



1. Purpose

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

2. Responsibilities

CERU: CERU is responsible for ensuring study records and documentation is stored in accordance with industry and regulatory guidelines for a particular trial/project.

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

3. Procedures

3.1 CERU/Sponsor Regulatory Files

- 3.1.1 On initiation of the study CERU should prepare a CERU/Sponsor regulatory file containing documentation related to the study.
- 3.1.2 The CERU/Sponsor regulatory file should be organized in a logical manner which allows for rapid retrieval of study documents.
- 3.1.3 During the study, CERU is responsible for updating the CERU/Sponsor regulatory files by adding appropriate documents as they are generated or received. All original and revised versions of essential documents should be retained.
- 3.1.4 While the trial is ongoing, the study regulatory files should be kept in a secure area accessible only to authorized staff.
- 3.1.5 For Health Canada CTA trials, in accordance with regulations outlined in Division 5 of the Food and Drug Regulations, the regulatory files must be retained for a period of at least 25 years, unless otherwise specified by Health Canada.
 - 3.1.5.1 Study participant treatment codes must be kept for 25 years, unless otherwise specified by Health Canada.
- 3.1.6 In accordance with guidelines set out by Queen's University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board, for non-regulated projects, documentation should be maintained for 5 years.
- 3.1.7 Both hardcopy and electronic records should be archived in a secure location for the required retention time.
 - 3.1.7.1 The files should be secured from fire, theft, vandalism, tampering and loss.
- 3.1.8 Following the expiration of the required retention period for regulatory documents for a particular trial/project, it is permissible to destroy the records.



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- 3.1.8.1 If it is desired to dispose of regulatory files prior to the expiration of the required retention period, express written permission must be granted from the Sponsor and/or applicable regulatory body prior to any action being taken in this regard.
- 3.1.8.2 Destruction of any study related documents must be documented and provided to the applicable trial Sponsors and regulatory bodies. See Appendix 4.1 for a Destruction of Regulatory Documents template.
- 3.1.9 Regulatory files should contain documents in accordance with ICH GCP section 8.0 Essential Documents for the Conduct of a Clinical Trial, and when applicable, section C.05.012 of the Health Canada Food and Drug Regulations. Exceptions to the essential document list should be noted in writing (e.g. non-interventional observational study, surveys).

3.2 Research Site Regulatory Files

- 3.2.1 CERU will provide direction to participating research sites regarding the regulatory document requirements for a particular trial/project.
 - 3.2.1.1 Regulated trials require that research sites maintain regulatory documents in accordance with ICH GCP section 8.0 Essential Documents for the Conduct of a Clinical Trial, and when applicable, section C.05.012 of the Health Canada Food and Drug Regulations, and when applicable, requirements as outlined by other governing regulators.
 - 3.2.1.2 Non-regulated projects will not require sites to retain the same level of documentation as that of a regulated trial. The decision regarding the type of required regulatory documents for non-regulated will be made by CERU.
- 3.2.2 Upon initiation of the trial/project the research site is required to begin maintaining regulatory documentation. CERU will provide the site with a listing of documentation that is required for the trial/project. Refer to Appendix B for Regulatory Document Requirements for Regulated Trials and Non-Regulated Projects.
- 3.2.3 During the study the research site is responsible for updating the regulatory files by adding appropriate documents as they are generated or received. All original and revised versions of essential documents should be retained. Updates should be provided to CERU.
- 3.2.4 Research sites are should maintain documentation of study related communications (e.g. emails, telephone logs, etc...).
- 3.2.5 While the trial is ongoing, the study regulatory files should be kept in a secure area to ensure privacy and confidentiality is maintained. The files should be accessible only to authorized staff.



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- 3.2.6 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.
 - 3.2.7 Both hardcopy and electronic records from the CERU/Sponsor regulatory files should be archived in a secure location for the required period of time. Ensure that the files are secure from fire, theft, vandalism, tampering and loss.
 - 3.2.8 It is recommended that research sites ensure there is adequate funding for long-term storage of trial records.
 - 3.2.9 Consult with CERU on file disposal after the required storage time has elapsed.
- ### 3.3 Regulatory File Access for Inspectors and Auditors
- 3.3.1 All essential study documents must be made available in the event of an audit or regulatory inspection. Refer to SOP 601: Regulatory Inspections/Audits.
 - 3.3.2 If at all possible, do not remove original documents from archived records. Instead, make a copy and return the original to the archive.
 - 3.3.3 Inspectors/Auditors may require that part or all of the original archived files be available for their review.
 - 3.3.4 Refer to SOP 601: Regulatory Agency Inspections/Audits for further information in this regard.
- ### 3.4 Archiving of CERU Regulatory Files
- 3.4.1 As indicated in sections 3.1.5 and 3.1.6, trial/project regulatory documents are required to be retained for a period of time following the completion of the trial/project. Completion of the trial/project is defined as the time point when the last patient has completed their last study visit or follow-up.
 - 3.4.2 In addition to the regulatory documents required as outlined in section 3.1, the following are required:
 - 3.4.2.1 A copy of all versions of essential documents, including documents providing rationale for changes;
 - 3.4.2.2 Safety data from outside of Canada;
 - 3.4.3 The content, maintenance and storage of files pertaining to non-regulated studies such as surveys and observational studies will be subject to Sponsor/Project Leader discretion.

