SOP 002_12

Title	Informed Consent Forms
SOP Code	SOP 002_12
Effective Date	30-June-2023

Site Approval/Authorization to Adopt

Name and Title of Local Personnel (Type or print)	**Signature**	**Date dd/Mon/yyyy**
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1.0 PURPOSE

This Standard Operating Procedure (SOP) describes the activities involved in preparing the Informed Consent Form (ICF), including:
• essential elements of the ICF document;
• writing, reviewing and/or modifying an ICF;
• legal and cultural language considerations in the ICF document; and
• Research Ethics Board (REB)/Independent Ethics Committee (IEC) approval considerations.

Important Note: This procedure also applies to other written material supplied to the study participant, which may contain the same information, as included in the ICF.

2.0 SCOPE

This SOP is applicable to all clinical studies undertaken at the site (Erie Shores Health Care-ESHC), and to those clinical research personnel responsible for drafting, adapting, revising or reviewing the ICF at ESHC.

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 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 General Guidelines

4.1.1 The informed consent form is developed, adapted, or revised by the designated study staff member, and should be approved by the Sponsor-Investigator or Qualified Investigator (QI)/Investigator before submission to the Research Ethics Board (REB)/Independent Ethics Committee (IEC).

4.1.2 Industry-sponsored study: The Sponsor provides the site with a sample consent form that usually needs to be customized to meet the site and/or REB/IEC requirements. The revised ICF must be sent back to the Sponsor for approval prior to submitting it to the REB/IEC.

4.1.3 Investigator-initiated study: The site is responsible for developing the ICF.

4.2 General Informed Consent Form Guidelines

4.2.1 Use language that is as non-technical as possible, and understandable to the participant, without compromising the content. An eighth grade reading level is recommended.

4.2.2 Define all medical and technical terms (such as random assignment, probability, blinding, and placebo) and acronyms, common initials, and other abbreviations when first used.

4.2.3 Use headings, bulleted lists, and visit activity charts, and avoid dense paragraphs, in order to improve readability and assist comprehension.

4.2.4 Select a font size appropriate to the target population considering such factors as age and underlying conditions, when possible, unless otherwise specified by the REB/IEC.

4.2.5 It is recommended to have someone unfamiliar with the study, preferably a lay person, read the ICF and other written participant materials. This allows an assessment of comprehension of the material. Make adjustments to the content, as necessary.

4.3 Development of Informed Consent Form: Content

4.3.1 Ensure that the ICF includes the following, when developing or adapting an ICF template:
• All applicable regulatory, local, and REB/IEC requirements,
• All of the essential elements (required and additional) using an ICF checklist, or provided in the ICH GCP guidelines,
• If applicable: Discussion of consent withdrawal (including data and biological materials as per TCPS), and any limitations or conditions on withdrawal, such as any circumstances that do not allow withdrawal of data or human biological materials once collected, and secondary use of identifiable information, as per TCPS.
• Consistency with the protocol (e.g., number of visits, inclusion/exclusion, study procedures, expected risks, etc.),
• Major adverse (drug) reactions (ADRs), as described in the Investigator Brochure,
• Protocol title and number (and version/amendment number, if applicable),
• Sponsor name,
• Numbers on all pages,
• Protocol and/or ICF version number and/or date on each page,
• ICF printed on local letterhead, and
• Translation of the ICF into appropriate language/s by a qualified/certified translator, when required; Forward translations to the Sponsor or Sponsor-Investigator and QI/Investigator for approval, prior to submission to the REB/IEC (refer to local REB/IEC for specific requirements for translation of ICF and other participant documents.)

4.4 Revisions to the Informed Consent Form

4.4.1 Revise the ICF, as needed, based on safety reports/issues, protocol or Investigator Brochure (IB) amendments, REB/IEC recommendations, Data Safety Monitoring Board (DSMB) reports, Health Canada/regulator requests, or study Sponsor requests.

4.4.2 Clearly identify each ICF version with the version number and/or date on each page.

4.4.3 Submit ICF revisions to the Sponsor or Sponsor-Investigator for review, prior to submission to the REB/IEC (when applicable).

4.4.4 Submit the revised ICF with the changes to the REB/IEC for approval.

4.4.5 Do not begin using the revised ICF until written approval is received from the REB/IEC.

4.4.6 Maintain a record/audit trail of all communications related to the ICF revision (communications with Sponsor, Sponsor-Investigator, regulatory authorities, REB/IEC, etc.)

4.5 Waiver of Participant's Legal Rights

4.5.1 Do not use any language in the ICF that causes the participant, or their legally acceptable representative, to waive, or appear to waive, any legal rights.

4.5.2 Do not use any language in the ICF that releases, or appears to release, the investigator, the institution, the site, the Sponsor, or their agents from liability for negligence. Statements such as, "we are not responsible for …" must be avoided.

4.6 Cultural Considerations (Non-English/Non-French Populations)

4.6.1 Prepare or obtain an ICF in the foreign language/s. Ensure that the language respects the culture, traditions, and knowledge base of the cultural group being invited to participate in the clinical trial.

4.6.2 Forward translations to the Sponsor or Sponsor-Investigator for approval, prior to submission to the REB/IEC (refer to local REB/IEC for specific requirements for translation of informed consent and other participant documents.)• Participant inclusion and exclusion criteria,

4.7 REB/IEC Approval Considerations

4.7.1 Obtain approval from the Sponsor, Sponsor-Investigator, QI/investigator, (as applicable) and the REB/IEC before implementing any protocol amendments and revised ICFs. The only exception is in emergency situations (immediate safety hazard to participants), or as covered under exceptions to informed consent process.

4.7.2 Do not begin using the revised ICF until written approval is received from the REB/IEC.

4.8 Study Participant Re-consent

4.8.1 Re-consent participants continuing on study, whenever important new information becomes available that may be relevant to the participant's consent. Retain signed original hard copies of all ICF versions signed. Give copies to participants.

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).