



# WORK INSTRUCTION

## WI03 - Archiving

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

**Once printed this is an uncontrolled document**

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.

<b>Associated Trust Policies/ Procedural documents:</b>	<a href="#">RD&amp;E Records Management Policy</a> <a href="#">R&amp;D SOP S03 Archiving</a>
<b>Key Words:</b>	Archiving Retention Destruction
<b>In consultation with:</b> QA Administration Team (July 2018) QA Group (June 2019)	

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**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 (Regulation 31A (1) of SI 2004/1031). 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 & Exeter NHS Foundation Trust, be they Trust or University employees.

**4. DEFINITIONS**

CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
GCP	Good Clinical Practice
HRA	Health Research Authority
MHRA	Medicines and Healthcare products Regulatory Agency
ISF	Investigator Site File
PI	Principal Investigator
R&D	Research & Development
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**

The Chief or Principal Investigator and their 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.

## Research and Development

- 6.2.2 It is the responsibility of the study team to complete the Archiving Checklist before submitting paperwork for archiving to the Research & Development Department. In the event where there is a lack of capacity to carry this out, please contact the QA Coordinator in R&D on 01392 403056 for assistance. All documents listed in the checklist should be archived, unless they are duplicates.
- 6.2.3 Either the study team or the named Archivist's assistant (on request) may then continue with the process as follows:
- Remove documentation from lever arch file(s);
  - Remove plastic wallets, dividers, paper/bulldog clips 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;
  - All Case Report Forms (CRFs) should be removed from their binder, if applicable. 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. ECG printed results should be photocopied and the copy retained with the original in the medical notes (this is because original ECG results fade quickly). 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;
  - 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.
  - 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 and CRFs in the standard archiving boxes with lids (obtainable from R&D).
- 6.2.4 The R&D Named Archivist's designee will then:
- Prepare Archive Labels 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, details should be entered on to the Archiving Attribute section of EDGE.

**6.3 Retention Period**

Refer to the SOP S03 Archiving section 6.5 for details.

**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 J drive, R&D study folder and/or EDGE.

**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](#)

APPENDIX 1

CLINICAL TRIAL ARCHIVE LABEL

<b>R&amp;D Number</b>		<u><b>DESTRUCTION DATE</b></u>
<b>Study Title</b>		
<b>Study Closed Date</b>		

Investigator Details		Sponsor Details	
<b>Name</b>		<b>Name</b>	
<b>Address</b>		<b>Address</b>	
<b>Tel. No.</b>		<b>Tel. No.</b>	
<b>Email</b>		<b>Email</b>	

