York and Scarborough Teaching Hospitals NHS Foundation Trust R&D Unit
SOP
R&D/S52

R&D Unit procedure for archiving clinical research documents – Role of the Named Archivist

IT IS THE RESPONSIBILITY OF <u>ALL</u> USERS OF THIS SOP TO ENSURE THAT THE CORRECT VERSION IS BEING USED

All staff should regularly check the R&D Unit's website and/or Q-Pulse for information relating to the implementation of new or revised versions. Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.

The definitive versions of all R&D Unit SOPs appear online. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the R&D Unit website: www.research.yorkhospitals.nhs.uk/sops-and-guidance-/and/or Q-Pulse

SOP Reference:	R&D/S52
Version Number:	3.0
Author:	Jonathan Hawker
Implementation date of current version:	10th October 2023

Approved by:	Name/Position:	Monica Haritakis, Research QA Manager
	Date:	11th September 2023
	Name/Position:	Sarah Sheath, SOP Controller
	Date:	11th September 2023

This SOP will normally be reviewed at least every 3 years unless changes to the legislation require otherwise

Version History Log

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

Version	Date Implemented	Reviewers	Details of significant changes
1.0	4th April 2019		
2.0	7th December 2022		Details referring to Document Destruction Certificate removed
2.2	10th October 2023	Jonathan Hawker	Updated process with the changes recently made by the QA Team. Added section regarding archiving process on EDGE and electronic study files

Contents

1 Introduction, Background and Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe the procedure for the archiving of all study documents relating to research studies that are sponsored by, co-sponsored by or hosted by the Trust

To ensure 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 to ensure:
- Patient safety in using and recording information
- Up to date information is stored
- Protection of sensitive data
- Staff awareness of responsibilities and accountability
- Information is accessible when required

For CTIMPs the storage of personal data is subject to applicable elements of The UK Clinical Trial Regulations. For all study types the applicable elements of the Data Protection Act 2018 apply.

Study documents (known as 'essential documents' for CTIMPs) must be kept so that the data are accessible after a study 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.

The overall archiving arrangements for any study are the responsibility of that study's Sponsor (which may be delegated to the Chief or Principal Investigator). It is the Sponsor's responsibility to ensure that any such delegation is clearly documented.

For hosted CTIMPs the local essential document archiving arrangements described in this SOP must be followed to ensure compliance with GCP. If a Sponsor's procedure for such archiving conflicts with a procedure set out in this SOP then this SOP should take precedence.

2 Who Should Use This SOP

This SOP is aimed at the following people:

Named Archivist appointed by the R&D Unit & other Authorised Archiving Personnel

3 When this SOP Should be Used

When documents/data or media items are required to go into storage either on a temporary or permanent basis.

4   Procedure(s)

Role of the Named Archivist

It is a legal requirement that as a clinical trial Sponsor the York and Scarborough Teaching Hospitals NHS Foundation Trust appoints a named individual within the organisation to be responsible for archiving clinical trial documents and that access to these documents is restricted to this appointed individual.

For this reason, York Trust has an appointed Named Archivist overseeing the process of archiving of all clinical research documents: including studies that are sponsored by, co-sponsored by or hosted by the Trust, as well as other R&D Unit documentation that requires to be retained for longer periods of time.

Authorised access level were agreed & confirmed in writing with the archive facility service provider.

The main responsibilities of the appointed Named Archivist are:

- Check and assess each box presented to R&D as ready for archiving. These checks include:

*are all documents are packed and presented to R&D as specified in R&D SOP/S11
 *records are not dangerous to people or property when stored under normal conditions; no noxious, hazardous, dangerous, toxic, radioactive, narcotic, highly inflammable or contaminating substances are included in the records submitted for storage and that the records do not include vermin, insects or any material which is illegal, dangerous or unsafe to handle or store in an enclosed area;
*Boxing items/ boxes are not damaged/torn; boxes are able to support its own weight; Lid aren't missing or torn

- Confirm with the research staff responsible for the boxes presented for archiving if these contain any items that may require special conditions or electronic media & notify the archiving facility in writing in advance of any special precautions that are required in relation to any particular records due to the nature, weight or condition or any statutory duties specific to the records with which the service provider will have to comply with.

