SOP 003_02

Title	Clinical Data Management
SOP Code	SOP 003_02
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 management of clinical study data at the site (Erie Shores Health Care), whether paper or electronic, to ensure that the data collection is complete, accurate, and verifiable.

2.0 SCOPE

This SOP is applicable to all clinical studies undertaken at the site, and to those clinical research personnel responsible for collection and management of clinical study data.

3.0 RESPONSIBILITIES

The Sponsor-Investigator or Qualified Investigator (QI)/Investigator is responsible for ensuring that clinical data management activities at the site 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 Considerations

4.1.1 Record, process, and store all clinical study information in a way that allows its accurate reporting, interpretation and verification.

4.1.2 Ensure the integrity and tracking of all clinical data through procedures for collecting, capturing, controlling, verifying, correcting, and processing data, while respecting the fact that the study may be blinded, if applicable.

4.1.3 Establish and maintain appropriate authorizations for access to clinical data within the clinical research unit, whether physical or electronic.

4.1.4 Ensure the protection and security of clinical study data.

4.2 Good Documentation Practices

4.2.1 Create site-specific work sheets or forms, as needed, to collect information necessary to the protocol. Retain these records as source documents.

4.2.2 Observe the following data entry practices, as appropriate for the data collection method:

• Use permanent ink; entries must be legible;
• Enter data in a sequential manner, without leaving any empty spaces;
• Sign and date entries (authorized person/s only);
• Include both data collection and data entry dates, for data obtained after a visit (late data);
• Do not insert late data between existing lines or in the margin. Record data following other entries, with the notation of late entry;
• Data entered by several team members: sign and date each entry corresponding to the authorized person who made the entry;
• Clearly report missing elements (e.g., visit or tests not conducted) in the source document; and
• Entries entered directly into the Case Report Forms (CRF) are defined as source data; ensure that the protocol (or other study document) describes these direct entries.

4.2.3 Make corrections to source data and CRFs, as follows:
• Do not use liquid corrector or correcting material;
• Draw a single line through the data to be corrected, without obscuring the original data;
• Initial/sign and date corrections, according to the prescribed format; and
• Ensure that changes are made by the person who made the initial entry, or by others authorized to do so. See delegation of authority form.

4.3 Confidentiality and Direct Access to Clinical Data and Source Documents

4.3.1 Participants through informed consent authorize access to their data, in the belief that all verified and collected information will be kept confidential by the Sponsor, Sponsor-Investigator, QI/Investigator, their authorized representatives, auditors, and regulatory inspectors.

4.3.2 Carry out data management in such a way as to respect privacy and meet the standards for privacy and confidentially required by the Research Ethics Board (REB)/Independent Ethics Committee (IEC), privacy legislation (Personal Information Protection and Electronic Documents – PIPEDA, and the applicable provincial legislation), Tri-Council Policy Statement, institutional policies and procedures, confidentiality agreement, and the Clinical Study Agreement (CSA).

4.3.3 Protect the privacy and confidentiality of study participants, as follows:
• Collect data only for REB/IEC-approved studies;
• Do not allow identifying information to leave the institution with data collected for research purposes, unless approved by the REB, and in accordance with institutional policies. Personal identifiers may be required for specific reasons.
• Ensure that electronic devices that are used for study purposes, such as handheld computers and personal digital assistants, do not contain any participant identifiers;
• Retain a signature sheet identifying those who have access, and those who can enter or correct source data, as an essential study document, as described in ICH-GCP E6, Section 8, Essential Documents for the Conduct of a Clinical Trial;
• Identify participant data by using unambiguous identification codes (i.e., study identifier), that allows identification of all data reported for each participant; and
• Maintain a system, or list, to link study participants to their study identifier.

4.3.4 See confidentiality and privacy SOP for additional requirements and details.

4.4 Collection and Documentation of Source Data

4.4.1 Source documents are defined as the place where the data are first recorded, including:
• hospital records,
• clinical and office charts,
• laboratory notes and reports,
• memoranda,
• participants' diaries or evaluation checklists,
• pharmacy dispensing/accountability and storage records,
• recorded data from automated instruments,
• certified copies or transcriptions,
• microfiches and microfilm,
• photographic negatives,
• magnetic media,
• x-rays,
• participant files, and
• other medico-technical records.

4.4.2 Ensure that all data collected are supported by source documentation in the health record and/or research records.

4.4.3 Ensure that data collection tools and guidelines are available prior to study commencement, and that the entire study team is familiar with, and understands, the guidelines. Quality of data is dependent on accuracy and consistency of data collection.