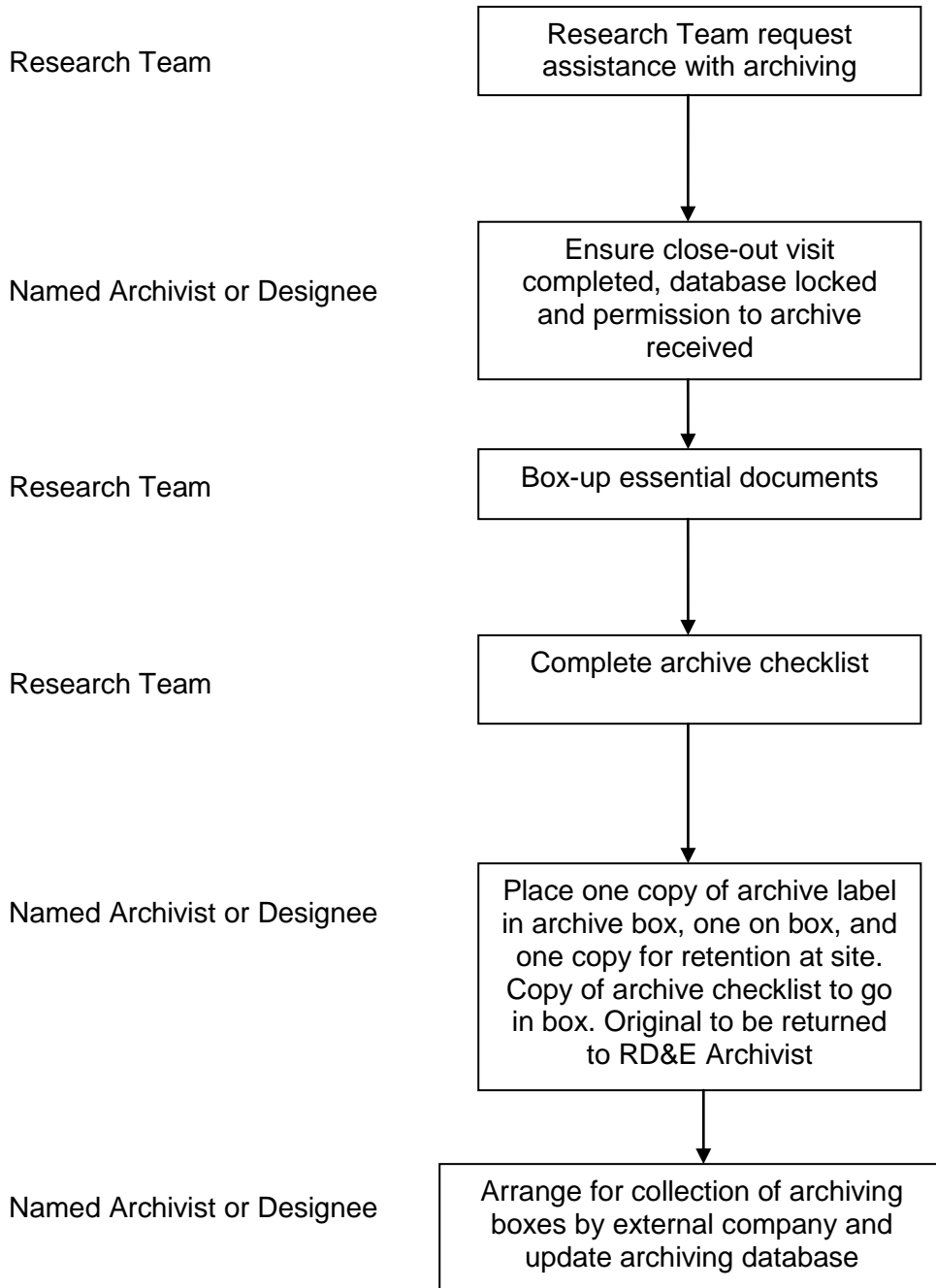
<b>Box Contents</b>	<b>Box</b>		<b>of</b>	

<b>CI/PI Authorisation</b> <i>To confirm authorisation to archive the above trial documentation</i>		<b>Person who archived</b> <i>To confirm the archiving has been prepared as per SOP S03 and WI W103</i>	
<b>Name</b>		<b>Name</b>	
<b>Signature</b>		<b>Signature</b>	
<b>Date</b>		<b>Date</b>	

R&D Confirmation of Receipt of Archiving			
<b>Name</b>		<b>Date</b>	
<b>Signature</b>		<b>Total number of boxes</b>	