4 Appendix

4.1 Destruction of Regulatory Documents

4.2 Regulatory Document Requirements for Regulated Trials and Non-Regulated Projects



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5 References

- 5.1 Food and Drug Regulations Division 5: Drugs for Clinical Trials Involving Human Subjects section C.05.012
- 5.2 ICH GCP Section 8: Essential Documents for the Conduct of a Clinical Trial
- 5.3 ICH GCP Section 4.9: Records and Reports
- 5.4 Network of Networks Standard Operating Procedures for Clinical Research (N₂ organization).



Date:

Attn:

Study Title:

Study ID:

Sponsor:

Re: Destruction of Regulatory Documentation

To Whom It May Concern,

Please note the following regarding the above referenced trial:

Trial initiation date: yyyy

Required Regulatory Document Retention period: yyyy – yyyy

Regulatory records concerning the above referenced trial were destroyed on <<date>>. Records were destroyed by <<how they were destroyed, e.g. shredded using confidential hospital system>>.

Name

Title

Contact details



Required Regulatory Documents

Regulated Trials	Non-Regulated Projects
<p>Examples: Trials requiring a Health Canada CTA, trials requiring a US FDA IND.</p>	<p>Examples: non-interventional observational studies, surveys.</p>
<p>Regulatory Document Requirements</p> <p><u>Health Canada Trials</u></p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Protocol, Protocol Amendments <input checked="" type="checkbox"/> Investigator’s Brochure, Product Monograph <input checked="" type="checkbox"/> Health Canada – Letters of No Objection <input checked="" type="checkbox"/> Health Canada – Qualified Investigator Undertaking Form <input checked="" type="checkbox"/> Health Canada – Research Ethics Board Attestation Form <input checked="" type="checkbox"/> Health Canada – Clinical Trial Site Information Form <input checked="" type="checkbox"/> Financial Agreements <input checked="" type="checkbox"/> Research Ethics Board (REB) Approvals <input checked="" type="checkbox"/> REB Membership Lists <input checked="" type="checkbox"/> REB Approved Informed Consent Forms <input checked="" type="checkbox"/> Site Qualifications: <ul style="list-style-type: none"> ○ Site Investigator curriculum vitae ○ Site Investigator Medical License ○ Pharmacist curriculum vitae ○ Other relevant personnel curriculum vitae <input checked="" type="checkbox"/> Delegation of Authority Logs <input checked="" type="checkbox"/> Laboratory Accreditation <input checked="" type="checkbox"/> Laboratory Reference Ranges <input checked="" type="checkbox"/> Training Logs <input checked="" type="checkbox"/> Investigational Product Inventory Records <input checked="" type="checkbox"/> Investigational Product Accountability Records <input checked="" type="checkbox"/> Investigational Product Shipping/Destruction Records <input checked="" type="checkbox"/> Participant Screening & Enrollment Logs <input checked="" type="checkbox"/> Patient Identification List (site only) <p><u>US FDA Trials</u></p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Instead of Health Canada documents, the following are required: <ul style="list-style-type: none"> ○ FDA IND Approval Letter ○ FDA 1572 ○ FDA 3500 <p><u>Other Regulatory Bodies</u></p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Instead of Health Canada documents, the following are required: <ul style="list-style-type: none"> ○ Regulator Approval Letter ○ Other documents as per Regulator 	<p>Regulatory Document Requirements</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Protocol, Protocol Amendments <input checked="" type="checkbox"/> Financial Agreements <input checked="" type="checkbox"/> Research Ethics Board (REB) Approvals <input checked="" type="checkbox"/> REB Membership Lists <input checked="" type="checkbox"/> Participant Screening & Enrollment Logs <input checked="" type="checkbox"/> Patient Identification List (site only)

* The lists found above are a guideline, the necessary regulatory requirements should be consulted for each individual trial/project to ensure all requirements are met.