York Foundation Trust R&D Unit
Standard Operating Procedure
R&D/S11

Archiving of Research Study Documents

IT IS THE RESPONSIBILITY OF ALL 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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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

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	Date:	4th April 2019
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	Signature:	Signed copy held by R&D Unit
	Date:	4th April 2019

This SOP will normally be reviewed 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	Details of significant changes
1.0	8th March 2010	
2.0	16th January 2012	• Expanded SOP remit to include all study types rather than just CTIMPs. • Expanded on co-sponsorship arrangements. • Added University of York Archiving Facilities to Appendix 1. • Change of SOP Controller
3.0	24th March 2014	Removal of references to the North and East Yorkshire R&D Alliance.
4.0	2nd May 2017	Two yearly review. No changes required.
5.0	15th August 2017	Removal of NHS Permission references
6.0	2nd May 2019	• Updated Responsible Personnel • Updated Preparing Documents for Archiving • Footnote added to Archiving of Medical records Change of link to R&D website. Change of date for Data Protection Act, from 1998 to 2018.

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 1998 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:

- Chief Investigators (CIs) of research studies sponsored or co-sponsored by the Trust
- Principal Investigators (PIs) of research studies sponsored by an external organisation but running in the Trust (known as 'hosted studies').
- Staff working in research teams on either sponsored or hosted studies (Research Nurses and Clinical Trials Support staff).
- York Foundation Trust R&D Unit staff.

3 When this SOP Should be Used

For studies Sponsored by the Trust this SOP should be referred to during the study design phase and again as soon as practicable, within 12 months of the end of the study.

For all hosted studies this SOP should be referred to during the Confirmation of Capacity and Capability process to ensure that any costs of local archiving have been identified, and as soon as practicable within 12 months of the end of the study.

4 Procedure(s)

4.1 Determining the end of a study

The end of a study should be defined in the study protocol but may be for example, when the last patient entered onto the study has had their last study visit.

For hosted studies a study is deemed to have ended locally following study close down or formal notification from the Sponsor.

4.2 Responsible Personnel

The R&D Unit has appointed a 'Named Archivist' who is responsible for ensuring that all archiving requirements are met as defined in the UK Clinical Trial Regulations and with this SOP. In the absence of the Named Archivist, the Unit Administrator with the approval of the Head of R&D will be responsible for the archiving of trial related documents.

For CTIMPs it is a legal requirement that access to archived essential documents is restricted to authorised personnel only. Any changes in the ownership and location of archived essential documents should be documented in order to allow tracking of the stored records; this SOP extends that requirement to all archived study documents (i.e. all non-CTIMPs).

4.3 Duration

The Sponsor of a research study is responsible for determining the archiving duration of that study's documents, taking into account:

- The type of study (e.g. a CTIMP for regulatory submission)
- Any regulatory requirements at the time that the study is ready for archiving
- Any statements made in the protocol or other submissions.

For CTIMPs only, at the end of a study, a minimum period of six months should be allowed to ensure that all queries are answered and study related paperwork collected. Archiving should take place following this period but within twelve months of the end of a CTIMP.

For all hosted studies (CTIMP or otherwise) archived study documents must be retained for at least 5 years after the end of the study and during that period must be:

- Readily available to a licensing authority on request
- Complete and legible

Retention for 5 years is considered appropriate under circumstances when studies are not to be used in regulatory submissions. However, longer retention may be required if requested by the Sponsor, funder, or regulatory bodies.

If CTIMPs are to be included in regulatory submissions then study-specific (essential) documents should be retained until at least 2 years after the last approval of a marketing application to the EU (where appropriate).

For CTIMPs sponsored or co-sponsored by the Trust it is the responsibility of the CI to determine and to notify the Sponsor (via the Named Archivist) if he/she wishes essential documents to be retained for longer than the originally agreed duration.

For all hosted studies the Named Archivist will contact the Sponsor on the agreed destruction date to obtain written authorisation for destruction or written authorisation to extend the archiving duration.

