

Effective Date:

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SOP No: SC2

ARCHIVING OF STUDY DATA**CLINICAL TRIALS CENTRE DEVELOPMENT TEAM:**

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APPROVED BY:

Investigator's Name

Signature/Date**REVISIONS:**

No.	Section No.	Page No.	Initials/Date

DATES OF NEXT REVISION OF THIS SOP:

Date	Signed	Date	Signed

SOP No: SC2**ARCHIVING OF STUDY DATA****I. Purpose**

To describe the procedures relating to the archiving of study documents at the end of a clinical trial.

II. Other Related Procedures

SOP SC1: Study Closeout Visit

SOP QA1: Audits

SOP QA2: Inspections

III. Procedures

- 1) Discuss and agree with the Sponsor as early as possible the procedures and the exact requirements for archiving study data, so that the necessary arrangements can be made.
- 2) Access to the study data should only be allowed to the Investigator, the study site team and the Regulatory Authorities.
- 3) Complete the checklist for archiving study documents (Appendix A) in order to determine what study data needs to be archived, and also to document the location of the archived data.
- 4) Advise the Sponsor of any new arrangements associated with the archiving of the study data.
- 5) Make any necessary arrangements to transfer the responsibility for the archived data to the Investigator's successor, in the event that they leave the department before, during or after the study.
- 6) Check that the coded subject list containing the subjects full names together with their year of birth and subject code number, together with the subject consent forms are archived and included along with all of the study data that is archived.
- 7) Note that all the essential documents as defined in the ICH GCP Guidelines must be retained until the Investigator receives notification from the Sponsor that they no longer need to be retained.
- 8) Clearly mark in the subject(s) hospital records or clinic notes that he/she has taken part in a clinical trial and that the information should not be destroyed until the Investigator has given written consent to destroy them.

APPENDIX A**CHECKLIST FOR ARCHIVING STUDY DOCUMENTS**

Are the following study documents archived at the study site?

	Y	N		Y	N
Investigator's Brochure	<input type="checkbox"/>	<input type="checkbox"/>	Copies of Signed CRF's	<input type="checkbox"/>	<input type="checkbox"/>
Investigator Brochure Update	<input type="checkbox"/>	<input type="checkbox"/>	SAE Reports	<input type="checkbox"/>	<input type="checkbox"/>
Signed Protocol	<input type="checkbox"/>	<input type="checkbox"/>	Regulatory Documents	<input type="checkbox"/>	<input type="checkbox"/>
Signed Protocol Amendments	<input type="checkbox"/>	<input type="checkbox"/>	Investigator CV's	<input type="checkbox"/>	<input type="checkbox"/>
Regulatory Approval Documents	<input type="checkbox"/>	<input type="checkbox"/>	Co-Investigator CV	<input type="checkbox"/>	<input type="checkbox"/>
Recruitment Advertisement	<input type="checkbox"/>	<input type="checkbox"/>	Lab Reference Ranges	<input type="checkbox"/>	<input type="checkbox"/>
Consent Forms	<input type="checkbox"/>	<input type="checkbox"/>	Lab Reference Range Updates	<input type="checkbox"/>	<input type="checkbox"/>
Patient Information Sheet	<input type="checkbox"/>	<input type="checkbox"/>	Laboratory Quality Control Data	<input type="checkbox"/>	<input type="checkbox"/>
Sample CRF	<input type="checkbox"/>	<input type="checkbox"/>	Code Break Procedure	<input type="checkbox"/>	<input type="checkbox"/>
Sample Diary Card	<input type="checkbox"/>	<input type="checkbox"/>	Subject Screening Log	<input type="checkbox"/>	<input type="checkbox"/>
Sample Questionnaire	<input type="checkbox"/>	<input type="checkbox"/>	Subject Identification Code List	<input type="checkbox"/>	<input type="checkbox"/>
Insurance / Indemnity Statement	<input type="checkbox"/>	<input type="checkbox"/>	Subject Enrolment Log	<input type="checkbox"/>	<input type="checkbox"/>
Ethics Committee Approval	<input type="checkbox"/>	<input type="checkbox"/>	Drug Accountability Records	<input type="checkbox"/>	<input type="checkbox"/>
Ethics Committee Composition	<input type="checkbox"/>	<input type="checkbox"/>	Meeting Reports	<input type="checkbox"/>	<input type="checkbox"/>
Notifications to Ethics Committee	<input type="checkbox"/>	<input type="checkbox"/>	Signature Sheet	<input type="checkbox"/>	<input type="checkbox"/>
Safety Updates from Sponsor	<input type="checkbox"/>	<input type="checkbox"/>	Trial Initiation Report	<input type="checkbox"/>	<input type="checkbox"/>
Drug Destruction or Return Log	<input type="checkbox"/>	<input type="checkbox"/>	Trial Report	<input type="checkbox"/>	<input type="checkbox"/>
Contact Notes and Letters	<input type="checkbox"/>	<input type="checkbox"/>	Record of Retained Samples	<input type="checkbox"/>	<input type="checkbox"/>

Name of Investigator:

(Forename)

(Surname)

Location/address of archived documents:

Location for archived source documents, if different from above address:

Date of earliest possible destruction of archived documents:

(DD)		(MM)		(YY)	

Checklist completed by: _____ on _____

(Signature)

(Date)