

	Standard Operating Procedures for Research and Innovation	Dorset County Hospital  NHS Foundation Trust	
SOP Reference: RESSOP006	Author: Anthony Homer, Research Governance & Quality Lead	Authorised by: Sarah Doyle, Joint Head of Research	Page 1 of 5
TITLE: Closedown and Archive			

1 Purpose

The purpose of this Standard Operating Procedure (SOP) is to define the requirements for archiving essential documents and for retrieving them from archive.

2 Introduction

Good Clinical Practice outlines the requirements for archiving which is a standard that all NHS sites undertaking research, should adhere to. 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.

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

Review: 19th February 2026

Job Titles and version number updated

5 Procedure

Archiving occurs at the end of the study. Archiving can also occur when all activity has been completed at site, as long as approval has been sought from the Sponsor as to whether the files can be stored in the Archiving facility.

5.1 Retention timelines.

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According to the DHSC Records Management Code of Practice 2021 states; (p. 70) based on the Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 (specifically Regulations 18 and 28).

- **CTIMPS** Trial Master Files and Investigator Site Files, REC records, should be retained for 5 years after full closure of the study.
- For **CTIMPs involving a marketing authorisation (i.e. a new to the market drug, and not simply a change in use)**, all essential Site File documents, CRF's, and medical records need to be kept for *15 years*. Alternatively, they will be kept *for 2 years* after the granting of the last marketing authorisation in the European Community and when there are no pending or contemplated marketing applications in the EC, *or two years* after formal discontinuation of clinical development of the investigational product.
- **All other documentation pertaining to the trial** is retained as long as the product is authorised (retention of documentation is the responsibility of the sponsor or the owner of the data).
- If the trial is using **Advanced Therapy Medicinal Products** (gene therapy), then essential documents are archived for *20 years* or longer.
- **Final Report** (kept by sponsor or other owner of the data) is retained for *5 years*, and then destroyed under confidential conditions once the product is no longer authorised for use.
- **All other research** should be retained for an appropriate period to allow for further analysis by the original or other research teams subject to consent (check your protocol or with the trial Sponsor – the Trust minimum is 2 years).
- Archiving requirements for **observational Studies** should be checked with the Trial Sponsor (with the Trust minimum of 2 years archiving).

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.

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- 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 DCH is *2 years*.
- Some research departments are also required to comply with other accreditator's requirements.

Once agreed, sponsor specified requirements should be followed at all times, but may be disputed through the Research Governance & Quality Manager.

5.2 How notes are destroyed at Dorset County Hospital NHS Foundation Trust

- Destruction of medical records at DCHFT is to be found in the Trust's Health Records Operational Policy.
- At the time of reviewing this SOP, there is a hiatus on destruction of notes and Research is set to be involved in a new records policy which will include retention periods for notes involved in research, therefore reference to health records have been removed from this SOP.

5.3 Storage and documentation

- Use archive boxes to store the study documents. The boxes should be labelled clearly with the Restore reference number and "*Do Not Destroy until after.....*". The box will contain a 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. In the event that a sponsor has been contacted and has no record of their project, the MHRA (where applicable) or HRA will be contacted requesting further contact details and to proceed with the destruction. This should occur with no less than six (6) attempts in a twelve (12)

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month period to contact and an evidence trail of which organisations have been contacted and their relation to the study. In the event that the HRA and MHRA give no reason to retain, and have no further sponsor contact, the file may be destroyed.

- 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. . In the case of electronic data to be stored by DCH on behalf of the Sponsor, it is the Sponsor’s responsibility to ensure the data can be read at the end of the archive period. DCH-Sponsored studies which archive electronic data will obtain a statement from the IT department ensuring the chosen storage format will be readable at the end of the archive period. If this cannot be guaranteed, then an alternative data storage method must be found.
- 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. Off-site archiving is permissible provided documents can be accessed quickly and easily and security can be assured.
- 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

DHSC Records Management Code of Practice 2021

7 Responsibilities

It is the responsibility of Research staff to ensure they understand and adhere to the guidance set out in this SOP and similarly, in GCP guidelines.

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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).

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 named person (post) responsible for archiving research records at Dorset County Hospital NHS Foundation Trust is the Research Administrator.

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