NOTE: consideration must be given to any changes in legislation or governance requirements that require a change to the archiving duration. This should be at the time of archiving, periodically during document retention, and prior to destruction.

4.4 Planning Storage

Research study documents should be archived in a legible condition and prompt retrieval should be possible when required.

For Trust Sponsored studies plans for archiving of study documents should be made during the design phase of the study and any associated costs should be considered and factored into the study finances.

For hosted studies the archiving arrangements will be considered by the R&D Unit prior to capacity and capability being confirmed.

Adequate and suitable space should be provided for the secure storage of all study documents upon completion of the trial. These facilities should be secure, with appropriate environmental controls and adequate protection from fire, flood and unauthorised access.

The archiving facilities to be used under this SOP are listed in Appendix 1.

For some studies the Sponsor may deem it appropriate to remove documents from site and store centrally (e.g. to a subcontracted commercial archive); this decision resides with the Sponsor. In such situations the research team at site should make copies of the documents listed in Section 4.5.5 which should be archived locally through the Named Archivist along with details of how the removed documents can be recalled if required.

4.5 What to archive

4.5.1 For a CTIMP sponsored by the Trust

- The Trial Master File (TMF) (see R&D/F11) which should include:
    - Local site files
    - Case Report Forms (CRFs)
    - Pharmacy Site File
    - Laboratory File
    - Sponsor File
    - R&D File
    - Any other documents that may be required to show a clear audit trail of a process performed in relation to a CTIMP
    - Any source data documents that are not part of a participant's medical notes.

4.5.2 For a Non-CTIMP sponsored by the Trust

- Local site files
- Case Report Forms (CRFs)
- Sponsor File
- Pharmacy and/or Laboratory File
- R&D File
- Any other documents that may be required to show a clear audit trail of a process performed
- Any source data documents that are not part of a participant's medical notes.

4.5.3 For hosted CTIMPs that are to be archived by the Trust

- Site File(s)
- R&D File
- Trust held copies of CRFs
- Pharmacy Site File
- Laboratory File
- Other Support Department Files (e.g. radiology, labs)
- Source data documents that do not form part of a participant's medical notes.
- Any other documents that may be required to show a clear audit trail of a process performed in relation to a CTIMP which have not been included in participant's medical notes.

4.5.4 For hosted non-CTIMPs that are to be archived by the Trust

- Site File(s)
- R&D File
- Trust held copies of CRFs
- Other Support Department Files (e.g. radiology, labs)
- Source data documents that do not form part of a participant's medical notes.
- Any other documents that may be required to show a clear audit trail of a process performed in relation to the study which have not been included in participant's medical notes.

4.5.5 For hosted studies which are to be archived off-site by the Sponsor

The Sponsor's archiving procedures should be followed. The study Sponsor should provide the Principal Investigator (PI) with details of exactly what is to be archived off-site. The Sponsor may also provide details of what documents are to be archived locally but at a minimum the following should be retained (copies taken where required)

- R&D File
- Consent Forms
- Trust held copies of CRFs

The Sponsor should also provide details of how centrally archived documents can be recalled and the PI is responsible for ensuring that the Named Archivist has a copy of this information. All documents to be archived locally should be archived using this SOP via the Named Archivist.

Following archiving, a PI may receive new correspondence relating to a completed study. Such documents do not need to be added to the already-archived documents and should be retained by the PI in a secure manner.

4.6 Contact the named archivist

For Trust Sponsored studies:

As soon as practicable (not less than six and within 12 months of the end of study), the Chief Investigator should contact the Named Archivist. In the absence of the Named Archivist then the Unit Administrator should be contacted.

For Hosted studies:

If responsibility for archiving documents has been delegated to the Trust then as soon as practicable after the end of the study (and not less than six and within 12 months of the end of a CTIMP), the PI should contact the Named Archivist. In the absence of the Named Archivist then the Unit Administrator should be contacted.