- Maintain up to date, complete & accurate inventory tracking system with clear traceability of all archived boxes & content (see section 4.. for details)

- Process & co-ordinate request from authorised staff for box storage/box retrieval (permanent & temporary)/box destruction with traceable and complete record of all requests (see section 4… for details)

- Perform regular checks for passed 'retention dates' to ensure timely & efficient destruction of old study documents (see section 4… for details)

- Communicate with the archive facility service provider & ensure that any required changes are agreed with Head of R&D, are within the contractual agreement and are communicated to research staff in timely manner.

- Ensure that R&D procedures for archiving research documents are kept up to date & documented in R&D SOPs and available on the R&D website & Q-Pulse

- Provide support with staff training in relation to archiving procedures as required

- Receives invoices form the services provider and arranges for payments

- Complete the electronic archiving process by moving any electronic study files to the secure folder

- Keep EDGE up to date when studies are archived. Update the Archiving Boxes project page on EDGE.

In the absence of the Named Archivist, the Head of R&D will be responsible for delegating and authorising the archiving duties to appropriate staff members.

To contact the Named Archivist an e-mail should be sent to yhs-tr.research.governance@nhs.net with the subject "FAO Named Archivist". This email is checked every working day to ensure any urgent retrieval requests can be processed efficiently.

The R&D Unit will periodically audit the archiving facility to ensure that it meets the requirements of being secure, with appropriate environmental controls and adequate protection from fire, flood and unauthorised access. The frequency of such audits will be no more than 24 months apart.

4.1 Boxes to go for Archiving

All boxes need to be logged on a spreadsheet before being sent to storage. This can be found in **X:\Research & Development\Research Governance - new folder\Archiving\Admin for Archiving**.

Arrangements should have been made prior to this with regards to the receipt of the boxes in R&D:

- Notifications from Research Teams regarding trial closure & copy of the End of trial Report/Checklist should be provided to R&D;

- End of study report/ Checklist should be scanned to EDGE as a documented confirmation of the documents that are presented as complete and ready for archiving;

- Confirmed retention date received from the research staff responsible for archiving the box content

- Confirmed the study sponsors' contact details & Research nurse/PI contact details for future queries

- Confirmed if any electronic media/ any items that may be subject to rapid deterioration or need special requirements in order to be retained, for example: photographs/films/dummy IPM/medical device/packaging are included in the content of the box

- Confirmed that all presented documents were prepared and packed in appropriate archiving boxes as detailed in R&D SOP/S11

- Confirm that the archiving workflow on EDGE has been started and complete the steps assigned to the Named Archivist

Once all of the above arrangements have been satisfied:

1. Open Spreadsheet **R&D Box Inventory combined**

2. On Tab named **Boxes for Archiving**, complete columns A, B, C & D using information on the Archiving label provided. There should be 2 copies, 1 of which remains in the box.

3. Check the contents & condition of the box (if unsure refer to R&D/S11) to ensure suitable for archiving. In columns E & F add details of any electronic media or special precautions if applicable, this should be specified on the label or information should be provided by the person responsible for sending the box for archiving. Once all checked and happy add your name to column G.

If for any reason information is missing or you are not happy with the contents or box, contact the person responsible and ask them to collect the box, provide the missing information or re-box

4. Take the next Box number (R&D….) from column H, write it on both box labels in the space at the top where indicated. Place one label in the box & seal box by using parcel tape and the other label in a plastic wallet & tape to the side of the box. Write the box number on the side of the box in the space marked 'Box Reference'.

