

Standard Operating Procedure

<b>Title: ARCHIVING</b>		
<b>REF: SOP 013</b>	<b>Version: 04</b>	<b>Issue No: 1</b>
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## 1. BACKGROUND

To ensure that results from clinical trials can be examined at a later date, for example for audit purposes, it is necessary that both the Sponsor and the Investigator keep accurate records of the trial process.

The ICH GCP Guidelines are specific about which documents are essential for the conduct of a clinical trial, and which of these must be located in the Investigator's study file. ICH Good Clinical Practice Guidelines state that:

*“Essential documents should be retained until at least 2 years after the last approval of a marketing application in an ICH region, and until there are no pending or contemplated marketing applications in an ICH region, or at least 2 years have elapsed since the formal discontinuation of clinical development of the investigational product.”* In practice this mean archiving of source documents and essential study-related material for a **minimum of 15 years**.

For the purposes of non-commercial and academic studies (or studies which may involve medicinal products or devices that have already had the last intended change to the marketing approval) documents must be kept for a period of **at least 10 years**.

This is not expected to be the sole responsibility of the investigator; as the guidelines also state *“It is the responsibility of the Sponsor to inform the investigator and/or institution as to when these documents no longer need to be retained.”*

The Investigator has the responsibility to allow the representatives from the Sponsor, Regulatory Authorities or the Research Ethics Committee direct access to archived study documentation on request. The Patient information Sheet includes reference to this mandatory access, together with an assurance regarding confidentiality of patient data.

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## **2. PURPOSE**

To describe the procedure for archiving the study documents at the end of a clinical trial.

## **3. OTHER RELATED PROCEDURES**

SOP 006 Study Files and Filing  
SOP 007 Informed Consent

## **4. WHEN**

Archiving occurs at the end of the study.

## **5. WHO**

The investigator must agree with the Sponsor the exact requirements for archiving and make or assist in making the necessary arrangements. If the Principal Investigator leaves the institution during the archival period, he/she must make arrangements for safekeeping and security and must also inform the sponsor of the new arrangements. The task of labelling the appropriate documentation and study file may be delegated to the research practitioner assigned to the trial.

## **6. HOW**

All documentation as defined in ICH GCP Guidelines should be retained until notification from the Sponsor, in compliance with the timeframes described above.

All data and documents should be made available if requested by relevant authorities.

The patient's medical record should be clearly marked that the patient has taken part in a clinical trial and that the record should not be destroyed. After being labelled the records can be archived in the hospital/clinic filing system.

Use archive boxes to store the study documents, and label the boxes clearly with the name and reference number of the study, sponsor name, investigator and either "Do Not Destroy" or "Do Not Destroy until after.....".

Documents should be archived in a suitable location – The Trust may arrange off-site archiving through a commercial archive company (eg: Squirrel) that archives other sensitive Trust documents.

It may be arranged that the documentation be archived by the sponsor. The details should be agreed with the sponsor of the individual study. Access to the material should be restricted to the investigator and the regulatory authorities.