Dorset HealthCare University
NHS Foundation Trust

Standard Operating Procedure for Archiving

Objectives	The objective of this SOP is to define the requirements for archiving research documents.
Scope	Applicable to all Research & Development staff.
Responsibility	The Research & Development Facilitator is responsible for ensuring this SOP is adhered to.
Related Document	DHC/DoH Clinical Retention Schedules IN-274

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1 Purpose

The purpose of this Standard Operating Procedure (SOP) is to define the requirements for archiving research documents and research patient records at Dorset HealthCare University NHS Foundation Trust.

2 Introduction

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 study organising body and the investigator keep accurate records of the trial process.

This Standard Operating Procedure (SOP) describes the requirements for archiving of all research hosted by Dorset HealthCare University NHS Foundation Trust (DHC). Its purpose is to ensure that Investigator Site Files (ISFs) for studies are readily available at all reasonable times for inspection by the MHRA or by any other person appointed by DHC to audit the study.

Retention of the ISF for Clinical Trials of Investigational Medicinal Products (CTIMPs) and the medical records of subjects involved is a legal requirement. The Sponsor and Principal Investigator (PI) must ensure that the documents contained in the ISF, as well as the medical files of study subjects are retained for at least 5 years after the conclusion of a study and that they are complete and legible.

Arrangements for retention of documents for non-CTIMP studies must be appropriate to the requirements for each individual study.

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."

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, the documents must be kept for a period of at least 15 years.

N.B. The sponsor may stipulate the length of time that records are to be kept. Other organisations state varying lengths of time for research record retention e.g. the MRC guidance states 20-30 years.

Some research departments are also required to comply with other accreditor's requirements e.g. The Joint Accreditation Committee – ISCT & EBMT is a non-profit body established in 1998 for the purposes of assessment and accreditation in the field of haematopoietic stem cell (HSC) transplantation (JACIE). JACIE standards state that records must be kept for no less than ten years after the administration, distribution, or expiration of the cellular therapy product, whichever is latest.

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/institution as to when these documents no longer need to be retained."*

The investigator has the responsibility to allow the representatives from the study organising body, regulatory authorities or the Research Ethics Committee direct access to archived study documentation on request.

3 Training

New users must read and understand this SOP before carrying out this procedure. Existing users must read and understand the Revisions Section

4 Revisions

This is the second version of this SOP.

5 Procedure

5.1 Archiving occurs at the end of the study.

5.2 All study documentation defined in ICH GCP Guidelines should be retained until notification from the study organising body, in compliance with the timeframes described above. It is the responsibility of the Sponsor to inform the hospital as to when these documents no longer need to be retained. The Sponsor should notify investigators in writing when records are no longer required and trial records can be destroyed. The ultimate responsibility for documents to be retained at site lies with the site. The standard minimum period for retention at DHC is 15 years which is subject to variation in line with individual studies.

5.3 Superseded master SOPs and training records must also be archived. Training records should be archived when the staff member has left the organisation. Superseded SOPs should be archived when there are sufficient numbers to justify the administration time involved.

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

5.5 The patient's medical records form part of the ICH definition of essential documents (e.g. source documents). Original patient records should be stored in line with Trust policy. The patient's medical record should be clearly marked that the patient has taken part in a clinical trial on the inside front cover and that the record should 'not be destroyed without contacting the DHC Research Department first'. After being labelled, the records may be archived according to the local hospital filing system.

5.6 Use archive boxes to store the study documents. The boxes should be labelled clearly with the DHC reference number and "Do Not Destroy until after…..". The box will contain a

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contents sheet which will agree with the electronic record maintained in the research department.

N.B. No storage boxes should be destroyed without seeking the permission of the sponsor, even if the timescale for storing has expired.

5.7 Password protected data discs may be sent by the Sponsor for archiving with the investigator site files at the end of the study. The password for the data disc may be kept in the archive box as all archive boxes are stored in a secure location. A file note should be placed in the archiving box, with the disc, stating the password.

5.8 Documents should be archived in a suitable location – secure, dry, etc. Staples and paper clips rust, so where possible, should be removed, and plastic pockets can stick to the paper and remove the print, so these should also be removed where possible. As an alternative, a blank sheet of paper may be inserted into the pocket to separate printed sheets from the plastic. Off-site archiving is permissible provided documents can be accessed when required.

5.9 It may be arranged ***and is encouraged*** that documentation be archived by the study organising body. The details should be agreed with the study organising body of the individual study. Access to the material should be restricted to the investigator and the regulatory authorities.

6 Appendices

There are no appendices to this SOP.

7 Responsibilities

Archiving arrangements should be clearly documented within the Clinical Trial Agreement and agreed by the sponsor and the Trust prior to the study commencing.

The investigator must agree with the study organising body 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 study organising body of the new arrangements. (This may be delegated via responsibilities for care of the Investigator Site File).

The named person (post) responsible for archiving research records at Dorset HealthCare University NHS Foundation Trust NHS Foundation Trust is the Research & Development Facilitator.

8 Review

This SOP should be reviewed every two years unless new guidance or legislation dictates a review any sooner.

Date reviewed: 29/04/19 Date of next review: 22/04/21

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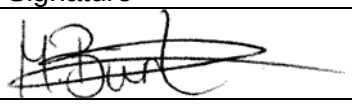
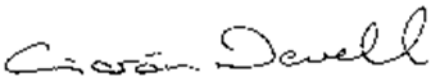
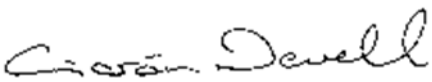
Hazel Eaton		29/04/19
Reviewed By	Signature	Date
Dr Ciarán Newell		29/04/19
Authorised By	Signature	Date
Dr Ciarán Newell		29/04/19

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