WORK INSTRUCTION

WI03 – Archiving
Version 5

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DISCLAIMER

This generic R&D Work Instruction (WI) must be followed unless a study specific SOP/WI exists.

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Full History			
Version	**Date**	**Author**	**Reason**
1.0	04 March 2011	Research Management & Governance Manager	Detailed instructions for process as referred to in accompanying SOP.
1.1	15 April 2014	Research Management & Governance Manager	Minor changes to format and appendices
1.2	30 September 2014	Research Management & Governance Manager	Amended Appendix 6 - the Investigator Study Archive Form Checklist
1.3	09 June 2015	Research Management & Governance Manager	Further update of Appendix 6
2.0	June 2019	Quality Assurance Coordinator	Transfer into new template. Process reviewed.
3	September 2020	Quality Assurance Coordinator	More detailed guidance on destruction of electronic archiving added to Section 6
4	May 2021	Quality Assurance Coordinator	Additions to Section 6.2 with specific instructions on Consent Forms.
5	11 January 2023	Quality Assurance Coordinator	Updated with new Trust logo/referencing. Added delegation log to PI Checklist.

Associated Trust Policies/ Procedural documents:	RD&E Records Management Policy R&D SOP S03 Archiving
Key Words:	Archiving Retention Destruction
In consultation with: QA Administration Team (July 2018) QA Group (June 2019) QA Group (September 2020) QA Group (May 2021) QA Group (November 2022)	

Contents

1 INTRODUCTION

Retention of the documents within the Trial Master Files/Investigator Site File and the medical records of trial subjects is a legal requirement (The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 (legislation.gov.uk)). Study documentation ('essential documents') should be prepared for archiving in a manner so that they remain readily available to the licensing authority on request as well as complete and legible for the retention period.

2. PURPOSE

This Work Instruction is designed to accompany the Standard Operating Procedure on Archiving (S03) and provide detailed steps of the process with regard to all types of study, whether CTIMP, non-CTIMP, sponsored or hosted.

3. SCOPE

This Work Instruction should be followed by all those associated with the task of archiving clinical trial paperwork at the Royal Devon University Healthcare NHS Foundation Trust (the Trust), be they Trust or University employees.

4. DEFINITIONS & ABBREVIATIONS

CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
EDGE	Online Clinical Research Management System
GCP	Good Clinical Practice
GOG	R&D Governance Oversight Group
HRA	Health Research Authority
ISF	Investigator Site File
MHRA	Medicines and Healthcare products Regulatory Agency
PI	Principal Investigator
R&D	Research & Development
RD&E	Royal Devon and Exeter Hospital
REC	Research Ethics Committee
Royal Devon	Royal Devon University Healthcare NHS Foundation Trust
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

The Chief or Principal Investigator (CI/PI) and their study teams should be responsible for the initial preparation of essential documentation for archiving, up until the point where Research & Development's Named Archivist's team takes over to complete the process. See section 6 for details.

6. PROCEDURES

6.1 Determining the End of Study

A Study is usually deemed complete following close-down by the Sponsor.

The actual date of end of study is best determined from the End of Study Notification to Ethics form by the Chief Investigator. However, it might be when the last patient entered onto the study has had their last study visit and it should also be shown on EDGE.

6.2 Preparing Documents for Archiving

6.2.1 All essential documents for hosted or sponsored studies (which are to be archived by the Trust) should be prepared for archiving as described below. Essential documents include the Trial Master File (TMF) Investigator Site File (ISF), completed case report forms (CRFs), pharmacy files, laboratory records and source data. For more detailed guidance see ICH GCP E6 (section 8).

6.2.2 It is the responsibility of the CI/PI or delegated study team to complete the Archiving Checklist (see Appendix 5) before submitting paperwork for archiving to the Quality Assurance Team (RD&E) . In the event where there is a lack of capacity to carry this out, please contact the QA Team (RD&E) for assistance. All documents listed in the checklist should be archived, unless they are duplicates.