5. Take the next Barcode from the sheet provided, place on the side of the box, next to the box reference in the space marked 'Affix Barcode Here' the number then needs to be entered into Column I

6. When box is ready for collection, request on database

7. Column J should state if Archived or Temporary Storage. If only temporary, reasons for this need to be entered.

7. Column K is the date that the box was collected by the archiving company. This will be entered once boxes have gone. Column L requires the date receipt confirmed by Restore (taken from database – see separate internal instructions)

8. Column M contains the Destruction Date, which will be on the box label

9. Column N is to be completed when a box or document has been destroyed.

10. Details of all boxes sent to archiving will then have to be added to the Local (red pages) & Notes section on EDGE. Include Box Ref, Contents, Date sent to archiving & destruction date.

11. The study will then need to be added to the "Archiving Boxes" project page on EDGE. Finally the study workflow will need to be updated. The previous workflow steps will have been completed by the CTA/delivery teams.

The arrangement for collection of the boxes from the Trust & Scarborough Hospital is to be done via the RSWeb – See separate appendix for instructions

4.2 Retrieval of Archived Boxes

Any boxes that require returning back to the York or Scarborough Hospital also need to be logged on the spreadsheet. The studies archiving page on EDGE will also need updating.

1. Open same spreadsheet **R&D Box Inventory combined**

2. On Tab named **Retrieved Boxes,** complete columns A, B, D & E with the information provided by the person requesting the box retrieval. Column C is the barcode that can be obtained from database, Converted Box Inventory (depending on the age of the box) or the tab named Boxes for Archiving on the R&D Box Inventory as of 1.11.18 **NB: information for column B may have to be found by the Archivist by using the Inventory spreadsheet or the List of Boxes Taken By Magnum (same file path) if the person requesting doesn't have this information**

3. Request the box retrieval from Restore via the database & complete column F & G on the spreadsheet. **NB: If this is for Permanent Retrieval, an email will require sending to RESTORE the day after the box/es have been received to request the status to be changed from OUT to PERM OUT on the database (see separate instructions)**

4. Upon receipt of the box in R&D, complete column H, inform the person that requested the retrieval & complete column I when they collect

5. Column J is the date that the box is returned to R&D. Check with the person returning if there has been any alterations to the contents & confirm in column K. Check condition of box & contents before resealing then add your name to column L. **NB: If there are any additional documents in the box or anything has been removed, the labels should be updated by the Team in question before returning back to archiving.**

6. Request collection of box via database & complete columns M & N on the relevant dates.

For boxes that are being retrieved and then returned back to archives, the content should be checked again to ensure all originally archived records are still present/ or if anything else was added

When boxes temporarily pulled out of storage – record of reasons, temporary location, return date and any changes and checks performed must be recorded.

Clear distinction & traceability for temporary retrievals and permanent withdrawals….
It is of high importance that R&D inventory is complete & up to date

--- RSWeb is the external Database held by the archiving company that is used to log all boxes sent for archiving, all retrieved boxes & the ordering of materials such as new boxes & barcodes. See separate appendix for full instructions

4.3 Destruction of Archived Boxes

A destruction date for all boxes should be listed on the aforementioned documents & database for easy monitoring. These should be checked on a regular basis so as to keep records up to date.

1. When a destruction date approaches, contact the relevant team with details of the study. The team should then in turn contact the Sponsor requesting permission to destroy the study documents or a revised destruction date.

2. Upon receipt of confirmation from the team/sponsor contact Restore Records Management with the details & request for destruction. . Restore will then forward a password protected spreadsheet for confirmation that the details are correct. Once confirmed by Archivist, Restore will then arrange for the destruction of the documents, this is has replaced the Destruction Certificate In **X:\Research & Development\Research Governance - new folder\Archiving\Admin for Archiving\Destruction Certificates** & also on EDGE if applicable, file a copy of the email confirmation from the Sponsor/QA Manager by adding a folder with the local reference number & study name if possible.