**APPENDIX 3**

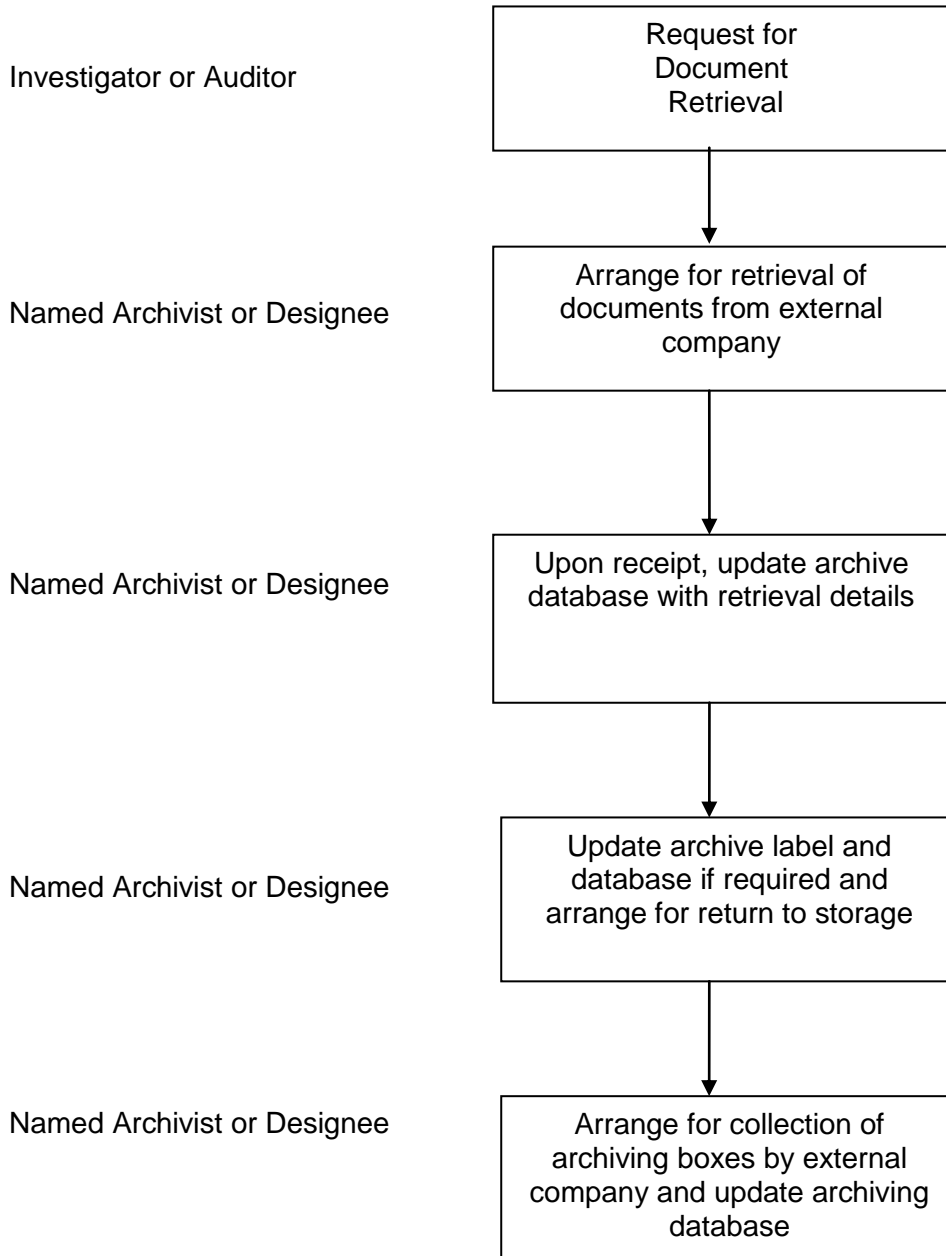
**Archiving Process Map**





APPENDIX 4

### Document Retrieval Process Map



**APPENDIX 5**

<b>CTIMP CERTIFICATE OF DESTRUCTION</b>	
The information described below was destroyed in the normal course of business pursuant to the organizational retention schedule and destruction policies and procedures.	
Organization:	Organization Contact:
Date of Destruction:	Authorized By:
Description of Information Disposed Of/Destroyed:	
Long name of trial:	
Description of Documents relating to trial destroyed:	
<b>METHOD OF DESTRUCTION:</b> <ul style="list-style-type: none"> <li><input type="checkbox"/> Overwriting</li> <li><input type="checkbox"/> Pulping</li> <li><input type="checkbox"/> Pulverizing</li> <li><input type="checkbox"/> Reformatting</li> <li><input type="checkbox"/> Shredding</li> <li><input type="checkbox"/> Other: _____</li> </ul>	
Records Destroyed By*:	
If On Site, Witnessed By:	
Department Manager:	
<p>* 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.</p>	

