STANDARD OPERATING PROCEDURE

S03 – ARCHIVING Version 5	
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Controlled document

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DISCLAIMER

This generic R&D Standard Operating Procedure (SOP) must be followed unless a study specific SOP exists.

Once printed this is an uncontrolled document

Full History			
Version	**Date**	**Author**	**Reason**
V1.0	04 March 2011	Research Management & Governance Manager	New policy to meet standards
V2.0	15 April 2014	Quality Assurance Coordinator, R&D	Significant changes made throughout document to clarify procedure.
V2.1	22 September 2014	Quality Assurance Coordinator, R&D	Included reference to the archive spreadsheet and annual inspections of the archive facility.
V3.0	20 April 2018	Quality Assurance Coordinator, R&D	Review of process. Update into Trust template
V4.0	26 June 2019	Quality Assurance Coordinator, R&D	Review of process in combination with updating WI03. Addition of 'Minimum Requirements' for audit purposes.
V5	11 January 2023	Quality Assurance Coordinator, R&D	Review of process in combination with updating WI03

Associated Trust Policies/ Procedural documents:	Trust Records Management Policy Trust Health Records Policy R&D Work Instruction WI03 Archiving
Key Words:	Archiving Retention Destruction
In consultation with: Clinical Research Facility Representatives (February 2018) Quality Assurance Group (April 2018) Quality Assurance Group (April 2019) Quality Assurance Group and Governance Oversight Group (November 2022)	

Contents

KEY POINTS OF THIS PROCEDURAL DOCUMENT:

- On completion of a trial final closeout visit, all essential documents contained, or which have been contained in the TMF and ISFs must be archived.
- Clarification of staff responsibilities for archiving study documentation linked to their role within a study.
- Requirements for archiving of specific study documentation i.e. source documents, linked medical records.
- Guidance on retention periods for archived study documentation.

1 INTRODUCTION

The Regulations require trial Sponsors and Chief Investigators (CIs) to ensure that all essential documents contained, or which have been contained, in their Trial Master File (TMF) and or Investigator Site File (ISF) be retained for audit and inspection by regulatory authorities once the trial has been completed. Archiving a TMF/ISF also enables a trial to demonstrate compliance to standards of Good Clinical Practice (GCP) and to safeguard against claims of misconduct.

Study documentation ('essential documents') must be kept so that the data is accessible after a trial is completed. This is because future studies may suggest a further period of follow-up, allegations may be made of fraudulent behaviour, or concerns may arise about side effects and participants may need to be contacted.

Importantly, although it is a legal requirement to retain essential documents only for Clinical Trials of Investigational Medicinal Products (CTIMPs), the principles should still apply for the retention of study related documentation for ALL research projects within the NHS, which have to meet the UK Policy Framework for Health and Social Care Research and any other clinical research which may have an impact on the safety and wellbeing of human participants.

2. PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to describe the process to be followed by all parties concerned with archiving study documents relating to trials which are sponsored or hosted by the Royal Devon University Healthcare NHS Foundation Trust. The SOP has regard to both The UK Clinical Trial Regulations and the Data Protection Act 1998.

3. SCOPE

This SOP is aimed at two groups:

I. Investigators and their research teams
II. Research & Development Department (R&D) staff

4. DEFINITIONS AND ABBREVIATIONS

CI	Chief Investigator
CIMD	Clinical Investigation of a Medical Device
CTIMP	Clinical Trial of an Investigational Medicinal Product
CTU	Clinical Trials Unit
EU	European Union
EUCTD	European Union Clinical Trials Directive
GCP	Good Clinical Practice
GOG	R&D Governance Oversight Group
HRA	Health Research Authority
IMP	Investigational Medicinal Product
ISF	Investigator Site File
IRAS	Integrated Research Application System
MHRA	Medicines and Healthcare products Regulatory Agency
PI	Principal Investigator
Royal Devon	Royal Devon University Healthcare NHS Foundation Trust
RD&E	Royal Devon and Exeter Hospital
R&D	Research & Development
RG&Q	Research Governance & Quality (Manager)
REC	Research Ethics Committee
SOP	Standard Operating Procedure
Sponsor	An individual, company, institution or organisation which takes responsibility for the initiation, management and financing of a clinical trial. Sponsorship activities may be delegated to the Investigator, CTU and/ or other organisations as appropriate
TMF	Trial Master File

5. DUTIES AND RESPONSIBILITIES OF STAFF

In the current UK Clinical Trial Regulations, archiving is recognised as a responsibility of the study Sponsor. This responsibility may be delegated to the Chief or Principal Investigator. It is the Sponsor's responsibility to ensure that any such delegation is clearly documented. This is usually covered in the Contract or Clinical Trial Agreement and should be checked by the R&D Facilitator with responsibility for Contracts.