Either the CI/PI/delegated study team or the Named Archivist's assistant (on request) may then continue with the process as follows:

6.2.3
- Remove documentation from lever arch file(s);
- Remove plastic wallets, dividers, paper/bulldog clips, staples and duplicate documents;
- Only relevant correspondence that is necessary for reconstruction of key activities and decisions or that contains other significant information should be retained e.g. an email trail where the medical monitor allows an ineligible subject to remain in the trial. Irrelevant correspondence should be removed e.g. email correspondence between investigator site staff and the trial monitor discussing holidays or suitable hotels to stay in near the site;
- Where possible, fully identifiable subject information should either be removed or anonymised;
- Original signed Consent Forms should be included as part of the archived ISF/TMF and **should not be anonymised**.
- All Case Report Forms (CRFs) should be removed from their binder, if applicable. Ensure every page of the CRF is identifiable by subject number when removing staples or binders. Documents relating to participant visits should be bound in chronological order. These can then be filed looseleaf into the Archive box, or within individually labelled envelopes. One unused copy of the latest version of the CRF should also be retained if possible;
- If medical notes are being used in the Trial then Source Data documents that form part of the current set (such as ECGs, test results etc) should remain with the medical records and a note detailing the location of these source data documents included in the archived documents.Duplicate copies of Source Data documents should not be archived with essential documents. The above will apply to all Clinical Trials of an Investigational Medicinal Product (CTIMPs) and some non-CTIMPs;

- Any Documentation on thermal paper or prone to fading (e.g. ECG printouts, faxes) must be photocopied onto standard paper before archiving and signed and dated by the PI or delegated individual as being a true copy of the original. The original must also be retained.
- 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. For example copy GP letters, any spreadsheets created for tracking visits or storing participant contacts and copies of any documentation which will form part of the paper archive should all be deleted.
- Original copies of pharmacy prescriptions are to be included as part of the archived pharmacy file. Duplicate copies should not be archived with site file essential documents and should be destroyed at the time of archiving;
- Pack the Trial Master File/Investigator Site File in full together with CRFs, pharmacy file and R&D file (where applicable) in the standard archiving boxes with lids (obtainable from R&D).
- CD's (compact Disks) only last for five years and so contents should be checked against the printed contents in the site file and then check with the sponsor if the CD can be destroyed.

The R&D Named Archivist's designee will then:

6.2.

Prepare Archive Labels (see Appendix 1) and send for signature by the CI/PI (or designee) of the trial. Labels do not need to be over-detailed, but provide easy reference to their contents in case retrieval of a specific box is necessary in future. A copy of the signed label should be placed in each box, and another copy kept in R&D;

- Place a copy of the Archive label on the outside of each box. A copy of the label will also be placed within the box in case the outer label fades over time. The outer label should be secured to the box in a waterproof plastic sleeve;
- Seal the archive box with tape and affix a security label over the tape, ensuring that any unauthorised attempt to open the box will be evident;
- Arrange collection with the external storage company using their online portal, 'Bridge'. Their contact details are: Oasis Group, The Old Quarry, Caton Cross, Ashburton TQ13 7LH Tel: 01626 821618;
- Update the R&D archiving database with details of:
  - The archive box reference number (e.g. box ref 140125-1)
  - Sponsor details
  - The security seal number
  - Confirmation of PI/Sponsor notification
  - Confirmation of notification to finance (if applicable)
  - The date of archiving
  - The expected end date of archiving
- Write to the PI (copy to Sponsor)
- Notify Finance team (if applicable)
- Once the essential documents have been archived EDGE should be updated (status and archiving attribute).

6.3 Retention Period

Refer to the SOP S03 Archiving section 6.5 for details.

6.4 Archiving Destruction

Refer to the SOP S03 Archiving section 6.9 for details of the process to be followed. At the point of destruction of the paper archiving, all electronic study records should also be permanently deleted. The EDGE study record will remain but all personal identifiers should be removed. See Appendix 4 for the template Destruction Certificate to be completed when facilitating archiving destruction on site. Any external company completing archiving destruction at our request (e.g. Oasis or the study Sponsor) should be asked to provide a certificate of destruction to be stored with our records.

6.5 Retrieving Documents from Storage

Refer to Appendix 3 for the process to follow when retrieving archived paperwork from storage.

7. DISSEMINATION AND TRAINING

7.1 This WI 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 WI should ensure that they take time to read and understand the content of this WI.

