updated;
- 5.1.6 When the changes meet the criteria for delegated review, the EO forwards the revised consent form to the HSREB Chair or designee for review and approval;
- 5.1.7 When the HSREB Chair determines that the changes to the revised consent form do not meet the criteria for delegated review, the EO adds the revised consent form to the agenda of the next HSREB full Board meeting.

5.2 Translation

- 5.2.1 The informed consent document should be in language understandable to the participant (or acceptable representative);
- 5.2.2 When a study participant is non-English speaking, documentation of informed consent can be by one of two methods:
 - Written consent: The HSREB approved English version of the informed consent document is translated into the participant's native language. Translated informed consents must be accompanied by an attestation from the translator certifying that the translated informed consent accurately reflects the HSREB approved English informed consent. This method is preferred if it is anticipated that a significant percentage of the prospective study population is non-English speaking. A translated informed consent document does not replace the need for an interpreter to be present during the consent process and throughout the study. The participant will sign the translated version of the informed consent form document,
 - Oral consent: A qualified interpreter fluent in both English and the participant's native language orally interprets the HSREB approved English consent form to the participant. The interpreter should be an impartial person (i.e., not a friend or family member). When the person obtaining consent is assisted by an interpreter, the interpreter must sign and date the consent form;
- 5.2.3 The HSREB requires that the translated materials be submitted for review and approval prior to use in enrolling non English-speaking participants. The Investigator must include a certificate or

statement signed by the translator indicating that the translated materials are a true and accurate translation of the HSREB-approved English materials;

- 5.2.4 The HSREB may follow delegated review procedures to review and approve translated materials if the English language materials have already been approved and the signed translation certificate or statement is on file;
- 5.2.5 An interpreter should be available to the study participant throughout the study;
- 5.2.6 The interpreter must sign and date the consent form attesting that the study was accurately explained to, and appeared to be understood by the participant;
- 5.2.7 If a 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 informed consent document and any other written information is read and explained to the participant. Signatures will be obtained from the participant (if capable) and the impartial witness on the informed consent document, where applicable. The signature of the impartial witness attests that the information was accurately explained to, and apparently understood by the participant, and that informed consent was freely given by the participant.

5.3 Consent for Research Involving individuals with cognitive impairment

- 5.3.1 For research involving individuals with cognitive impairment, either permanently or temporarily, the HSREB must ensure that at a minimum the following conditions are met:
 - The researcher involves participants who lack the capacity to consent on their own behalf to the greatest extent possible in the decision-making process,
 - The researcher seeks and maintains consent from the substitute decision maker,
 - The substitute decision maker is not the researcher or any other member of the research team,
 - 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 how the participant's welfare will be protected during participation in the research;
- 5.3.2 If a substitute decision maker 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 researcher ascertains the wishes of that individual with respect to participation;
- 5.3.3 Assent from a participant is not sufficient to permit them to participate in a research project in the absence of consent by a substitute decision maker; however, their expression of dissent is respected;
- 5.3.4 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;

- 5.3.5 If assent for research is required, the Researcher must submit to the HSREB the proposed procedures for obtaining consent from the capable substitute decision maker and assent from the research participant. The Researcher must submit an Assent form or summary of the Assent process to the HSREB for approval as per the organization's guidelines;
- 5.3.6 When authorization for participation was granted by a substitute decision maker, and the participant acquires or regains capacity during the research, the Researcher will seek the participant's consent as a condition of continuing participation;
- 5.3.7 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, a substitute decision maker may be guided by these directives during the consent process.

5.4 Consent for Research in Health Emergencies

- 5.4.1 The REB establishes the criteria for the conduct of research involving medical emergencies prior to approval of the research. The Researcher must justify to the HSREB the reasons why an exception to obtaining informed consent from participants is required;
- A serious threat to the prospective participant requires immediate intervention,
 - Either no standard efficacious care exists, or the research offers a real possibility of direct benefit to the participant in comparison with standard care,
 - Either the risk of harm is not greater than that involved in standard therapeutic care, or it is clearly justified by the potential for direct benefit to the participant,
 - The prospective participant is unconscious or lacks capacity to understand risks, methods and purposes of the research project,
 - A Substitute decision maker cannot be secured in sufficient time, despite diligent, and documented efforts to do so, and
 - No relevant prior directive by the participant is known to exist;
- 5.4.2 When a previously incapacitated participant regains capacity, or when a substitute decision maker is found, free and informed consent is sought for continuation in the project and for subsequent research-related procedures.

