SOP 002_04

Title	Investigator Study Files and Essential Documents
SOP Code	SOP 002_04
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 creation and maintenance of the study files, including both general operational documents, and the essential documents, as defined by the International Conference on Harmonisation (ICH).

2.0 SCOPE

This SOP is applicable to all clinical studies undertaken at the site (Erie Shores Health Care), and to those clinical research personnel responsible for creating and maintaining clinical study files.

3.0 RESPONSIBILITIES

The Sponsor-Investigator or Qualified Investigator (QI)/Investigator is responsible for ensuring that study file creation and maintenance meet all of the applicable regulatory, 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

4.1.1 Identify the clinical research team member(s) who are responsible for collecting, filing, and storing study-related documents.

4.1.2 Open a study file after the first contact by the Sponsor or Sponsor-Investigator is made, or as soon as an outline protocol is available.

4.1.3 Create a logical, organized filing system that allows for rapid retrieval of study documents. Industry sponsors may provide the site with Investigator Study Files template and/or binder/boxes.

4.1.4 Create a separate reference binder/file to store regulations and guidelines and other relevant clinical trial references (e.g., published papers, articles).

4.1.5 Maintain a delegation log and training log.

4.1.6 Store the study files in a secure location (e.g., locked cupboard or file cabinet).

4.1.7 Protect the confidentiality of all participant records (e.g., participant identification logs, Case Report Forms).

4.1.8 Ensure that adequate funding for long-term storage is negotiated in the study budget, as required.

4.2 Study File Maintenance (During Trial)

4.2.1 Maintain and update essential document storage as necessary, adding appropriate documents as they are generated or received. Retain all original and revised versions of essential documents.

4.2.2 Clinical Research Coordinator (CRC): Maintain a Communication Log for each study, and document relevant communications chronologically to the sponsor/monitor, project manager, study participants, investigator, etc. Communications by e-mail may be archived electronically during the course of the study. All e-mails related to the study should be saved in a dedicated and secure folder throughout the course of the study.

4.3 Study File Storage (After Trial Completion)

4.3.1 Store participant records in compliance with institutional policy, relevant privacy legislation, and regulatory requirements.

4.3.2 Store completed study documents in a secure location for the required period of time. Ensure that the files are secure from fire, theft, vandalism, tampering, and loss, but are easily accessible for review and audit.

4.3.3 Inventory the study file contents, and note the intended storage location. Maintain an inventory of electronic documents, type of media, and storage location. Be aware of the need to transfer to new and emerging storage technologies.

4.3.4 Update inventory documents, if stored items are moved. Notify Sponsor or Sponsor-Investigator.

4.4 Study File Access for Auditors and Regulatory Inspectors

4.4.1 All essential study documents are participant to, and must be available for, audit by the Sponsor or Sponsor-Investigator's auditor, and inspection by the regulatory authorities.

4.4.2 Study team access: Make a copy of the original document/s and return original to the archive, if a document is required. Do not remove original documents from archived records, if at all possible.

4.4.3 Inspectors/auditors may require that part or all of the 'original' archived file be available for their review (rather than copies). Ensure that any files removed from storage are properly secured at all times, and returned to the correct storage location.

4.5 Study File Destruction or Return

4.5.1 Consult Sponsor or Sponsor-Investigator on file disposition after the required storage time has elapsed, or if site storage is no longer possible at the time of, or following study completion (e.g., facility closure, etc.).

4.5.2 Destroy or return files to Sponsor or Sponsor-Investigator, as directed. Do not destroy any files without express written permission from the Sponsor. Forward destruction documentation to the Sponsor.

4.5.3 For trials not covered by Division 5 regulations, study files may be destroyed after the required document retention period prescribed by ICH GCP or provincial and/or local regulations and policies.

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.

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).