8. MONITORING COMPLIANCE AND EFFECTIVENESS OF THIS WI

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

No	Minimum Requirements	Evidenced by
1.	Determining the correct end of study date.	End of study document from the Sponsor, EDGE and/or Sponsor correspondence.
2.	The preparation of documentation for archiving is completed using a standardised checklist. Archive labels present and completed correctly.	A copy of the checklist and archive box label is stored in the archiving folder which is located in the office of the Quality Assurance Coordinator.
3.	Retention period – Documents are archived in line with the Trust Policy or in agreement with the Sponsor.	View of the study electronic records saved on the R&D shared drive, R&D study folder and/or EDGE.

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 RDE Research website

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

RD&E Records Management Policy
R&D SOP S03 Archiving
ICH GCP E6

APPENDIX 1

CLINICAL TRIAL ARCHIVE LABEL

R&D Number		**DESTRUCTION DATE**
Study Title		
Study Closed Date		

Investigator Details		**Sponsor Details**	
Name		**Name**	
Address		**Address**	
Tel. No.		**Tel. No.**	
Email		**Email**	

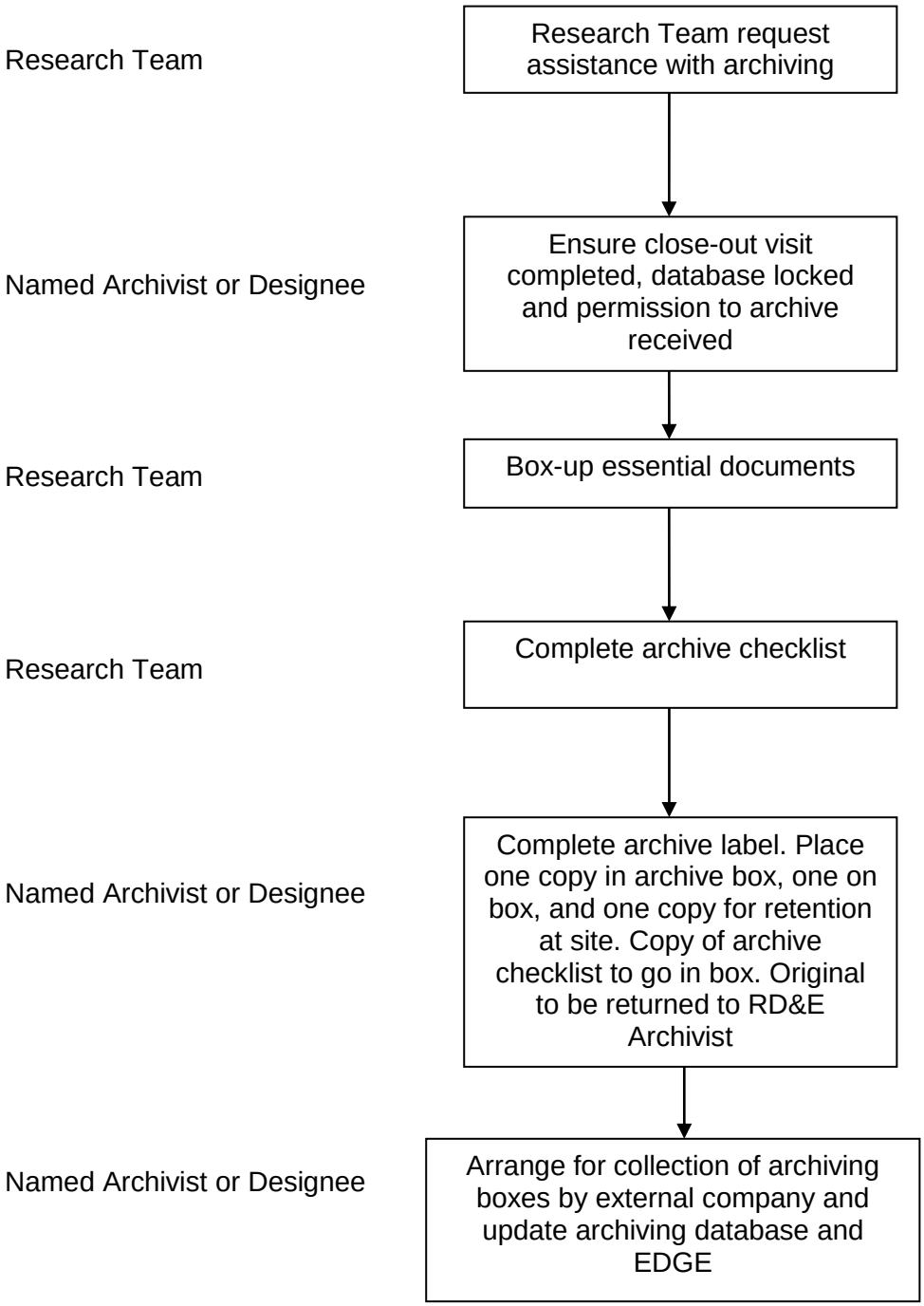
Box Contents	**Box**		**of**	

CI/PI Authorisation *To confirm authorisation to archive the above trial documentation*		**Person who archived** *To confirm the archiving has been prepared as per SOP S03 and WI WI03*	
Name		**Name**	
Signature		**Signature**	
Date		**Date**	

R&D Confirmation of Receipt of Archiving			
Name		**Date**	
Signature		**Total number of boxes**	