5.5 Consent update form for ongoing and completed study participants

- 5.5.1 The Investigator must inform research participants of any new information that might affect their willingness to continue their participation in the research or that may affect their long-term health even if they have completed their participation in the study, including those who have been withdrawn from the study;
- 5.5.2 The Investigator must obtain the currently enrolled participant's consent to continue to participate if there is a significant change to the protocol or risk;
- 5.5.3 If required, written documentation of ongoing consent for currently enrolled participants may be obtained by having the participant sign or capture their electronic signature on an HSREB approved consent update form;
- 5.5.3.1.1 This includes instances where participants may transition from not being capable to being capable of providing consent, for example within longitudinal pediatric studies.
- 5.5.4 If applicable, oral information for the implementation of the consent update form may be provided by contacting the participant by phone and by documenting their agreement to continue;

- 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 permission from the patient, the Investigator may initiate the call;
- 5.6.5 **Health Records Department:** The Investigator may ask the Health Records Department to identify patients who appear to meet the study's eligibility criteria. The Investigator should supply Health Records with a standard letter describing the study to give to the patient's physician, and asking whether the physician would be willing to approach his/her patients about participation, as in 5.5.2 above. It is NOT acceptable for the Investigator or his/her staff to contact patients identified through hospital records, clinic charts or other databases independently by phone, unless the patient has previously agreed (see 5.5.4 below), or is already under the medical care of the Investigator;
- 5.6.6 **Registries:** If the HSREB has previously approved a patient research registry and the patient has provided permission to be contacted for potential studies, the Investigator 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 they have agreed to be contacted. The patient must be offered the option of having his/her name removed from the database;
- 5.6.7 **Advertising:** The HSREB must first review and approve the text and the use of any advertisements, notices or media messages per 5.6 below.

5.7 Recruitment Materials

- 5.7.1 The HSREB reviews the recruitment materials (e.g., advertisements, letters, notices) for accuracy and for evidence of coercion or undue influence and consistency with the HSREB approved protocol and informed consent document;
- 5.7.2 Advertisements should be limited to the information that the prospective participant needs to determine their potential eligibility and interest. When appropriately worded, the following items may be included:
- Full study title
 - The name of the Investigator,
 - The condition under study and/or the purpose of the research,
 - In summary form, the eligibility criteria that will be used,
 - The time or other commitment required of the participants,
 - The location of the research,
 - The name and phone number of the person or office to contact for further information,
 - A clear statement that this is research and not treatment,
 - Notice of compensation and/or cost that would be incurred by study participants;
- 5.7.3 Advertisements may indicate that participants will be reimbursed for out-of-pocket expenses (e.g., parking) but this information should not be overly emphasized;
- 5.7.4 Advertisements should not name the study drugs or contain therapeutic claims;
- 5.7.5 All recruitment materials must be approved by the HSREB and by each Institution per local practice prior to their use.

5.8 Documentation of Informed Consent

- 5.8.1 The HSREB typically requires documentation of informed consent by the use of a written and/or electronic informed consent form approved by the HSREB and signed and dated by the participant or the participant's substitute decision maker, and by the person obtaining consent;
- 5.8.2 As required by the Research Sponsor or if required by organizational policies, the Researcher must also sign and date the informed consent form for clinical trials;
- 5.8.3 A copy of the signed consent form will be provided to the participant or the participant's substitute decision maker;
- 5.8.4 The Investigator or designate must document details of the consent process in the participant's medical record and/or source documentation, according to the organization's guidelines;
- 5.8.5 The HSREB may approve a short form written consent document in situational cases where time may be limited, for example, research conducted in emergency situations. The Investigator will need to clearly outline in their application/protocol the need for this short form written consent process. . The short form consent form contains all required elements of informed consent. A written summary of the information can be presented orally to the research participant or their substitute decision maker. The short form consent document is signed by the research participant or the substitute decision maker. An impartial witness may be present during the oral presentation in accordance with any regulatory or institutional requirements. The witness must sign both the short form consent document and a copy of the written summary. The person obtaining consent must sign a copy of the written summary of the information that is presented orally ;

- 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 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 HSREB may approve the process of oral consent, a verbal agreement or a handshake;
- 5.8.8 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;
- 5.8.9 Whenever possible, the research participant should have written documentation of participation in a research project unless it may compromise their safety or confidentiality.

