Plymouth Research and Development

University Hospitals Plymouth NHS Trust

Standard Operating Procedure

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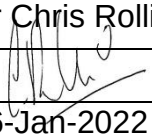
Title:	Research archive details and destruction		
Approver		Document No:	SC3
Name:	Dr Chris Rollinson	Version No:	1.0
Signature:		Effective Date:	Jan-2022
Date:	26-Jan-2022	Review Date:	Jan-2025

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.

Data collected during the course of the study must be retained for an appropriate retention period in line with current legislation. The Sponsor may specify greater periods of record retention as described within the study protocol or contract, or if required by other applicable regulatory requirements. The study retention period will commence from the date of all close out activities being completed, and the final report being provided to regulatory bodies.

It is the responsibility of the sponsor to inform the site of the archive period and to inform sites when archived documents may be destroyed.

2. Purpose

The purpose of this SOP is to define the local procedure for destroying research data at the end of the archiving retention period, to ensure that University Hospitals Plymouth NHS Trust (UHP) Research & Development (R&D) department meets the best current practice.

3. Scope

This policy covers all the research data that UHP holds to undertake its archiving requirements. This includes electronic documentation, paper documentation and any supporting media. The integrity of the archive and ultimately its destruction rests with the Named Research Archivist and Deputy Research Archivist. This policy defines the processes and enables the senior research managers to allocate adequate resource to support the Archivists to manage the processes.

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, where appropriate, 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 Research Archivist is the R&D Research Governance Manager, and the Deputy Research 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.

The Archivist and Deputy Archivist are responsible for ensuring that systems are in place for tracking, retrieval and disposal of archived documents as well as ensuring that regulatory requirements for archiving are met. The Archivists will ensure compliance of external archiving facility by periodic assessment and inspection of the facility and its processes. Access to the archive facility and the e-archiving drive is restricted to the nominated research archivists as stated above.

The storage address of the physical archive is

PLYMOUTH HOSPITALS NHS TRUST
Central Records Library
4 Bush Park
PLYMOUTH
PL6 7RG

This is a closed site with swipe card access only to the compound and building, access is reviewed every six months. Visitors must use an intercom to gain access.