The R&D Department appoints as its 'Named Archivist' the Research Governance & Quality (RG&Q) Manager. The holder of this post is responsible for ensuring that archiving requirements are met as defined in the UK Clinical Trial Regulations and with this SOP. The Named Archivist may delegate the archiving function to the Quality Assurance (QA) team on their behalf.

It is a requirement that access to archived essential documents should be restricted to authorised personnel only. Any changes in the ownership and location of the archived essential documents should be documented in order to allow tracking of the stored records.

Staff have a duty to ensure that confidential information is:

- Stored correctly
- Not passed on without the appropriate consent
- Accessed in line with Trust policies and procedures
- Only used for the defined purpose

And that they have regard for ensuring:

- Patient safety in using and recording information
- Protection of sensitive data
- Staff awareness of responsibilities and accountability
- Information is accessible when required

5.1 Chief Investigator (CI)

The CI, on behalf of the Royal Devon as the Sponsor, is responsible for the archiving of essential documents. Although this task may be delegated to another member of the research team, overall responsibility for archiving will reside with the CI. In a multi-centre study, the CI is also responsible for overseeing the archiving of essential documents at participating sites, although this can be delegated in writing to the PI at each site. It is the responsibility of the CI to inform the PI at each site as to when these documents no longer need to be retained.

5.2 Principal Investigator (PI)

The PI is responsible for archiving essential documents at their site in accordance with the requirements of the Sponsor (or CI if appropriate), the Institution and local requirements. This responsibility may be delegated to another member of the research team but must be recorded on the delegation log.

5.3 Quality Assurance Team (RD&E)

The QA Team (RD&E) are responsible for: -

- Ensuring study paperwork is prepared for archive in accordance with WI03.
- Liaising with the site's designated off-site storage facility to order supplies and coordinate the collection and retrieval of archiving.

5.4 Research Delivery Team

The Research Delivery Team is responsible for: -

- Obtaining confirmation from the Sponsor that the study can be archived.
- Preparing study paperwork for archive in accordance with WI03.
- Liaising with the QA Team to facilitate the timely archiving of research studies within their teams.

6. PROCEDURES

6.1 Preparation for Archiving

Plans for archiving study documentation, including the Trial Master/Site File

must be drawn up at the grant application stage of the trial to ensure that archiving costs can be included. This is particularly important if the Trust's offsite storage facility is to be used for storing the TMF/ISF and associated documents, or if electronic data or records require archiving.

For commercial trials, where the Trust is hosting on behalf of an external Sponsor and we have agreed to archive the documentation, the price is usually, but not exclusively, in line with the NIHR Industry Costing Template.

6.2 Documentation for Archiving

All essential documents contained, or which have been contained in the TMF and ISFs (including source documents) must be archived once the trial has undergone a final closeout visit, confirmation to archive has been issued and the final report has been written. If these documents are unattainable please contact the Named Archivist.

Note: If source data is contained within medical notes, archiving should be in accordance with requirements of the Trust (or host Trust in multi-centre studies).

For hosted CTIMPs which are to be archived off-site by the Sponsor, the Sponsor's archiving procedures should be followed. The Sponsor will provide the PI with details of exactly what is to be archived offsite and what (if anything) is to be retained locally. The Sponsor should also provide details of how archived essential documents can be recalled. The PI should ensure that the Named Archivist's team has a copy of such information, if provided by the Sponsor.

Documents to be retained locally should be archived using this SOP via the Named Archivist. For a list of what to archive, and details of process, see the Archiving Work Instruction WI03.

Following archiving, a PI may receive new correspondence relating to a completed CTIMP. Such documents do not form part of the essential documents; however, they should be retained by the PI in a secure manner.

6.2.1 PIC Site Documentation

When our site has acted as a Patient Identification Centre (PIC) only, it is unlikely that there will be a requirement to archive the documentation, as paperwork will likely be a duplicate already contained in the Trial Master File at the host site. However, the key is to seek advice from the Sponsor on an individual study basis before destroying any paperwork.