5.9 Consent and Secondary Use of Identifiable Information and/or Human Biological Materials for Research Purposes

- 5.9.1 The HSREB allows the secondary use of identifiable information and/or human biological materials for research purposes without obtaining consent from research participants if the Researcher is able to satisfy the following conditions:
- Identifiable information/materials are essential to the research,
 - The use of identifiable information/materials without the participant's consent is unlikely to adversely affect the welfare of individuals to whom the information relates,
 - The Researchers will take appropriate measure to protect the privacy of individuals, and to safeguard the identifiable information/materials,
 - The Researchers will comply with any known preferences previously expressed by individuals about any use of their information/materials,
 - It is impossible or impracticable to seek consent from individuals to whom the information relates/materials were collected, and
 - The Researchers have obtained any other necessary permission for secondary use of information/materials for research purposes;
- 5.9.2 In cases where the secondary use of identifiable information/materials without the requirement to seek consent has been approved by the HSREB, if the Researcher proposes to contact individuals for additional information and/or materials, HSREB approval must be obtained prior to contact.

5.10 Consent Monitoring

- 5.10.1 In considering the adequacy of informed consent procedures, the HSREB may require monitoring of the consent process by an impartial observer;
- 5.10.2 Such monitoring may be particularly warranted where the research presents significant risks to participants, or if participants are likely to have difficulty understanding the information to be provided;

5.10.3 Monitoring may also be appropriate as a corrective action where the HSREB has identified problems associated with a particular Investigator or a research project.

5.11 Waiver or Alteration of Informed Consent

5.11.1 The HSREB may approve a consent procedure that does not include, or which alters, some or all of the elements of informed consent, or waive the requirement to obtain informed consent, provided that the HSREB finds and documents that:

- The regulatory framework supports the waiver,
- The research involves no more than minimal risk to the participants,
- The waived or altered consent does not involve a therapeutic intervention,
- The waiver or alteration is unlikely to adversely affect the rights and welfare of the participants,
- The research could not practicably be carried out without the waiver or alteration,
- The information is used in a manner that will ensure its confidentiality,
- The public interest in conducting the research exceeds the public interest in protecting the privacy of the individuals,
- Whenever appropriate, the participants will be provided with additional pertinent information after participation;

5.11.2 Debriefing should be a part of all research involving an alteration to consent requirements whenever it is possible, practicable and appropriate;

5.11.3 Participants should have the opportunity to refuse consent and request the withdrawal of their data and/or specimens whenever possible, practicable and appropriate;

5.11.4 These findings and their justifications shall be clearly documented in the HSREB minutes or Recommendation Letter to the Investigator when the HSREB exercises this waiver provision.

5.9. Waiver of Informed Consent Requirements for Emergency Research.

5.9.1. The HSREB may approve research that will be performed in emergency settings without requiring informed consent from participants, under certain circumstances. These involve:

- participants must be in a life-threatening situation for which available treatments are unsatisfactory/unproven,
- need to collect valid scientific evidence...to determine the safety and effectiveness of particular interventions,
- obtaining informed consent is not feasible,
- participants will not be able to give their informed consent as a result of their medical condition,
- the intervention under investigation must be administered before consent from the participants Substitute Decision Maker (SDM) is feasible,
- there is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the clinical investigation.
- Participation in the research must hold out the prospect of direct benefit to the participants in the study.

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 to 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 Drug Act;
- 6.2. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2);
- 6.3. The International Conference on Harmonization (ICH) Guidelines for Good Clinical Practice (GCP), Section 4.8;
- 6.4. US Food and Drug Administration (FDA) Code of Federal Regulations (CFR) Title 21 Part 50.20, 50.23, 50.24, 50.25, 50.27;
- 6.5. US Department of Health and Human Services (HHS) CFR Title 45 Part 46.116, 46.117;
- 6.6. FDA Information Sheets: Guide to Informed Consent;
- 6.7. OPRR Informed Consent Tips, 1993

7. SOP HISTORY

SOP Number.Version	Key Changes	Effective Date mm/dd/yyyy
701.001	original	02/17/2014
701.002	Minor administrative changes for clarification	05/29/2014
701.003	Addition of 5.4.2 Minor administrative changes for clarification	07/29/2014
701.004	Removal of section 5.4.2 - Perioperative and Critical Care Patients	04/11/2016
701.005	Minor administrative corrections for clarity	05/10/2016
701.006	Minor administrative corrections	09/10/2018
701.007	Update to Section 5.31. to include withdrawn participants	02/21/2020
701.008	Update to Section 5.5.3 to include electronic signature Updated References to include TCPS2 (2018) instead of (2010)	
701.009	Updates to include N2 SOP 701 v003	12/06/2021