5. Documents needed for this SOP

- Destruction Certificate which is included in the Appendices

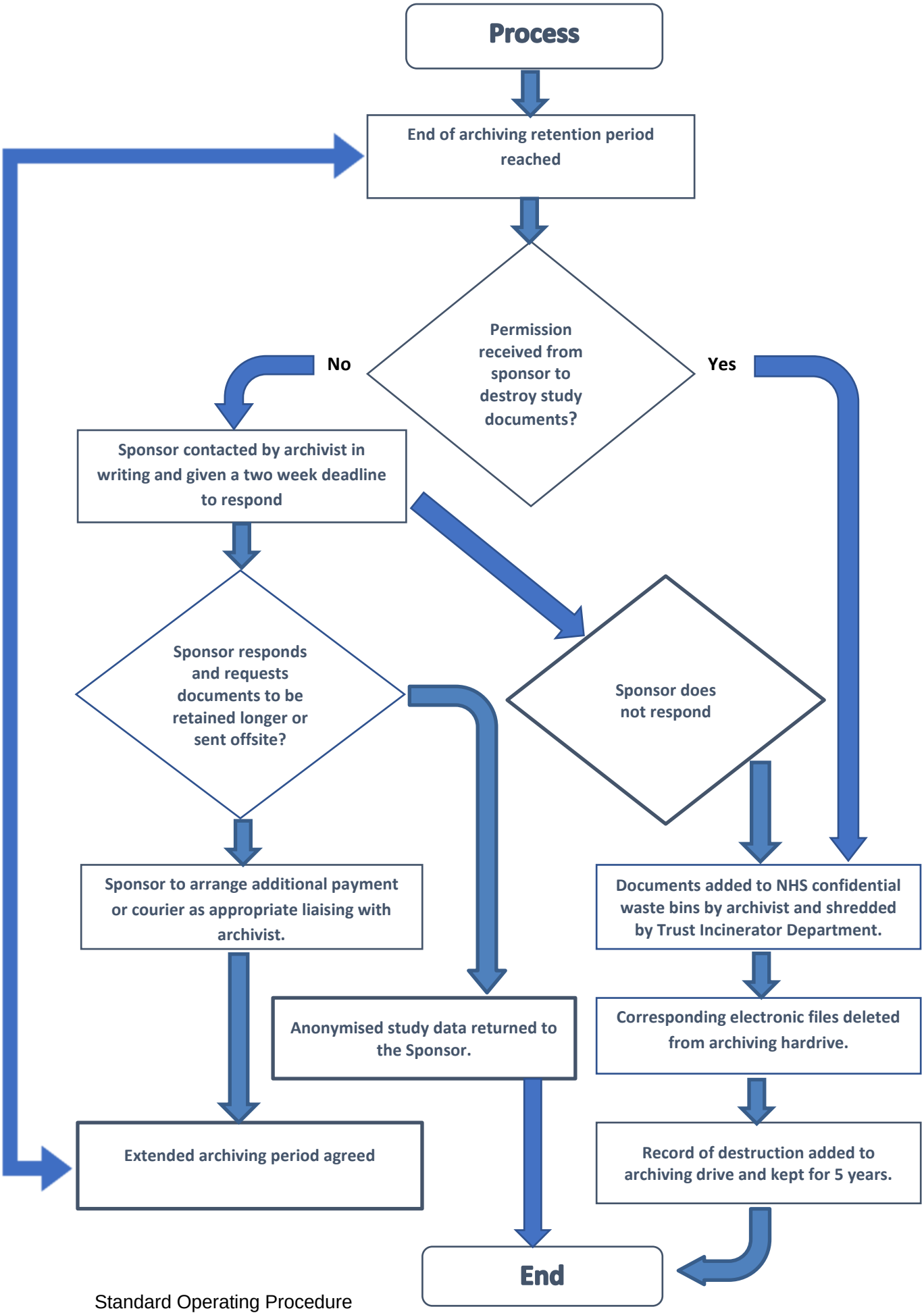
6. Related documents

- 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_2020 Study Data (Source Data, Medical notes and CRF) (R&D SOP T10)
- Research Archiving (R&D SOP SC2)
- WI R&D to Bush Park Archiving Process
- User Requirements Specification G:\ARCHIVING drive e-Archive
- Validation report for e-archive
- e-archiving risk assessment

7. Definitions

CI:	Chief Investigator
CTIMP:	Clinical Trial of an Investigational Medicinal Product
Deputy Research Archivist:	Appropriately trained individual which supports and covers the Named Archivist
End of Retention Period:	Defined as the date of the End of archive period as confirmed by sponsor at study set-up
GCP:	Good Clinical Practice
Named Research Archivist:	The person responsible for ensuring archiving requirements are met as defined and required in the Regulations.
PI:	Principal Investigator
R&D	Research and Development
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
Sponsor:	The sponsor is the individual, company, institution or organisation that takes on legal responsibility for the initiation, management and/or financing of the research
SOP:	Standard Operating Procedure
UHP:	University Hospitals Plymouth NHS Trust

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



9. Procedure

Step	Action	Responsibility
1	Archive retention period is reached. Sponsor notifies R&D department in writing that documents may be destroyed, retained for a longer period or relocated	Sponsor
2	Archive retention period is reached, with absence of sponsor communication. Archivist emails last sponsor contact, copying in CI, requesting permission to destroy documents. Sponsor is given a two week deadline to respond	Deputy Archivist
3	Sponsor replies within 2 weeks stating documents may be destroyed, retained for a longer period or relocated to their archive	Sponsor
4	Sponsor and CI fail to reply to email request within 2 week timeline, the Research Archivist's authorises data to be destroyed but retain evidence of non-response.	Deputy Archivist
5	**a) <u>Documents to be destroyed</u>** All study documents removed from research archive boxes, and put into confidential waste bags. Bags added to NHS confidential waste bins at Bush Park	Deputy Archivist
	Confidential waste shredded to level 4 grade Cross Cut particles, recommended for secret documents, then paper pulped	Incinerator Dept.
	All corresponding electronic files deleted from archiving hardrive.	Deputy Archivist
	Archiving log and EDGE research data management system updated to reflect the changes.	Deputy Archivist
	b) <u>Documents to be retained for a longer period</u> Archive box retention date details updated Archiving log and EDGE research data management system updated to reflect the changes	Deputy Archivist
	c) <u>Documents to be relocated offsite</u> Identifiable information to be redacted Boxes to be sent to be used for offsite archive, and courier to be arranged	Deputy Archivist
	Any core essential documents that are electronically stored to be printed off and added to the archiving box, or electronically transferred to sponsor as per sponsor's preference	Deputy Archivist
	Documents to be re-boxed and sponsor contacted to arrange collection	Deputy Archivist / Sponsor

Step	Action	Responsibility
	Archiving log and EDGE research data management system updated to reflect the changes	Deputy Archivist
6	A record of destruction to be kept in the electronic study file on the designated research archiving drive, and disseminated to Sponsor upon sponsor's request	Deputy Archivist

10. Changes from last revision

None.

Appendix 1: Certificate of Destruction

Certificate of Destruction

All data held at University Hospitals Plymouth NHS Trust relating to the research study described below was destroyed in accordance to the Research Archive Details and Destruction SOP (SC3)

Study Title:	
Chief Investigator:	
Principal Investigator	
Sponsor:	
IRAS number:	
Study R&D Reference number:	
Date data transferred into locked confidential waste bins for destruction by incinerator department:	
Date of deletion of electronic files:	
Records destroyed by:	
Notes:	
Nominated Trust Research Archivist's signature or Deputy:	

A copy of this record will be retained on the R&D designated research Archiving drive for a minimum of 5 years