Plymouth Research and Development

University Hospitals Plymouth NHS Trust

Standard Operating Procedure

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Title:	Research archiving		
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1. Introduction

Archiving is the process of preserving records and essential documents which individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator, sponsor, and monitor with the standards of Good Clinical Practice (GCP) and with all applicable regulatory requirements. The data must be stored in a way that makes certain long-term accessibility, readability and usability whilst ensuring the authenticity and integrity of such documents. This applies to both paper and digital records and documents.

Retention Requirements – European Union (EU)

The current archive period is 15 years for CTIMP studies in the UK which are supporting marketing authorisations. However, EU law requires archiving for a longer period, the sponsor and the investigator must archive the content of the clinical trial master file for at least 25 years after the end of the clinical trial [Regulation (EU) No 536/2014 (57)]. This regulation was adopted in the EU on the 31st of Jan 2022 but does not currently apply to UK only CTIMP studies.

For Clinical Studies of Investigational Medical Products and Devices carried out under MHRA authorisation essential clinical trial documents are to be retained

- for a minimum of 5 years after the completion of a clinical study, as defined by the Medicines for Human Use (Clinical Trials) Amendment Regulations 2006.

***For Clinical Trials of Investigational Medical Products (CTIMPS) supporting marketing authorisations that commenced after 31.01.2022 and have EU sites** the contents of the clinical trial master file are to be retained

- For multinational studies involving the EU nation states, for at least 25 years after the end of the clinical trial, unless other Union law requires archiving for a longer period [Regulation (EU) No 536/2014 (57)].

For CTIMP studies with sites only in the UK:

- for at least 15 years after completion or discontinuation of the trial, **or**
- for at least two 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 European Community, **or**

- for at least two years after formal discontinuation of clinical development of the investigational product as defined by the Medicines for Human Use (Fees and Miscellaneous Amendments) Regulations 2003), **or**
- for 30 years in the case of an Advanced Therapy Medicinal Product (ATMP), as defined in SI 2010/1882. Advanced therapy products and miscellaneous amendments, **or**
- As defined in the sponsor's protocol (as long as this supersedes the requirements of National law).

For non-CTIMPs essential trial documents are to be retained

- for a minimum of five years after its completion, or unless the protocol or sponsor/funding body stipulates otherwise.

Documents may be retained for a longer period, if required by other applicable regulatory requirements, or by educational establishments. It is the responsibility of the sponsor to inform the site of the archive period and to inform sites when archived documents no longer need to be retained.

A Clinical Trial participant's medical files should be retained in accordance with applicable legislation and in accordance with the maximum period of time permitted by the hospital, institution or private practice.

The final report shall be retained by the sponsor or subsequent owner, for five years after the medicinal product is no longer authorised.

For obstetric, paediatric, and studies involving mental health

There are special archiving arrangements which apply to the data relating to these studies, please see NHSX Records Management Code of Practice_2021 for further details.

Where there are no specified national or regional requirements for retention of study materials, the archive should be maintained for at least five years after final report or first publication of study results, whichever comes later. [ISPE Guidelines for Good Pharmacoepidemiology Practices]

2. Purpose

The purpose of this SOP is to define the local procedure for preparing essential study documentation to ensure that the Research and Development (R&D) department meets the best current practice. The standards are applied to all research that is hosted at University Hospitals Plymouth NHS Trust (UHP). All essential documents relating to the clinical study must be archived in accordance with this SOP and the requirements of the UK Regulations.

3. Scope

This policy applies to **all University Hospitals Plymouth (UHP) staff** that are undertaking or involved in Trust Sponsored or Hosted research studies within UHP. It includes Investigators and their research teams, and R&D staff.

4. Responsibilities

It is the responsibility of the study sponsor, with the support of Chief/Principal Investigator (CI/PI) to ensure that essential study documentation is retained after a study is completed.