6.3 Archiving Medical Records

After the completion of a CTIMP and prior to the archiving of documents, it is the responsibility of the CI and/or PI to ensure that the medical notes of all research participants (both paper and electronic) are clearly labelled in order to retain according to the Trust's Records Management Policy.,

For all CTIMPs sponsored and hosted by the Royal Devon, medical records will be identified and highlighted for retention using the Trust's Records Management Policy.

For multi-centre CTIMPs, medical records should be stored according to the host Trust's own policy at each site.

6.4 When to Archive

6.4.1 The completion of a clinical trial shall be determined by the CI and may vary among studies. The end of study should be defined in the protocol but may be for example, when the last patient to enter the trial has had their last study visit. If the definition of end of study is not detailed in the protocol, notification of the end of study must be documented in the TMF/ISF.

For hosted studies the study is deemed to be complete following study close-down by the Sponsor.

At the end of a CTIMP a minimum period of six months should be allowed to ensure that all queries are answered and study-related paperwork collected. Archiving should take place following this period.

6.4.2 Trials Not Approved or with No Recruitment

Trials which never received formal NHS approval can be destroyed without being archived, once written permission of the Sponsor has been obtained.

Archiving of paperwork for trials which did not recruit should be discussed on a case-by-case basis with the R&D Named Archivist's team and Sponsor. This will depend on factors such as whether any screening occurred, whether there are specific external regulations governing the retention of Site Files and so on.

6.5 Retention Period

Essential documentation from clinical trials that are not to be used in regulatory submissions must be retained for at least 15 years after completion of the trial, unless the Sponsor instructs otherwise (in line with approvals). These documents should be retained for a longer period if required by other applicable requirements (e.g. genetic studies) or by agreement between the Sponsor and the CI, or the funder of the trial.

Essential documentation from clinical trials to be included in regulatory submissions should be retained until at least 2 years after the approval of the last marketing application in the EU and when there are no pending or contemplated marketing applications in the EU or 15 years after the completion of the trial, whichever is longer. These documents should be retained for a longer period if required by the applicable regulatory requirement(s) or by agreement between the Sponsor and the CI or the funder of the trial. All queries regarding record retention should be addressed to the Research Governance & Quality Manager (as the named Archivist) within the R&D Department.

If the clinical research involves minors under 18 years old, essential documents should be archived until three years after the youngest subject

reaches 18 years old, or five years after the conclusion of the research, whichever is longer.

Retention of records are managed at the Royal Devon in line with the NHS Records Management Code of Practice, refer to the Trust Records Management Policy.

All queries regarding record retention should be addressed to the Named Archivist within the R&D Department.

It is the responsibility of the CI to determine and inform the Sponsor via the Named Archivist as to when essential documents are to be retained for longer than stated.

Participants' medical records should be retained in accordance with the Trust Records Management Policy.

6.6 Storage of Trial Documentation

Documents need to be stored in a way that preserves their integrity and readability and restricts access to appropriate individuals only.

The documents should be retained in a secure storage area with appropriate protection against unauthorised access. The storage area should be weatherproof and have stable environmental conditions to ensure that the records remain in a legible condition. Appropriate protection measures should be in place to protect against fire, flood and the entry of pests and rodents. Basement and attic locations should be avoided as well as areas with water pipes running through them. The storage area should be in a location which will enable prompt retrieval and ensure that essential documents are readily available upon request to the regulatory authorities. It should be regularly monitored to ensure early detection of any problem such as rodent infestation or mould growth.

For some studies the Sponsor may deem it appropriate to transfer storage to a subcontractor (e.g. Commercial archive). This decision resides with the Sponsor.

6.7 How to Archive

At the end of the study period, written confirmation from the Sponsor will be required by the Named Archivist before study documents can be archived off site by R&D. Once permission has been obtained, the study team (or whichever team holds the essential documentation) should refer to Work Instruction for Archiving (WI03) up until the point of passing the files on to the Named Archivist's designee to complete the process of sending the archiving boxes to the Trust's approved off-site storage facility.

For commercial studies, the Named Archivist or designee will check whether a fee for archiving was agreed with Sponsor at study set-up and notify the Research Finance Office accordingly.

