SOP 002_01

Title	Informed Consent Process
SOP Code	SOP 002_01
Effective Date	30-June-2023

Site Approval/Authorization to Adopt

Name and Title of Local Personnel (Type or print)	**Signature**	**Date dd/Mon/yyyy**
Neelu Sehgal Director, Interprofessional Practice & Research Chief Nursing Executive, Erie Shores Health Care		
Dr. Munira Sultana Office of Research, Erie Shores Health Care		23/06/2023

1.0 PURPOSE

This Standard Operating Procedure (SOP) describes the procedures for obtaining and documenting initial and ongoing informed consent. This SOP also describes informed consent guidelines, and the roles of the legally acceptable representative and impartial witness.

It does not apply to obtaining informed consent from minors or to exceptions to informed consent requirements for emergency situations.

2.0 SCOPE

This SOP is applicable to all clinical studies undertaken at the site (Erie Shore Health Care), and to those clinical research personnel responsible for performing, reviewing, and/or approving the informed consent process.

3.0 RESPONSIBILITIES

The Sponsor-Investigator or Qualified Investigator (QI)/Investigator is responsible for ensuring that the Informed Consent process and the Informed Consent Form (ICF) meet all of the applicable regulatory, International Conference on Harmonisation (ICH) Good Clinical Practice (GCP), sponsor, and local requirements.

Any or all parts of this procedure may be delegated to appropriately trained study team members, but remain the ultimate responsibility of the Sponsor-Investigator or Qualified Investigator (QI)/Investigator.

4.0 PROCEDURE

4.1 Informed Consent before Study Entry

4.1.1 Ensure that the person obtaining informed consent (as documented on the Task Delegation form) is qualified by training to do so, and is knowledgeable in the study procedures, and the therapeutic area being studied.

4.1.2 Review the study details with the participant, preferably in a quiet, private location. Do not coerce or unduly influence a participant to participate, or to continue to participate in a study.

4.1.3 Assess the participant's competence to consent to research, and document if the participant is deemed not competent to consent.

4.1.4 Fully inform the participant of all pertinent aspects of the research (i.e., all essential elements as described in the ICF), including any additional Research Ethics Board (REB)/Independent Ethics Committee (IEC)-approved written information, in non-technical language that is easy for the participant to understand.

4.1.5 Provide the participant with a copy of the ICF (ensure that the most recent version of the REB/IEC-approved ICF is used), and any other REB/IEC-approved written information. Allow the participant ample time to read the informed consent form and ask questions. This may include taking the ICF home to review with a family member, or other trusted individual.

4.1.6 Ask the participant questions to assess his/her comprehension of the material reviewed. Ensure that he/she fully understands the information.

4.1.7 Ascertain the participant's willingness to participate. Document the decision of any participant who declines to participate (on study screening log, or similar).

4.1.8 Inform the participant that they may withdraw consent at any time. If applicable, as per TCPS: Inform the participant that this may include withdrawal of their data and human biological materials. Any circumstances that do not allow withdrawal of data or human biological materials once collected shall be clearly explained to the participant.

4.1.9 Recommended as per ICH E6: Where applicable: Request the participant's permission to notify his/her family physician about his/her participation in the research. If the participant either does not have a family physician or does not wish him or her to be notified of participation in the study, document this accordingly (on the ICF or separate signed/dated document).

4.1.10 Request that the participant sign (and initial, if required) and date the ICF in the indicated places.

4.1.11 Sign and date the ICF as the person who conducted the informed consent discussion. Obtain any other signatures/dates, as indicated on the ICF.

4.1.12 Note: All required signatures must be obtained prior to enrolling the participant into the research study, or conducting any study-related procedures.

4.1.13 Provide the participant with a photocopy (or similar) of the signed document, and any other REB/IEC-approved written information reviewed during the informed consent discussion.

4.1.14 File the original signed ICF with the study-related essential documents (participant chart or other).

4.2 Ongoing Informed Consent

4.2.1 Ensure that the participant's consent to participate in the study remains valid throughout the study by providing ongoing opportunities for the participant to ask questions about the study.

4.2.2 Communicate any important new information that becomes available, and that may be relevant to participant's consent, in a timely manner. This communication should be documented in the participant's source documents.

4.2.3 Revise the ICF (and any other written material), and submit to the REB/IEC for approval (refer to specific SOP/s for REB/IEC submission process).

4.2.4 Re-consent the study participant s affected by the changes, after REB/IEC approval is obtained (if required).

4.2.5 Provide copies of the revised ICF, etc., to the study participant/s.

4.2.6 File the original signed revised ICF with the study-related essential documents (participant chart or other).

4.3 Participants Incompetent to Provide Informed Consent

4.3.1 A Legally Acceptable Representative (LAR) may consent on behalf of participants who are unconscious, or who are so severely ill or cognitively impaired that they cannot provide informed consent. See specific provincial or local regulations and policies, if required.

