SOP 002_11

Title	Protocol Development
SOP Code	SOP 002_11
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 process for developing study protocols specifically for human subject research.

2.0 SCOPE

This SOP is applicable to investigator-initiated human subject research whereby protocol development is the responsibility of the Sponsor-Investigator.

3.0 RESPONSIBILITIES

The Sponsor or Sponsor-Investigator is responsible for ensuring the study protocol is written in compliance with all applicable regulatory, International Conference on Harmonization (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 remains the ultimate responsibility of the Sponsor or Sponsor-Investigator.

4.0 PROCEDURE

4.1 Protocol Preparation

4.1.1 Optional: Prepare a draft protocol synopsis outlining the rationale for the research study, study hypothesis, objectives, design, eligibility criteria and procedures to be performed. Consult with methodologists, statisticians, etc., as necessary. Ensure that the contents are in accordance with applicable regulatory, ICH GCP, and local requirements.

4.1.2 Circulate the draft protocol synopsis to all interested parties, such as select Steering Committee members, research study manager, methodologists, statisticians and study sponsors, etc., as required, for review and discussion/comments. Revise draft, as required.

4.1.3 Optional: Form a protocol development committee to expand the synopsis into a full research study protocol.

4.1.4 Develop the protocol, including the following sections:
- Introduction
- Rationale
- Hypothesis
- Design
- Eligibility Criteria

• Primary and Secondary Study Outcomes (as applicable)
• Study Procedures
• Statistical Considerations
• Investigational Product (if applicable)
• Handling of Adverse Events, including Serious Adverse Events (as applicable)
• Investigators Responsibilities, according to regulatory guidelines (as applicable)
• Description of Study Committees (Steering Committee, Data Monitoring Committee, Events Adjudication Committee) (as applicable)

4.1.5 Obtain agreement on the final study protocol from all reviewers and concerned parties, as described above.

4.1.6 Generate final study protocol, including a version control number and/or date.

4.1.7 Obtain approval signatures, as required. This usually includes the Sponsor or Sponsor-Investigator, and all site QI/investigators.

4.1.8 Retain a copy of the approved/signed protocol in the study file.

4.2 Protocol Amendments

4.2.1 Determine need for amended protocol, e.g., study procedure change, changes requested by Research Ethics Board (REB)/Independent Ethics Committee (IEC) and/or regulatory authorities, etc.

4.2.2 Prepare, review, and finalize protocol amendments, as described above (with or without synopsis step).

4.2.3 Finalize protocol amendment, and assign new version control number and/or date.

4.2.4 Obtain approval signatures, as required. This usually includes the Sponsor or Sponsor-Investigator, and all site QI/investigators.

4.2.5 Retain a copy of all approved/signed protocol amendments in the study file.4.2.1 Ensure that documentation (paper and/or electronic) is kept up-to-date, in preparation for each monitoring visit, as described below.

4.3 Informed Consent Form (ICF) Preparation

4.3.1 Prepare a draft ICF. Ensure that the contents are in accordance with the protocol, and applicable regulatory, ICH GCP, and local requirements.

4.3.2 Review ICF, and revise, as required. Finalize ICF, and assign version control number and/or date. Recommended: Document ICF verification in study file.

4.3.3 Translate ICF, as required.

4.3.4 Revise ICF if the study protocol is modified, if changes are requested by regulatory authorities, or REB/IEC, or if any new information becomes available that may affect the subject's willingness to participate in the clinical study.

4.3.5 Obtain approval signatures, as required. This may include the Sponsor or Sponsor-Investigator, and all site QI/investigators.

4.3.6 Retain a copy of all approved/signed ICF and ICF amendments in the study file.

4.3.7 Submit the ICF to regulatory authorities and/or REB/IEC, as applicable.

4.4 Submission to Regulatory Authorities and REB/IEC

4.4.1 Submit the study protocol/ protocol amendment and/or ICF/ICF amendments to Health Canada, or other regulatory authority, as required.

4.4.2 Obtain the No Objection Letter (NOL) or equivalent issued by the regulatory authority/ies. Submit this document to the REB/IEC.

4.4.3 Submit the study protocol/ protocol amendment, ICF/ICF amendment to the REB/IEC, as required by local procedures.

4.4.4 Research studies not subject to regulatory authority oversight: the protocol and ICF are considered final following approval by protocol development committee, Steering Committee, Sponsor, and/or other team members, as applicable. Submit final protocol to REB/IEC.

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.

Health Canada, Guidance for Industry, Clinical Safety Data Management Definitions and Standards for Expedited Reporting, ICH Topic E2A, 1995.

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).