6.8 Access of Archived Documents

Access to records that have been officially archived through R&D should be restricted to the appointed personnel responsible for archives and the regulatory authorities only, to prevent any alteration to the essential documents. For trials archived by the Trust, requests for retrieval of boxes should be requested by contacting the R&D Quality Assurance Coordinators (RD&E). Confirmation of authorisation may be requested from the PI if necessary. Requests will only be accepted by authorised personnel.

6.9 Record Destruction

At the end of the retention period, the Named Archivist or designee will notify the CI/PI that the destruction date for their trial documentation is approaching and will verify these dates. Records must not be destroyed until written confirmation of destruction from the Sponsor has been received stating that the files can be destroyed. If there is no longer an identifiable Sponsor or the Sponsor does not respond after all reasonable efforts have been made, the Named Archivist will authorise destruction on the agreed date.

An electronic record of destructions and permission to archive confirmations will be retained indefinitely. Archiving labels should be retained for seven years from the date of destruction.

6.10 Digital Archiving

It is the responsibility of the CI/PI to notify the Named Archivist as soon as it is known that electronic study data will need to be archived.

Electronic study data should be encrypted and copied onto a read-only media device for archiving with the essential documents as described above. Study data held on computer servers should then be permanently deleted as soon as the study has been reported and the participants notified of the results. This is the responsibility of the CI/PI.

It is important to consider the most appropriate media for archiving of electronic documentation. The selected medium should be unlikely to become obsolete during the planned period of storage. Archived data should be transferred to a newer or more appropriate media format if necessary. Consideration must also be given to the software or hardware requirements in order to maintain readability of the data for the planned archive period.

Electronic study records stored on the clinicaltrials$ shared drive which were only relevant during the active stage of the study should be reviewed and deleted as necessary at the point of study closure.

6.11 Archiving Logs

The Named Archivist will record details of all archived studies on a spreadsheet located in the archiving folder on the R&D shared drive.

It is the responsibility of the Clinical Trials Administrators to keep their own archive logs detailing which studies in their own area have been

moved/archived, when they were moved/archived and their current location. These logs must be kept up to date and presented to the R&D Department upon request. The logs will be cross-referenced with R&D's records.

6.12 Inspections of the Archive Facility

The selected off-site storage facility will be inspected annually and visit findings documented in the archiving folder on the R&D shared drive. The inspection findings should include, for example, the physical security, internal conditions, fire control measures, location, level of service, quality control checks etc. Please see Work Instruction for Archiving (WI03) for details of the current storage facilities used by the Royal Devon.

7 DISSEMINATION AND TRAINING FOR THIS DOCUMENT

7.1 This SOP and associated templates and forms will be uploaded to the RDE Research website shortly after having been released.

7.2 All staff whose activities are subject to this SOP should ensure that they take time to read and understand the content of this SOP.

7.3 If applicable, a training log within the Investigator Site File/Trial Master File should be completed to document that members of staff have read and understood the contents of this SOP.

8. MONITORING COMPLIANCE AND EFFECTIVENESS OF THIS SOP

8.1 In order to monitor compliance with this SOP, the auditable standards will be monitored as follows:

No	Minimum Requirements	Evidenced by
1.	Is the Work Instruction (Archiving WI03) being followed?	Monitoring the compliance of the WI.
2.	Medical Records of CTIMP study subjects sponsored and hosted by the Trust should be clearly labelled prior to archiving.	Spot check of archived medical records.
3.	Archiving Facilities – The selected off-site archiving facility is inspected annually.	Visit findings documented in the Archive folder on the R&D shared drive.

8.2 Outcomes from audit will be presented to the R&D Governance Oversight Group (GOG) which will monitor any resulting action plans until all issues have been addressed to satisfaction.

8.3 Issues identified via the audit process which require escalation will be referred to GOG.

9. ARCHIVING ARRANGEMENTS

9.1 The original of this document will remain with the R&D Quality Assurance Coordinator. An electronic copy will be maintained on the R&D section of the Q-Pulse document management system and a pdf copy on the Trust Intranet.

9.2 Archive copies must be maintained for any documents which have been superseded. Archive copies in electronic format should be retained indefinitely.

10. REFERENCES

NIHR Clinical Trials Toolkit

https://www.legislation.gov.uk/uksi/2006/1928/regulation/18/made

NHS Records Management Code of Practice