	701.004
	15-May-2023

PURPOSE

This standard operating procedure (SOP) describes the requirements for the informed consent form and the process for waiving or obtaining and documenting initial and .Tc 0 Tw 1.39 0 T1.

When a written informed consent form is used, the Researcher, the research sponsor and the REB are jointly responsible for ensuring that the consent form contains all of the basic elements of consent and the applicable additional elements of consent. The REB is responsible for verifying that the consent form (if applicable) contains the required elements.

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

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

DEFINITIONS

See Glossary of Terms.

PROCEDURE

REB Review of

5.2.4 The REB requires that the translated informed consent materials be submitted for review and approval prior to use in enrolling non-English/French-speaking participants. The REB may require that the Researcher include a certificate or statement signed by the translator indicating that the translated materials are a true and accurate translation of the REB approved English materials;

5.2.5 The REB may follow delegated review procedures to review and approve translated informed consent materials if the English language materials have already been approved (particularly if a signed translation certificate or statement is on file);

5.2.6 An interpreter should be available to the participant throughout the research;

5.2.7 The interpreter must sign and date the consent form attesting that the research was accurately explained to, and appeared to be understood by, the participant.

Consent Update for Ongoing and Completed Participants

5.3.1 The Researcher must inform 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affect their long term health even if they have completed their participation in the research, including those who have withdrawn or been removed from the study;

5.3.2 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;

5.3.3 If required, written documentation of ongoing consent for currently enrolled participants may be obtained by having the participant sign an REB approved consent document containing the updated information;

5.3.4 If applicable, ongoing consent may be obtained orally by contacting the participant by phone, providing the updated information, and documenting their agreement to continue;

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

5.3.6 The Researcher must inform former 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.


Recruitment Methods

5.4.1 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;

5.4.2 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;

5.4.3 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;

5.4.4 Researcher may ask the Health Records Department to identify 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 their 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;

5.4.5 the REB has previously approved a patient research registry and the patient has provided permission to be contacted for potential research, the Researcher or their 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 their name removed the database;

5.4.6 REB must first review and approve the text and the use of any advertisements, notices or media messages.

presented orally;

5.6.7 The REB 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 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;

5.6.8 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;

5.6.9 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;

5.6.10 Whenever


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protected during participation in the research;

5.9.2 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 ascertains the wishes of that individual with respect to participation;

5.9.3 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 is respected;

5.9.4 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;

5.9.5 If assent for research is required, the Researcher must submit to the REB the proposed procedures for obtaining consent from the capable substitute decision maker and assent from the participant. The Researcher must submit an assent form or summary of the assent process to the REB for approval as per the organization's guidelines;

5.9.6 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;

5.9.7 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, an authorized third party may be guided by these directives during the consent process.

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

5.10.1 The REB will deterssng Td((will)Tj0 6 (y2CID 89 >0.3 0Tw)Tj0.001p 0Tw)Tj0.7 (2 (10.)2 (1)-/

additional protections. For these individuals and groups, the REB will take into account the risks and benefits of the research, and will consider protections afforded by University 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;

5.10.2 In addition, when the REB regularly reviews research involving individuals, groups or populations who may be vulnerable 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,
- Prisoners;

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

Consent for Research in Health Emergencies

5.11.1 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 REB the reasons why an exception to obtaining informed consent from participants is required;

5.11.2 The REB allows 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;

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

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

5.12.1 The REB allows the secondary use of identifiable information and/or human biological materials for research purposes without obtaining consent from participants if


REFERENCES

See References.

REVISION HISTORY

SOP701.001	15-Sept-2014	Original version
SOP701.002	08-Mar-2016	No revisions needed
SOP 701.002_1	08-Mar-2017	5.8.1 : removal of the criteria for a waiver that excludes a study with a therapeutic intervention; addition of 'The precise nature and extent of any proposed alteration is defined,' 5.8.2 : addition of 'Debriefing should be a part of all research involving an alteration to consent requirements whenever it is possible, practicable and appropriate'; 5.8.3 : addition of 'Participants should have the opportunity to refuse consent and request the withdrawal of their data and/or specimens whenever possible, practicable and appropriate'; 5.8.5: addition of 'Researchers are not required to seek participant consent for secondary use of non-identifiable information or non-identifiable biological specimens.'
SOP 701.003	08-Oct-2019	5.3.1: addition of, 'including those who have withdrawn or been removed from the study'; 5.10: revised Title to state ' 5.10 : 5.10.1; 5.10.2 revised language for consistency with TCPS2 updated definition of vulnerable participants - i.e., vulnerable in the context of the research; 5.10.1 : addition of, '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'; 5.10.2: revision of ' involving a vulnerable population'

		to ‘involving individuals, groups or populations who may be vulnerable in the context of research’; deletion of ‘ Potentially vulnerable groups’ in heading and change to ‘Participants’; bullet #6: change to Indigenous from Aboriginal; 5.13.1: revision from, ‘Researchers have an obligation to disclose to the participant any material incidental findings discovered in the course of research.’ to, ‘Within the limits of consent provided by the participant researchers shall disclose any material incidental findings discovered in the course of research.’
SOP 701.004	15-May-2023	5.2.2: addition of French 5.6.3 addition of “and dated” as per GCP 4.8.11? "*Prior to participation in the trial, the subject or the subject's legally acceptable representative should receive a copy of the signed and dated written informed consent form and any other written information provided to the subjects*"