TITLE	**701: Informed Consent Document Requirements and Documentation**
SCOPE	All health research submitted to the Health Research Ethics Board (HREB) operating under the direct authority of the Health Research Ethics Authority (HREA)
APPROVAL AUTHORITY	Ethics Director
EFFECTIVE DATE	April 2021

1.0 PURPOSE

This standard operating procedure (SOP) describes the requirements for the informed consent document and the process for waiving or obtaining and documenting initial and ongoing informed consent. For the purpose of this SOP, "consent document" includes consent forms, information sheets and verbal scripts, depending upon the process used to obtain informed consent.

2.0 DEFINITIONS

See the Glossary of Terms.

3.0 RESPONSIBILITIES

All HREB members and Research Ethics Office (REO) Personnel are responsible for ensuring that the requirements of this SOP are met.

The Researcher is responsible for providing the HREB with the consent document(s) and a description of the consent process or a detailed description of the rationale for a consent waiver. The Researcher is also responsible for providing a description of the recruitment methods and recruitment materials (if applicable).

The Researcher and the research sponsor, if applicable, are jointly responsible for ensuring that the consent document contains all of the basic elements of consent and the applicable additional elements of consent. The HREB is responsible for verifying that the consent document contains the required elements.

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

The HREB Chairperson or designee is responsible for reviewing consent documents or changes to consent documents if the changes meet the criteria for delegated review.

4.0 PROCEDURE

4.1 HREB Review of Required Elements of Informed Consent

4.1.1 The HREB will review the proposed consent process to ensure that prospective participants shall be given adequate time and opportunity to review the information provided, pose any questions they may have, and discuss and consider whether they will participate. The proposed consent document(s) will be reviewed for readability (if applicable), for appropriateness of the language and content, and for the inclusion of the applicable elements per TCPS2 guidelines and all applicable regulations.

4.1.2 The HREB will review the proposed consent document(s) to ensure that adequate information to safeguard the privacy and confidentiality of research participants is included.

4.1.3 The HREB may require a separate consent document for optional procedures or substudies (e.g., tissue, blood, genetic testing or specimen banking collected for exploratory objectives).

4.1.4 Following the review, the HREB may approve the consent document(s) as submitted or require changes.

4.1.5 When changes are required by the HREB and are made by the Researcher, the HREB or designee will review the consent document(s) to confirm that the required changes have been made and that the version date has been updated.

4.1.6 When the changes meet the criteria for delegated review, the revised consent document will be provided to the HREB Chairperson or designee for review and approval.

4.1.7 When changes do not meet the criteria for delegated review, the revised consent document will be reviewed at the next Full Board meeting.

4.2 Documentation of Informed Consent

4.2.1 If applicable, the HREB will require documentation of informed consent by the use of a written informed consent document approved by the HREB and signed and dated by the research participant or the research participant's legally acceptable representative, and by the person obtaining consent. Where consent is not documented in a signed consent form, Researchers will use a range of consent procedures (e.g., oral consent, field notes, implied consent through the return of a completed questionnaire, electronic consent). The procedures used to seek consent will be approved by the HREB and documented by the Researcher.

4.2.2 As required by the Research Sponsor or if required by the Researcher's organizational policies, the Researcher will also sign and date the informed consent form for clinical trials.

4.2.3 Where applicable, a copy of the signed consent document shall be provided to the research participant.

4.2.4 Where applicable, the Researcher or designee will document details of the consent process in the applicable research file or in the research participant's medical record, according to the Researcher's/organization's guidelines.

4.2.5 Where applicable, the Researcher will inform the research participant's primary physician about the research participant's involvement in clinical trial research if the research participant agrees to the primary physician being informed.

4.2.6 In cases where the research participant may lack the capacity to consent but written consent is required, the HREB may approve a short form written consent document. The short form consent document will contain all required elements of informed consent. A written summary of the information will be presented orally to the research participant or their substitute decision maker. The short form consent document will be signed by the research participant or the substitute decision maker. An impartial witness must be present during the oral presentation. 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.

4.2.7 The HREB 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 a consent interview by telephone, videoconference or other platforms that allow the participant to read the consent document as it is being discussed. All other applicable conditions for documentation of informed consent must also be met when using this procedure.

4.2.8 In some types of research, and for some groups or individuals who may feel that written signed consent indicates mistrust on the part of the Researcher, the HREB may approve the process of oral consent, a verbal agreement or a handshake.

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

4.3 Consent for Research Involving Individuals Who Lack Capacity

4.3.1 The HREB will ensure that, at a minimum, the following conditions will be met for research involving individuals who lack capacity, either permanently or temporarily, to allow them to decide for themselves whether to participate:

- to the greatest extent possible, the research involves such participants in the decision-making process;
- the Researcher seeks and maintains consent from authorized third parties;
- the authorized third party is not the Researcher or any other member of the research team; and
- 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.