The individual study protocol should outline the responsibilities of the team members for archiving and the sponsor will inform a site as to how long data must be retained. All studies conducted on Trust premises will have their essential study documents stored electronically on the Trust's designated research Archiving drive. Their original site specific (paper) documents will be stored in the Trust archive facility, unless otherwise stated in the protocol or contract. The exception to this will be UHP sponsored non CTIMP studies which will be exclusively archived electronically.

The Trust Named Archivist is the R&D Research Governance Manager, and the Deputy Archivist is the Senior Research Support Facilitator, who are responsible for ensuring that archiving requirements are met as defined in the UK Clinical Trial Regulations and with this SOP.

5. Documents needed for this SOP

- All related documents are included in the Appendices

6. Related documents

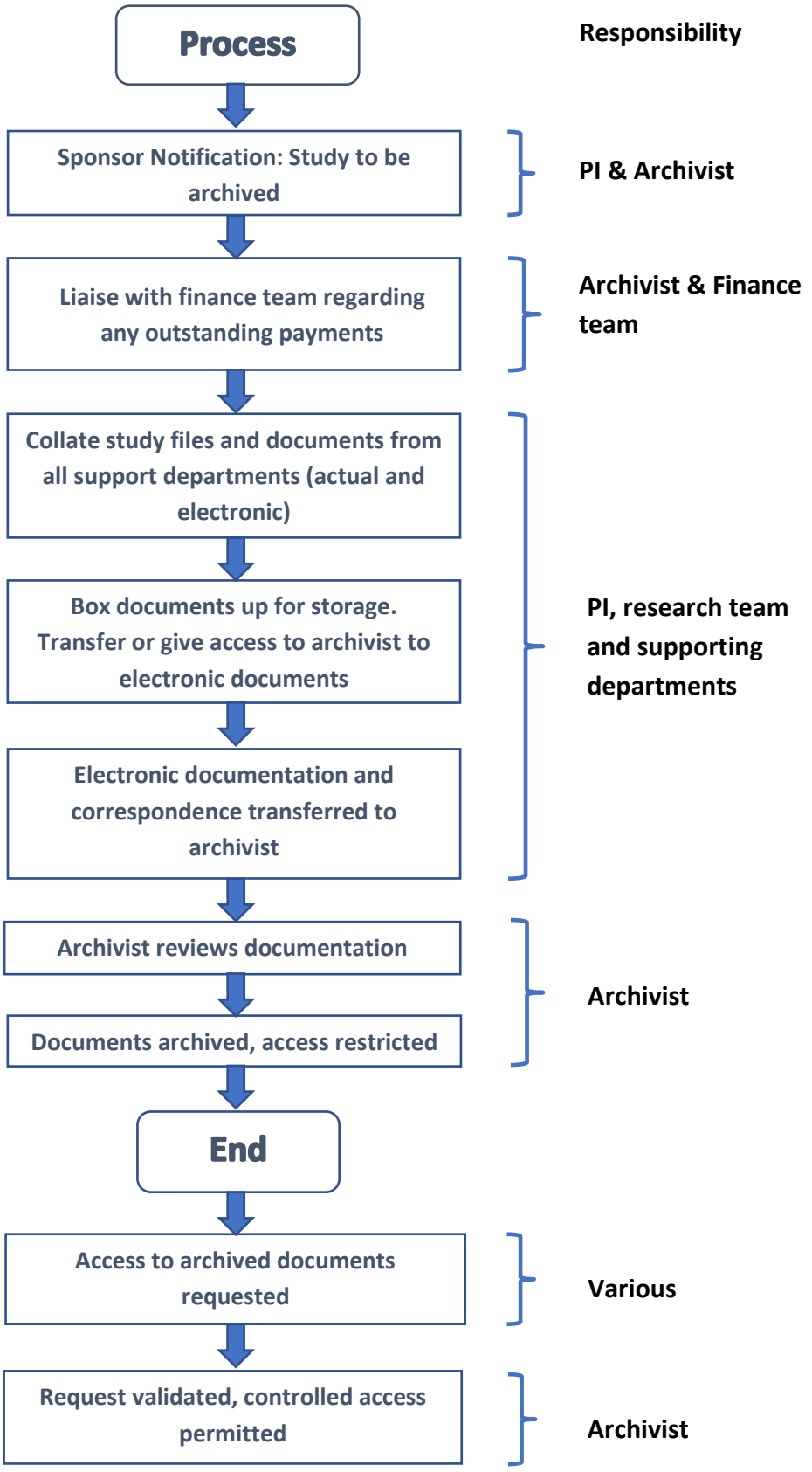
- Study Data (Source Data, Medical notes and CRF) (R&D SOP T10)
- TRW.CRM.POL.529 5.0 Health Records Policy
- NHSX Records Management Code of Practice_2021
- SC3 Research Archive Details and Destruction

