SOP 002_03

Title	Case Report Form Design
SOP Code	SOP 002_03
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 processes involved in the design, development, approval and distribution of Case Report Form(s) (CRFs). CRFs are designed to collect the information required by the clinical research or study protocol for each study subject.

2.0 SCOPE

This SOP applies to investigator-initiated clinical research at Erie Shores Health Care, whereby Case Report Form design through distribution is the responsibility of the Sponsor-Investigator.

3.0 RESPONSIBILITIES

The Sponsor-Investigator or Qualified Investigator (QI) is responsible for ensuring that the processes involved in case report form(s) design through distribution are followed and meet the applicable regulatory, International Conference on Harmonisation (ICH) Good Clinical Practice (GCP), 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).

4.0 PROCEDURE

4.1 CRF Design, Development, and Review

4.1.1 Create a draft of the CRF using the appropriate software, taking into account the following:
- The study protocol
- Consistency within the project/therapeutic indication
- Applicable regulatory requirements
- Data collection
- Data entry
- Monitoring requirements
- Avoidance of the collection of data not required by the protocol
- Consistency with protocol statistical plan

4.1.2 Assign a version control number and/or date to the CRF.

4.1.3 Provide the draft CRF, for review by the clinical research team, as required. This may include the following: Sponsor-Investigator or QI, Study Coordinator(s), Data Management personnel, Biostatisticians, Drug Safety representative, and Quality Assurance personnel.

4.1.4 Revise CRF, based on comments received, and obtain formal sign-off, as/if required.

4.2 Research Ethics Board (REB)/Independent Ethics Committee (IEC) Approval of CRFs

4.2.1 Obtain REB/IEC approval prior to study activation, if required by local procedures.

4.2.2 Revise CRF, if required by REB/IEC.

4.3 Final CRF Distribution

4.3.1 Generate the final CRF, and distribute to the Clinical Research Team and participating sites, as required.

4.3.2 Retain a copy of the final CRF in the Investigator Study File or Trial Management File.

4.4 CRF Revisions

4.4.1 Revise the CRF, as a result of protocol amendments, or the need to clarify or expand data collection to better reflect the protocol.

4.4.2 Follow the same process as described above for original CRFs.

4.4.3 Assign a new version control number and/or date to the revised CRF.

4.4.4 Retain a copy of all revised CRFs in the Investigator Study File or Trial Management File.

6.0 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).