4.3.2 If an authorized third party 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 must ascertain the wishes of that individual with respect to participation.

4.3.3 Assent from a participant is not sufficient to permit them to participate in a research project in the absence of consent by an authorized third party; however, their expression of dissent must be respected.

4.3.4 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 of 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.

4.3.5 If assent for research is required, the Researcher must submit to the HREB 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 HREB for approval.

4.3.6 When authorization for participation was granted by an authorized third party, and the participant acquires or regains capacity during the research, the Researcher will seek the participant's consent as a condition of continuing participation.

4.3.7 If a participant signed a research directive indicating their preference for ongoing and/or future participation in research, in the event that the participant loses capacity or upon their death, an authorized third party may be guided by these directives during the consent process.

4.4 Other Individuals and Groups who may be Vulnerable in the Context of Research

4.4.1 The HREB will determine appropriate protections for individuals and groups who might be inappropriately excluded from research on the basis of attributes such as culture, language, sex, race, ethnicity, age and disability, and who require additional protections. For these individuals and groups the HREB will take into account the risks and benefits of the research, and will consider protections afforded by the Researcher's organizational policies, and provincial and federal law.

Other individuals or groups whose circumstances may make them vulnerable in the context of research should not be inappropriately included or automatically excluded from participation in research on the basis of their circumstances.

4.4.2 In addition, when the HREB regularly reviews research involving individuals, groups or populations who may be vulnerable or require special consideration in the context of research, consideration shall be given to the inclusion of one or more individuals who are knowledgeable and experienced in working with these participants.

Participants may include, but are not limited to:

- children;
- the elderly;
- individuals with mental illness;
- pregnant women;
- individuals with limited language skills;
- indigenous individuals and communities; and
- prisoners.

4.4.3 If research involves prisoners, children, pregnant women, fetuses and/or neonates, and is funded or supported by the U.S. Federal government, the HREB shall apply the requirements of 45 CFR 46, including as appropriate, Sub-Parts, B, C and D.

4.5 Consent for Research in Health Emergencies

4.5.1 The HREB will establish the criteria for the conduct of research involving medical emergencies prior to approval of the research. The Researcher must justify to the HREB the reasons why an exception to obtaining informed consent from participants is required.

4.5.2 The HREB will allow research that involves health emergencies to be carried out without the free and informed consent of the participant or of their authorized third party if ALL of the following apply:

- 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;
- third-party authorization 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.

4.5.3 When a previously incapacitated participant regains capacity, or when an authorized third party is found, free and informed consent must be sought for continuation in the project and for subsequent research-related procedures.

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

4.6.1 The HREB will allow 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 and/or materials are essential to the research;
- the use of identifiable information/materials without participant 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 from whom the information/material were collected; and
- the Researchers have obtained any other necessary permission for secondary use of information/materials for research purposes.

4.6.2 In cases where the secondary use of identifiable information/materials without the requirement to seek consent has been approved by the HREB, and the Researcher proposes to contact individuals for additional information and/or materials, HREB approval must be obtained prior to contact.

4.7 Consent Monitoring

4.7.1 In considering the adequacy of informed consent procedures, the HREB may require monitoring of the consent process by an impartial observer.

4.7.2 Such monitoring will 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.

4.7.3 Monitoring will also be appropriate as a corrective action when the HREB has identified concerns associated with a Researcher or a research project.

4.8 Translation of Informed Consent Documents

4.8.1 The informed consent document(s) will be in language understandable to the research participant (or acceptable representative). If this is not possible, an interpreter will be present to translate the language of the consent document.

4.8.2 When a research participant is unable to speak/read the language of the consent document, documentation of informed consent will be by one of two methods:

- **Written consent:** The HREB-approved version of the informed consent document will be translated into the research participant's native language. The HREB requires that translated informed consents be accompanied by an attestation from a translator certifying that the translated consent document accurately reflects the HREB-approved consent document. A translated informed consent document does not replace the need for an interpreter to be present during the consent process and throughout the research. The research participant will sign the translated version of the consent document attesting that the research was accurately explained to, and appeared to be understood by, the research participant.
- **Oral consent:** If applicable/acceptable, a qualified interpreter fluent in both the language in the consent document and the research participant's native language will orally interpret the HREB-approved consent form to the research participant. The interpreter should be an impartial person. When the person obtaining consent is assisted by an interpreter, the interpreter must sign and date the consent document attesting that the research was accurately explained to, and appeared to be understood by, the research participant.

4.8.3 The HREB may follow delegated review procedures to review and approve translated informed consent materials if the English language materials have already been approved;

4.8.4 An interpreter will be available to the research participant throughout the research.

4.8.5 If written consent is required and a research participant is unable to read, an impartial witness must be present during the entire informed consent discussion. Verbal consent may be obtained from the research participant after the informed consent document and any other written information is read and explained to the research participant. Signatures will be obtained from the research participant (if capable) and the impartial witness on the informed consent document. The signature of the impartial witness attests that the information was accurately explained to, and apparently understood by, the research participant, and that informed consent was freely given by the research participant.