7. Definitions

ATMP:	Advanced Therapy Medicinal Product
CI:	Chief Investigator
Completion of study:	Completion of trial/study is normally the date when the last participant has their last visit (of all sites, if multi-site) and sample processing has concluded.
CTIMP:	Clinical Trial of an Investigational Medicinal Product
Deputy Archivist:	Appropriately trained individual which supports and covers the Named Archivist
EDGE:	A dedicated, web-based, research database which is used within, and managed by, the R&D department at UHP
End of Study:	Defined as the date of the End of Study letter to REC (after all analysis has been completed), or for hosted trials, the date of close out letter from the sponsor.
GCP:	Good Clinical Practice

HRA:	Health Research Authority
MHRA:	Medicines and Healthcare products Regulatory Agency
Named Archivist:	The person responsible for ensuring archiving requirements are met as defined and required in the Regulations.
PI:	Principal Investigator
R&D:	Research & Development
REC:	Research Ethics Committee
Records:	Written or electronic documents which may include scans, x-rays, and electrocardiograms that describe or record the methods, conduct, and/or results of a trial, the factors affecting a trial, and the actions taken
SOP:	Standard Operating Procedure
Source data:	Any information in original records and certified copies of original records of clinical findings, observations or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial.
Source documents:	The medical record of the subject before, during and after the trial. It is the tool which confirms the eligibility criteria of the subject in the given trial. It documents the progress of the subject from consenting till the subject completes the study. Some, essential documents may also be source documents, which are often generated as part of the subject's medical care.
UHP:	University Hospitals Plymouth NHS Trust

8. Process map(s)/ flow chart(s)



9. Procedure

Step	Action	Responsibility
1	On receipt of the close out letter, the study team liaises with the sponsor **and** Deputy Archivist to ensure that the study is ready to be archived	Research Team
2	On receipt of the close out letter, the Deputy Archivist liaises with the finance team regarding any outstanding monies. Confirmation from finance team is uploaded to EDGE	Deputy Archivist Finance Team
3	The close out letter is added to EDGE, and recruitment is checked and updated as necessary	Research Team
4	The related service departments are contacted to enable collation of relevant documents (paper and electronic) for archive	Research Team
5	Using Archive Document Log (Appendix 1) and Archiving WI for Clinical Teams (Appendix 2) the site specific documents are prepared and boxed up for archive (with the exception of UHP sponsored non CTIMP studies which will be exclusively archived electronically	Research Team
6	Using Archive Document Log (Appendix 1) and Archiving WI for Clinical Teams (Appendix 2) all essential non-site specific documents to be organised electronically	Research Team
7	All boxes are checked, weighed (boxes must not exceed 10Kg) and labelled for archive	Deputy Archivist
8	All archive boxes are bound using the binding machine and left at reception (MSCP) or glass house (Main Hospital) for courier collection to the Trust's archive facility	Research Team
9	Electronic study documents to be forwarded to Deputy Archivist, or access to be granted to relevant drive/s	Research Team
10	All study documents/correspondence to be transferred from drives and added to designated study folder in the Research Archiving drive	Deputy Archivist
11	Access to archived study on EDGE restricted to read only	Deputy Archivist
12	Support sponsor and research team with obtaining	Deputy Archivist

	access to archived documents (if applicable)	
12	At the end of the archiving retention period, data will be destroyed as per R&D SOP SC3	Deputy Archivist

10. Changes from last revision

Update to regulations as of 31.01.2022. UK have adopted EU Regulation EU[536/2014] all CTIMPS set up after this time are to be archived for a period of 25 years.