4.3.2 In such cases, conduct the informed consent procedure with the participant's LAR, according to institutional policy, following the procedures described above.

4.3.3 Inform the participant to the extent compatible with his or her understanding. If capable, the participant also should also sign and date the ICF.

4.3.4 Obtain signed consent from the participant as soon as possible, if his/her ability to consent returns, e.g., regains consciousness.

4.3.5 Distribute and file documentation, as described above.

4.4 Participants or Legally Acceptable Representative Unable to Read

4.4.1 If a participant or LAR is unable to read, an impartial witness must be present during the entire informed consent discussion.

4.4.2 Obtain verbal consent from the participant or LAR, after the ICF any other written information is read and explained to the participant.

4.4.3 Obtain dated signatures from both the participant (if capable) or LAR, and the impartial witness on the ICF, where applicable. The signature of the impartial witness attests that the information was accurately explained to, and apparently understood by, the participant or LAR, and that informed consent was freely given by the participant or LAR.

4.4.4 Distribute and file documentation, as described above.

4.5 Participants Unable to Speak English/French

4.5.1 If the participant does not speak English or French (where applicable), the informed consent discussion must take place in the participant's first/preferred language, using a qualified interpreter/translator.

4.5.2 Obtain an REB/IEC-approved translated consent form, if possible.

4.5.3 Obtain the dated signatures of both the participant and the interpreter/translator on the REB/IEC-approved consent form. By signing the consent form, the interpreter/translator attests that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the participant, and that informed consent was freely given by the participant.

4.5.4 Distribute and file documentation, as described above.

4.5.5 Note: While an interpreter/translator may be helpful in facilitating conversation with a non-English speaking participant, routine ad hoc translation of the consent document should not be substituted for a written translation. Communities with a large non-English/French population may have interpreters/translators employed by the hospitals, who would be acceptable to an REB/IEC. Check with the local REB/IEC prior to considering enrolment of these participants.

Please be reminded that the study team must also communicate with this participant throughout the entire study, so the informed consent process is on-going, not just when the ICF is signed. Some authorities recommend not entering a participant under such circumstances.

4.6 Participant Consent for Non-Therapeutic Trials

4.6.1 Additional restrictions apply to non-therapeutic research studies (i.e., research studies in which there is no anticipated direct clinical benefit to the participant). Such studies should be conducted in participants who personally give consent, and sign and date the ICF.

4.6.2 Non-therapeutic research studies may be conducted with participants, with the consent of a legal representative, provided the following conditions are fulfilled:

• The objectives of the study cannot be met by means of a study with participants who can give personal informed consent;
• The foreseeable risks to the participants are low;
• The negative impact on the participant's well-being is minimized and low;
• The study is not prohibited by law; and
• The approval/favourable opinion of the REB/IEC is expressly sought on the inclusion of such participants, and the written approval/favourable opinion covers this aspect.

4.7 Documenting the Informed Consent Process

4.7.1 Record evidence of the informed consent process in the source documentation, including statements of:
• The participant's comprehension of the material reviewed;
• The participant having been given ample opportunity to read the informed consent form and to decide whether or not to participate in the research study;
• Adequate time having been given for all questions about the research study to be answered to the satisfaction of the participant;
• Informed consent having been obtained prior to initiating any study-related procedures; and
• Any other relevant information involving the process of informed consent.

5.0 REFERENCES

Health Canada, Food and Drug Regulations, Part C, Division 5, Drugs for Clinical Trials Involving Human Subjects, (Schedule 1024), June 20, 2001.

Health Canada, Guidance for Industry, Good Clinical Practice: Consolidated Guideline, ICH Topic E6, 1997.

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 2014.

Department of Justice (Canada), Personal Information Protection and Electronic Documents Act (PIPEDA), updated 2006.

Pharmaceutical Inspection Convention, Pharmaceutical Inspection Co-operation Scheme, Annexe 11, Computerised Systems.

US Food and Drug Administration, Code of Federal Regulations, Title 21, Volume 1:

• Part 11, Electronic Records; Electronic Signatures, (21CFR11).
• Part 50, Protection of Human Subjects, (21CFR50).

- Part 54, Financial Disclosure by Clinical Investigators, (21CFR54).
- Part 56, Institutional Review Boards, (21CFR56).
- Part 312, Investigational New Drug Application (21CFR312).
- Part 314, Applications for FDA Approval to Market a New Drug (21CFR314).

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