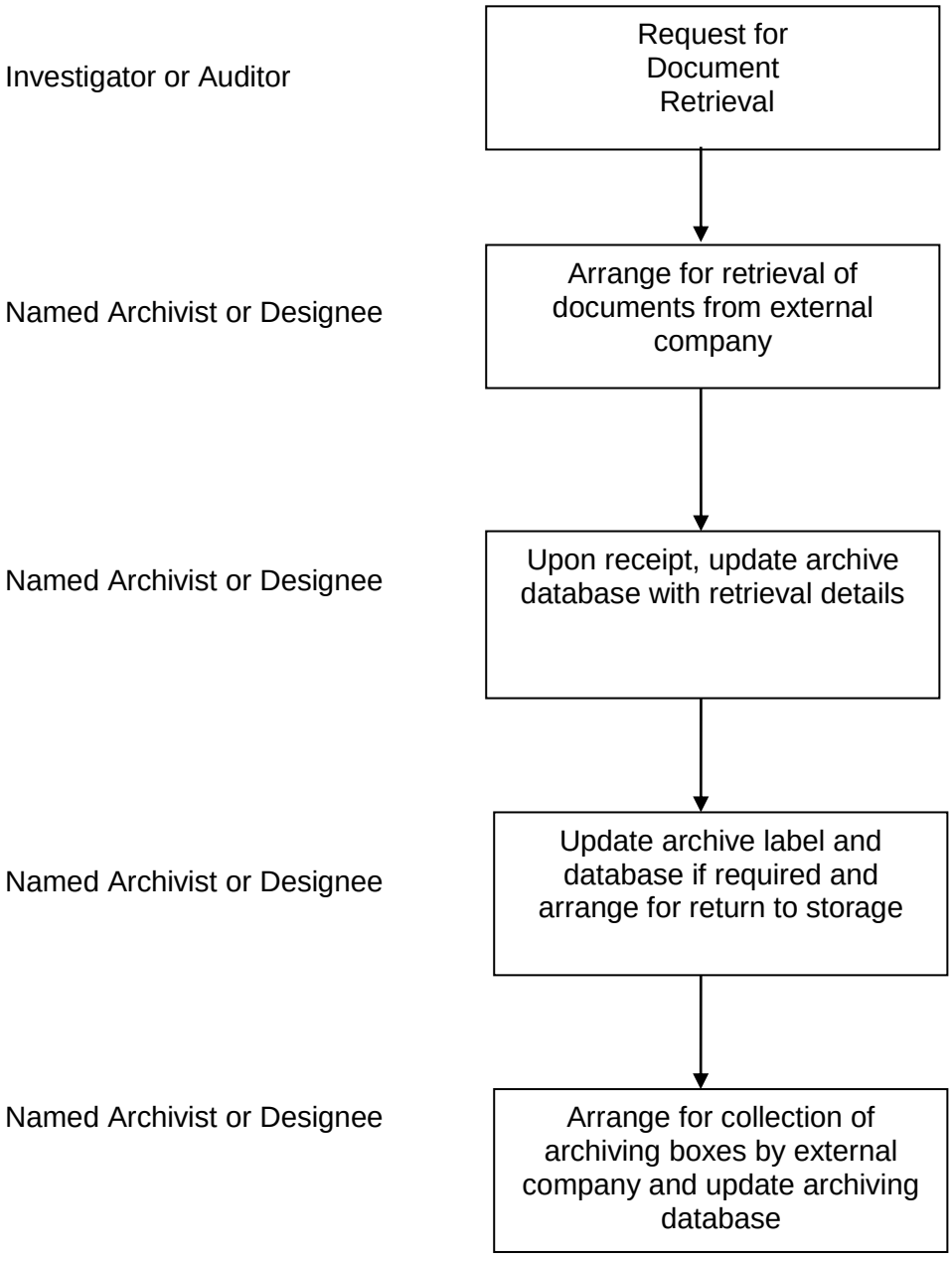
APPENDIX 2

Archiving Process Map



APPENDIX 3

Document Retrieval Process Map



APPENDIX 4

CTIMP CERTIFICATE OF DESTRUCTION The information described below was destroyed in the normal course of business pursuant to the organizational retention schedule and destruction policies and procedures.

Organisation:	Organisation Contact:
Date of Destruction:	Authorized By:
Description of Information Disposed Of/Destroyed:	
Long name of trial:	
Description of Documents relating to trial destroyed:	

METHOD OF DESTRUCTION:

- ❑ Overwriting
- ❑ Pulping
- ❑ Pulverizing
- ❑ Reformatting
- ❑ Shredding
- ❑ Other: _____

Records Destroyed By*:
If On Site, Witnessed By:
Department Manager:
* this certificate should be stored with the original archive label which has the words “destroyed” along with the destruction date written or stamped across it for 5 years after the date of destruction.

APPENDIX 5 INVESTIGATOR STUDY ARCHIVE FORM

Please complete this form, give the original to the clinical trial archivist and enter this study onto your archive log

SHORT TITLE	CI/PI NAME			R&D NUMBER.
INCLUDED FOR ARCHIVING		**Y**	**N**	
(Tick one box on each line)				**COMMENTS**
REGULATORY				
Investigator Brochure		☐	☐	
Summary of product characteristics		☐	☐	
All versions of the signed protocol and amendments		☐	☐	
Case report forms (CRFs) , please state how many are being archived in the comments sect.		☐	☐	No. archived:
Insurance Statement (RD&E Sponsored trials only)		☐	☐	
All appropriate Ethics Committee(s) documentation		☐	☐	
General communications with sponsor		☐	☐	
Site specific communications with sponsor (letters, Site selection/ initiation meeting notes, notes of telephone calls)		☐	☐	