Appendix 1: Archive Document Log

COMPLETE FOR ALL STUDIES

Study Name:

*Unique box reference no:	Sponsor:
REC no:	EudraCT no:

RD&I no:	IRAS no:
PI:	CI:

Packer's name / job title:	Signature & date:
*Expected date for study document destruction: _ _ _ / _ _ _ _ (Month / Year)	

Documents Archived (actual and electronic)		**Tick if copy archived**	
Protocol	Current/previous versions	☐	electronic
Patient Information Sheet/s	Current/previous signed versions	☐	actual
	Current/previous clean versions	☐	electronic
Consent form/s	Current/previous signed versions	☐	actual
	Current/previous clean versions	☐	electronic
GP Letter/s	Current/previous signed versions	☐	actual
	Current/previous clean versions	☐	electronic
Regulatory Approvals and correspondence	MHRA	☐	electronic
	REC	☐	electronic
	HRA	☐	electronic
UHP R&D C&C Approval letter		☐	electronic

Documents Archived (actual and electronically)		Tick if copy archived	
Screening log/s	Original signed versions	☐	actual
	Electronic versions	☐	electronic
Enrolment log/s	Original signed versions	☐	actual
	Electronic versions	☐	electronic
IRAS form/s -including amendments		☐	electronic
Safety Reporting documents- SAE's, SUSARS, Protocol violations etc	Original versions	☐	actual
	Electronic versions	☐	electronic
Case Report forms	Original signed versions	☐	actual
	Current/previous clean versions/electronic forms	☐	electronic
Legal Documentation- including but not limited to: CTA, Contract, MTA, Insurance Certificate, Sponsorship letter, Funding letter, Matrix of responsibilities	Original signed versions	☐	actual
	electronic versions	☐	electronic
Personnel docs – including but not limited to: CV's, GCP certificates, Delegation log, training logs etc	Original versions	☐	actual
	Electronic versions	☐	electronic
Reports- including but not limited to: Monitoring reports, Annual Reports, End of Study notification	Original signed versions	☐	actual
	Electronic versions	☐	electronic
Laboratory Documents- including but not limited to: lab ranges, lab manual	Original signed versions	☐	actual
	Electronic versions	☐	electronic
Pharmacy File including but not limited to: SMPC's, Investigator Brochures, Prescriptions, pharmacy manual	Original signed versions	☐	actual
	Electronic versions	☐	electronic
RD&I Office File		☐	electronic
Correspondence		☐	electronic
Other: specify		☐	actual
		☐	electronic

*Archivist to complete

Appendix 2: Archiving Work Instructions for Clinical Teams

Preparing Documentation for Archive

1 Purpose

1.1 Historically UHP R&D have used an off-site storage facility at Bush Park. However, the Archive has traditionally comprised all the physical files and folders and not the electronic documentation. Many of the studies have not been boxed in accordance with the requirements of today's standards, especially the studies dating back to before the introduction of the EU Directive 2001.

1.2 With the growing use of electronic means of capturing data for research studies and the need to store the Archive in accordance with the current regulations the Archiving SOP has been updated. The processes now include clear guidance on archiving both the physical and electronic files. The purpose of this work instruction is to provide guidance on how to prepare documentation for archiving.

2 Scope

2.1 The integrity of the files retained in the long-term storage and archiving of the files and folders ultimately rests with the Archivists. This work instruction defines one aspect of the processes that staff involved in the delivery of the research should follow and enables the senior research managers to allocate adequate resource to support the Archivist manage the processes.

3 Definitions

3.1 See Archiving SOP for details of acronyms used in archiving.

3.2 The address of the physical archive is Plymouth Hospitals NHS Trust, Central Records Library, Bush Park, Plymouth, PL6 7RG

3.3 e-archived documents will be stored at site level on EDGE (red page), and on the UHP designated Research Archiving drive.