4.9 Waiver or Alteration of Informed Consent

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

- the regulatory and ethics guidance framework supports the waiver;
- the research involves no more than minimal risk to the participants;
- 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 precise nature and extent of any proposed alteration is defined;
- the information is used in a manner that will ensure its confidentiality; and
- whenever appropriate, the participants will be provided with additional pertinent information after participation.

4.9.2 These findings and their justifications shall be clearly documented in the HREB minutes when the HREB exercises this waiver provision.

4.9.3 If the research study is funded by or supported by the U.S. federal government, waiver of informed consent of 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 U.S. FDA-regulated research, the HREB may not waive informed consent except under the specific provisions in the applicable regulations governing emergency research.

4.9.4 Debriefing will be a part of all research involving an alteration to consent requirements whenever it is possible, practicable and appropriate.

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

4.9.6 Researchers are not required to seek participant consent for secondary use of anonymous information or anonymous biological specimens, so long as the process of data linkage or recording or dissemination of results does not generate identifiable information.

4.10 Consent Update for Ongoing and Completed Research Participants

4.10.1 Throughout the research project, the Researcher will 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 research.

4.10.2 The Researcher will obtain the currently enrolled participant's consent to continue to participate if there is a significant change to the research or risk. New information will be provided to currently enrolled participants in a Letter with New Information.

4.10.3 If required, written documentation of ongoing consent for currently enrolled participants will be obtained by having the research participant sign an HREB-approved consent document containing the updated information.

4.10.4 If applicable, ongoing consent will be obtained orally by contacting the research participant by phone, providing the updated information, and documenting their agreement to continue.

4.10.5 The nature of the provision of the new information to currently enrolled participants and the documentation required will be determined by the HREB.

4.10.6 The Researcher will inform former research participants of any new information that may be relevant to their long-term health by contacting them via phone or mail or in person, as applicable.

4.11 Recruitment Methods

4.11.1 **Researcher's Patients:** If the participant is under the care of the Researcher, the Researcher may approach the participant directly, but in such a manner that the participant does not feel pressured or obligated in any way. In this instance, the participant'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 HREB for review.

4.11.2 **In circumstances where the Researchers will obtain consent:** The Researcher will ensure that the consent has been obtained without coercion or undue influence and that there is no likelihood of therapeutic misconception, if applicable.

4.11.3 **Referrals:** The Researcher may send a letter to colleagues asking for referrals of potential participants. The Researcher may provide colleagues with an HREB approved consent document to give to their patients (potential participants). The patient/participant will then be asked to contact the Researcher directly, or, with documented permission from the patient/participant, the Researcher may initiate the call.

4.11.4 **Health Records Department:** The Researcher may ask a Health Records Department to identity patients who appear to meet the research's eligibility criteria. The Researcher should supply Health Records with a standard letter describing the research to give the patient's physician, and asking whether the physician would be willing to approach their patients about participation. It is NOT acceptable for the Researcher or the research staff to contact patients identified through hospital records, clinic charts or other databases independently by phone, unless the patient has previously agreed, or is already under the medical care of the Researcher.

4.11.5 **Registries:** If the HREB has previously approved a participant research registry and the participant has provided permission to be contacted for potential research, the Researcher or their research team may contact these participants directly. The person contacting the participant should identify themselves as associated with the participant registry, and remind the patient that they have agreed to be contacted. The participant will be offered the option of having their name removed the database.

4.11.6 **Advertising:** All advertisements, notices and/or media messages must be approved by the HREB.

4.12 Recruitment Materials

4.12.1 The HREB will review recruitment materials (e.g., advertisements, letters, notices) for evidence of coercion or undue influence and consistency with the HREB-approved research and informed consent document.

4.12.2 All recruitment materials must be approved by the HREB and, where necessary, by each

organization where the recruitment material will be displayed, as per local practice, prior to their use.

4.13 Incidental Findings

4.13.1 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 HREB and approved prior to implementation.

5.0 REFERENCES

The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Article 3: http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter3-chapitre3/#ch3_en_a3.2

U.S. Department of Health and Human Services – Title 21 Code of Federal Regulations Part 50 (21 CFR 50.25): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.25

4. *U.S. Department of Health and Human Services – Title 45 Code of Federal Regulations Part 46 (45 CFR 46):* https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.117

Health Canada Guidance for Industry, Good Clinical Practice: Consolidated Guideline, ICH Topic E6, 1997, Sections 4.8.6 & 4.8.8: https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications- submissions/guidance-documents/efficacy/guidance-document-good-clinical-practice-integrated-addendum-e6- r1-topic-e6-r2.html#a4.8

The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Article 5: http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter5-chapitre5/#toc05-1c