4.4.4 Do not collect any data required specifically for the study until REB/IEC approval for the study has been obtained, and the participant has given informed consent.

4.4.5 Record all source data promptly from the time of collection or observation.

4.4.6 Prepare source notes in the health record and/or research record that include:
• Study title
• Participant identification code
• Protocol number (if applicable)
• Qualified Investigator (QI)/Investigator name
• Visit number
• Visit date
• Confirmation of continued consent to participate in the study
• Drug dispensing, return and compliance (or device compliance) (if applicable)
• Concomitant medications and treatments
• Diagnostic test completion
• Study specific clinical evaluation
• Adverse events/experiences, drug reactions
• Completion of questionnaires
• Return appointment
• Clinical notes

4.5 Transcription of Source Data to Paper Case Report Forms

4.5.1 CRFs are the property of the sponsor (this applies to externally-sponsored trials only).

4.5.2 Ensure that only authorized person/s transcribe data into the CRF. See delegation of authority form.

4.5.3 Transcribe data to the CRF as soon as possible after it is collected and recorded in the source documentation. See Good Documentation Practices, described elsewhere in this SOP.

4.5.4 Anonymize or de-identify any diagnostic films or e-films, specimens, or reports that accompany data (according to study requirements and local policies). Identify participants on such documentation by study identification code only, unless specifically required/permitted. Do not include source documents photocopies with CRFs. Do not keep copies of clinical records, consents, printouts, discharge summaries, or any identifiable clinical reports in CRF files. Check the data collected in the CRF to ensure that only data pertinent to the REB/IEC-approved protocol is recorded.

4.5.5 Qualified Investigator/Investigator or delegate: Sign and date the CRF where indicated, after the final entry.

4.6 Electronic Data Capture Systems

4.6.1 Validate any electronic data capture (EDC) system, within the infrastructure of the clinical research unit, in order to ensure its reliability and precision, as well as its expected performance.

4.6.2 Permit EDC access only to authorized persons with authenticated identification (see delegation of authority form). Ensure that measures of protection, detection, and correction should be in place (electronic signature or secure electronic signature).

4.6.3 Ensure that authorized study staff is trained in the use of the EDC system, as required by the study protocol, and follow correct procedures. Retain training records with essential study documents.

4.6.4 Ensure that clinical data transfer to another system (if required by protocol) is validated and secure.

4.6.5 Electronic source data document: Print, date, and sign to confirm the content (Qualified Investigator or his/her delegate). File with other study source documents.

4.6.6 Electronic source data document with electronic signature: Make track changes available for the storage period of the documents, according to the applicable regulations. The person using the electronic signature must not be able to modify the tracking system.

4.6.7 Direct entry of source data into EDC (if required by the protocol): Employ a track change system, for the duration of document storage time, according to the applicable regulations.

4.6.8 Retain the original or certified copy of the data backup, as well as an audit trail (tracking of electronic data).

4.7 Quality Control and Modifications to Clinical Data

4.7.1 Receive requests for data modification from the Monitor, CRO, or other team members, on a Data Clarification Form (DCF) or equivalent.

4.7.2 Justify and document all required modifications made to the CRF (paper or electronic).

4.7.3 Review and sign the DCF (or equivalent). Return the original document to the Sponsor or Sponsor-Investigator (or as otherwise agreed upon). Retain a copy with the essential study documents.

4.7.4 Ensure that a tracking system (paper or electronic) of all data modifications is retained for a minimum of 25 years, or as otherwise required by applicable federal, provincial, and local regulations, guidelines, and/or policies.

4.7.5 Ensure that this system is accessible for monitors, auditors, and regulatory inspectors.

4.8 Clinical Data Storage

4.8.1 Protect all paper and/or electronic data from deterioration, and accidental damage or destruction, for the duration of the record retention period.

4.8.2 Retain all essential study documents for a minimum of 25 years, or otherwise, as per applicable federal, provincial, or local regulations and policies, and ICH GCP requirements.

4.8.3 Prepare a dated and signed photocopy of source data registered on thermal paper (e.g., electrocardiogram, respiratory function test, etc.). Attach the copy to the original document.

4.8.4 Clearly identify source documents (including participants' medical/hospital charts), CRFs, and other essential study documents for archiving.

4.8.5 Record, manage, and store clinical study information in a manner which will permit the preparation of complete and accurate reports, as well as permit their interpretation and verification.

4.8.6 Inform the records department that clinical study files must be stored for 25 years, or otherwise, as dictated by applicable regulations, guidelines, and policies.

4.8.7 Store completed case report forms (CRFs) separate from participant identifying information in a secure area, accessible only to study personnel.

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).