4 Procedure

4.1 In accordance with the R&D SC2 Archiving SOP, the sponsor or delegate should inform all staff involved in the study to prepare documentation for archiving following notification from the sponsor.

4.2 A member of the study delivery team should inform the Archivists of the intention to archive. The archivist will liaise with the finance team that all relevant fees have been claimed and that there aren't any monies outstanding.

4.3 A member of the delivery team should contact all supporting services, to obtain all physical & electronic files relating to the study or arrange for them to be collated in one place and liaise with the Archivist regarding collection.

4.4 The study team should ensure they have received all end of study documentation and all the files are up to date. The sponsor may want to undertake a close out visit

or audit. The close out/End of study letter must be uploaded to Edge, patient status and recruitment figures must be up to date prior to a study being archived.

4.5 The documents to be **physically archived** should comprise of **all original site specific documents** which may include but not be limited to:

- Paper CRF's
- Completed consent forms
- Source data
- Delegation logs
- Screening/recruitment logs
- Safety reports
- Scans
- Contracts with wet signatures

Files should only be placed in R&D approved archived boxes available from the Archivist. **Care must be taken to ensure the following:**

- Archive boxes **must not be over filled** and **should be no heavier than 10kg**
- Ensure that there is sufficient carry handle space
- Documents must be stored upright in one layer as per photo

- **All duplicate** documents must be deleted or destroyed via confidential waste prior to archive
- All study files and documentation containing sufficient detail to reconstruct the study must be archived
- **Remove all** paperclips, folders, files, plastic wallets and file dividers
- Perishable documents should be photocopied onto paper before archiving, these include: photographs, film, ECG & ECG trace paper
- Multiple studies may be archived in one box – please ensure they are clearly separated by dividers within the box and inform the Archivists of this.

- An archive log for each study must be included in each box, this may be obtained from **Appendix 1**

4.6 The documents to be **electronically archived** should comprise of **all** current and previous versions **of essential none site specific documents** which may include but not be limited to:

- Protocols
- Patient Information Sheets
- Clean Consent forms
- GP Letters
- Regulatory Approvals and correspondence
- CV's, GCP certificates
- Investigator Brochures, SmPCs
- Correspondence
- Electronically signed documents
- Lab ranges

The electronic files should be collated into an orderly system, labelled appropriately, and be able to be accessed by the archivist on the teams relevant shared drive, or may be added to PenCLRN folder (G:\PenCLRN\VIC YATES emails and docs for archiving) in a separate folder with the study clearly identified using the RD&I number and short title.

4.7 Once the boxes are filled, inform the Archivist, who will inspect, weigh, label and barcode them, and check that the boxes can be sealed and transferred to the archive collection point.

4.8 The Archivist will arrange for the status of the study on Edge to be updated, and the archiving attribute to be completed.

4.9 The boxes/electronic archive will be logged, and a confirmation email will be sent to the delivery team to confirm receipt. Once acknowledgement has been received, all duplicate electronic archives should be deleted and access to these and the paper files will be restricted.

4.10 After the Archivist has provided formal acknowledgement of receipt, access to the electronic files and physical folders will be restricted to the Archivist, Deputy Archivists, and the Research Operations Manager for maintenance purposes. If staff require access to any files after archiving they must complete a retrieval notification form which may be obtained from **Appendix 3**.

Appendix 3: Request for Archive Retrieval (actual and electronic)

Date of request:	
To:	
From:	

Study Title:	
P I Name:	
R&D Number:	
IRAS number:	
Reason for requesting retrieval of research material:	
Documents required to be retrieved:	
Date material required by:	

Archivist use only

Details of boxes retrieved:			
No. of boxes:			
Date boxes received:		**Date boxes returned:**	

Details of temporary EDGE access permitted and date:		**Date of restriction reinstated on EDGE:**	
Additional information:			
Name/position of authorisee			
Signature:			

Once completed please email this form to victoriayates@nhs.net

****Please contact the Archivist if you do not hear back within 5 working days of sending this form****