**APPENDIX 6 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.
<b>INCLUDED FOR ARCHIVING</b>		Y	N	
<b>(Tick one box on each line)</b>				<b>COMMENTS</b>
<b>REGULATORY</b>				
Investigator Brochure		<input type="checkbox"/>	<input type="checkbox"/>	
Summary of product characteristics		<input type="checkbox"/>	<input type="checkbox"/>	
All versions of the signed protocol and amendments		<input type="checkbox"/>	<input type="checkbox"/>	
Case report forms (CRFs) , please state how many are being archived in the comments sect.		<input type="checkbox"/>	<input type="checkbox"/>	No. archived:
Insurance Statement (RD&E Sponsored trials only)		<input type="checkbox"/>	<input type="checkbox"/>	
All appropriate Ethics Committee(s) documentation		<input type="checkbox"/>	<input type="checkbox"/>	
General communications with sponsor		<input type="checkbox"/>	<input type="checkbox"/>	
Site specific communications with sponsor (letters, Site selection/ initiation meeting notes, notes of telephone calls)		<input type="checkbox"/>	<input type="checkbox"/>	
All appropriate Regulatory Authority authorisation/approvals documentation		<input type="checkbox"/>	<input type="checkbox"/>	
Sample Patient Information Sheets, Consent Form on site headed paper (all versions)		<input type="checkbox"/>	<input type="checkbox"/>	
CVs of Investigators and Sub-Investigators, including CVs which were superseded during the trial period		<input type="checkbox"/>	<input type="checkbox"/>	
GCP certificates of Investigators and Sub-Investigators, including certificates which were superseded during the trial period		<input type="checkbox"/>	<input type="checkbox"/>	
Training log/s, if applicable		<input type="checkbox"/>	<input type="checkbox"/>	
<b>IMP</b>				
Pharmacy File (Obtain from Clinical Trials Pharmacy Manager)		<input type="checkbox"/>	<input type="checkbox"/>	
Signature of Clinical Trials Pharmacy Manager :				
Signature sheets and Delegation logs		<input type="checkbox"/>	<input type="checkbox"/>	
Subject screening and enrolment log, and identification code list/randomisation log if appropriate		<input type="checkbox"/>	<input type="checkbox"/>	
<b>CLINICAL</b>				
Signed informed consent forms		<input type="checkbox"/>	<input type="checkbox"/>	
SAE notifications, and safety information		<input type="checkbox"/>	<input type="checkbox"/>	
Source documents (if appropriate)		<input type="checkbox"/>	<input type="checkbox"/>	
Signed Registration and Randomisation Confirmations or IVRS		<input type="checkbox"/>	<input type="checkbox"/>	
Medical/laboratory/ technical procedure(s) and/or test results		<input type="checkbox"/>	<input type="checkbox"/>	
Record of tissue samples released <i>(Copies of correspondence with pathology departments regarding the retrieval of tissue)</i>		<input type="checkbox"/>	<input type="checkbox"/>	
Fridge/ Freezer temperature Logs		<input type="checkbox"/>	<input type="checkbox"/>	
Confirmation of shipping/disposal of all study related samples		<input type="checkbox"/>	<input type="checkbox"/>	
<b>MONITORING</b>				
Monitoring log and reports		<input type="checkbox"/>	<input type="checkbox"/>	
R&D/Sponsor File if appropriate (ask archivist)		<input type="checkbox"/>	<input type="checkbox"/>	
Supplementary Information		<input type="checkbox"/>	<input type="checkbox"/>	
<b>ADDITIONAL DOCUMENTS:</b>				
<b>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.</b>				
<b>Name:</b>	<b>Signature:</b>	<b>Date:</b>		
<b>Print Name &amp; job title:</b>				