



1. Purpose

The purpose of this SOP is to outline the procedures for maintenance, storage and retention of study related documents and records.

2. Responsibilities

Methods Centre: The MC is responsible for ensuring study records and documentation is stored in accordance with industry and regulatory guidelines.

Research Site: The research site is responsible for ensuring they adhere to Sponsor, industry and regulatory guidelines concerning study records and documentation.

3. Procedures

3.1 Methods Centre Regulatory Files

3.1.1 On initiation of the study the MC must prepare a regulatory file containing documentation related to the study.

3.1.2 During the study the MC is responsible for updating the regulatory files by adding study related documents.

3.1.3 The study regulatory files should be kept in a secure area accessible only to authorized staff.

3.1.4 The regulatory files should be retained for at least 25 years, unless otherwise specified.

3.1.5 Study participant treatment codes should be kept for at least 25 years, unless otherwise specified.

3.1.6 The study regulatory files should contain documents in accordance with ICH GCP section 8.0 Essential Documents for the Conduct of a Clinical Trial. Exceptions to the essential document list will be documented in writing (e.g. unregulated observational study, surveys).

3.2 Research Site Regulatory Files

3.2.1 If the MC indicates to the site that regulatory files are appropriate for the type of study being conducted (i.e. regulated), the files should contain documents in accordance with ICH GCP section 8.0 Essential Documents for the Conduct of a Clinical Trial.

3.2.2 On initiation of the study the research site must prepare a regulatory file containing documentation related to the study.

3.2.3 During the study the MC is responsible for updating the regulatory files by adding study related documents.

3.2.4 The study regulatory files should be kept in a secure area accessible only to authorized staff.

3.2.5 The regulatory files should be retained for at least 25 years, unless otherwise specified. All requests to destroy or dispose of regulatory files prematurely must be forwarded to the study Sponsor.



Study Files and Regulatory Documents
208-00

4 **References**

4.1 Food and Drug Regulations Division 5: Drugs for Clinical Trials Involving Human Subjects section C.05.012

4.2 ICH GCP Section 8: Essential Documents for the Conduct of a Clinical Trial

4.3 ICH GCP Section 4.9: Records and Reports