3. Update column N on the spreadsheet, using the tab named Boxes for Archiving.

4. Update the study page in the "Archiving Boxes" project on EDGE.

To ascertain which boxes have passed their retention date & require Request for Destruction from the Sponsor, each January an audit will be run by the Named Archivist for the previous calendar year. This will be done by using the **R&D Box Inventory combined** & filtering the Destroy Date column

-- Please see RSWeb separate appendix for instructions

5   Related SOPs and Documents

R&D/S11 Archiving of Research Study Documents

R&D/F56 Archive Box Label

RSWeb Portal Instructions

6   Appendix A – Contact Details

Trust Archiving Facilities

Restore Plc
Brittania Way
Glews Hollow
Goole
East Yorkshire
DN14 6ES

Tel: 01045 720600
Fax: 01405 769197

Restore Portal Instructions

To Add Boxes

1. **https://rsweb.restore.co.uk/rswebnet/default.aspx**
2. Log on – User name = 697 – (initials)
3. In the Inventory Box at the left hand side, click Getting Started
4. Under Add Items, Click Container
5. Account Code – Divided into 3 boxes. Box 1 = 697, Box 2 = 00, Box 3 = Leave Blank
6. Open **R&D Box Inventory as of 1.11.18** spreadsheet, information for the next screen will be taken from this.
7. Complete next screen using information from the Inventory Spreadsheet
8. Click Submit (repeat for each item)
9. Click View Grid once all items have been submitted
10. Check grid at bottom of page to ensure all details are correct, Click Options at top of the page once happy with details
11. From the drop down, click Add to Cart then OK
12. Complete details requested, click Add to Cart
13. A Summary will now be shon on the screen to give you another hance to check details. If details need amendeing do so by doubble clicking on the relevant line
14. Once checked & happy, click Order Now
15. Clivk Workorder at bottom right of screen then click OK
16. Complete form (ensure you sleect collection from drop down) & correct address. To authorise enter name but no password is necessary. Click Create Workorder.
A notification will come up letting you know the order has been completed & the 'Cart' will be empty

To Retrieve a Box from RESTORE

1. **https://rsweb.restore.co.uk/rswebnet/default.aspx**
2. Log on – User name = 697 – (initials)
3. In the Order Box at the left hand side, click Getting Started
4. Under Add Items Into Cart, Click By Item
5. Enter Barcode(s) (taken from Inventory spreadsheet)
6. Once all items have been entered, click Next
7. Complete Service Type & Requester details, Click Add to Cart
8. Check details & Click Order Now & Work Order & Click OK
9. Complete Authorisation & Name, No password needed
10. Create Work Order
A notification will come up letting you know the order has been completed & the 'Cart' will be empty

To Return a Retrieved box to RESTORE

1. **https://rsweb.restore.co.uk/rswebnet/default.aspx**
2. Log on – User name = 697 – (initials)
3. In the Order Box at the left hand side, click Getting Started
4. Under Add Items Into Cart, Click By Item
5. Enter Barcode(s) (taken from box or Inventory spreadsheet)
6. Once all items have been entered, click Next
7. Complete Service Type & Requester details, Click Add to Cart
8. Check details & Click Order Now & Work Order & Click OK
9. Complete Authorisation & Name, No password needed

10. Create Work Order
A notification will come up letting you know the order has been completed & the 'Cart' will be empty

To Order Barcodes or Boxes

1. **https://rsweb.restore.co.uk/rswebnet/default.aspx**
2. Log on – User name = 697 – (initials)
3. In the Order Box at the left hand side, click Getting Started
4. Under Add Items into Cart, Click <u>Materials</u>
5. From Drop Down, choose either R14 – Std Box or Barcodes & quantity & complete Requestor Field. Add to Cart
6. View Cart. Click Checkout & then Workorder. Click Ok if correct
7. Check details & complete Authorisation as detailed above
8. Click CreateWorkorder
A notification will come up letting you know the order has been completed & the 'Cart' will be empty