All appropriate Regulatory Authority authorisation/approvals documentation		☐	☐	
Sample Patient Information Sheets, Consent Form on site headed paper (all versions)		☐	☐	
Delegation Log		☐	☐	
CVs of Investigators and Sub-Investigators, including CVs which were superseded during the trial period		☐	☐	
GCP certificates of Investigators and Sub-Investigators, including certificates which were superseded during the trial period		☐	☐	
Training log/s, if applicable		☐	☐	
IMP				
Pharmacy File (Obtain from Clinical Trials Pharmacy Manager)		☐	☐	
Signature of Clinical Trials Pharmacy Manager :				
Subject screening and enrolment log, and identification code list/randomisation log if appropriate		☐	☐	
CLINICAL				
Signed informed consent forms		☐	☐	No. archived:
SAE notifications, and safety information		☐	☐	
Source documents (if appropriate)		☐	☐	
Signed Registration and Randomisation Confirmations or IVRS		☐	☐	
Medical/laboratory/ technical procedure(s) and/or test results		☐	☐	
Record of tissue samples released *(Copies of correspondence with pathology departments regarding the retrieval of tissue)*		☐	☐	
Fridge/ Freezer temperature Logs		☐	☐	
Confirmation of shipping/disposal of all study related samples		☐	☐	
MONITORING				
Monitoring log and reports		☐	☐	
R&D/Sponsor File if appropriate (ask archivist)		☐	☐	
Supplementary Information		☐	☐	
ADDITIONAL DOCUMENTS:				
I confirm that the above documents have been submitted for archiving and electronic records have been reviewed and deleted as necessary *e.g. copy GP letters, logs containing patient identifiers.				
Name:	**Signature:**		**Date:**	
Print Name & job title:				