If the Sponsor has accepted responsibility for archiving the site documentation then as soon as practicable, the PI should contact the Sponsor and arrange for off-site archiving to be carried out. For CTIMPs documents should not leave the PI site until after a period of six months has passed following the end of the study. The PI should also contact the Named Archivist to arrange any local archiving of relevant documents.

Any investigator wishing to retrieve study documentation must make this request through the Named Archivist.

If required, the Named Archivist can arrange short term storage of study documents whilst final archiving arrangements are being arranged.

To contact the Named Archivist an e-mail should be sent to research.governance@york.nhs.uk with the subject "FAO Named Archivist".

4.7 Preparing documents for archiving

All documents for hosted or Trust Sponsored studies which are to be archived by the Trust must be presented to the R&D Unit in a state ready for archiving.

a) The Site File(s) should be organised in suitable binders, box files or wallets, all of which should be clearly labelled with the Sponsor's name, Sponsor's ID number, Short study title, the name of the CI (or PI for hosted studies) and a brief summary of the contents.

b) All CRFs should be filed with individual patient packs if applicable. Documents relating to participant visits should be boxed in chronological order. One unused copy of the latest version of the CRF should also be retained if possible.

c) For all studies Source Data Documents that form part of current medical records (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 patient notes (this is because original ECG results fade quickly). Duplicate copies of source data documents should not be archived with study documents.

d) For CTIMPs only 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.

e) Any other necessary documents should be filed in lever arch file(s) which should be clearly labelled.

f) Ensure that all trial related lever arch/box files /CRFs are placed into a suitable archive box (or boxes), which are available from the Named Archivist. Depending on the number of documents to be archived it is permissible to archive more than one study in one Archive Box.

g) Review all documentation to ensure that there is no unnecessary duplication of documentation. It is only necessary to keep one copy of each document. Duplication should be avoided to minimise cost.

h) For each archived study a list should be included detailing what has been included in the archived study documents. (R&D/F56)

Prior to archiving the Named Archivist will label each Archive Box with:

- The R&D Reference Number(s)
- The box number (R&D****) and how many boxes there are (e.g. 1 of 5)
- The name of the Sponsor(s)
- Contact number of the R&D Unit
- The short title(s)

- List of content for that particular Archive Box (e.g. TMF, CRFs for patients 001-023)
- Date of Archiving
- Expected end date of archiving for each study

An 'Archive Box Label' is available for this purpose (R&D/F56).

A copy of the outer label will also be placed within the box in case the outer label fades over time. The outer label will be secured to the box in a waterproof plastic sleeve once completed by the Archivist

Archive boxes should be brought to the Named Archivist within the R&D unit unsealed in order that the contents can be checked before the boxes are sealed by the Archivist and booked for collection.

Once documents have been archived a statement to this effect should be logged onto the EDGE database in the notes tab stating:

- The archive box numbers (e.g. box number 14)
- Where the documents have been archived
- The number of actual archive boxes
- The date of archiving
- The expected end date of archiving

4.8 Archiving medical records

After the completion of a study and prior to the archiving of documents, it is the responsibility of the CI and/or PI to ensure that the medical notes of all research participants are clearly labelled, to identify that the patient was involved in a research study.

For CTIMP studies only, request medical records and check that they contain a copy of the completed consent form and Patient Information Sheet.

Ensure that the last follow up is documented and document that the study has been archived and score through any remaining blank space on the page.

For multi centre studies, medical records should be stored according to the participating Trust's local policy at each site. **NB** R&D are not responsible for the archiving of medical records

4.9 Archiving facilities

The R&D Unit uses a commercial off-site archiving facility for archiving all study documents (see Appendix 1). The R&D Unit will periodically audit the facilities to ensure that they meet 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.

Study documents archived under this SOP must be archived using the facilities detailed in Appendix 1 unless the use of alternative facilities has been detailed and agreed during the Capacity and Capability confirmation.

4.10 Destruction of archived documents after storage

For all studies the following points apply to the destruction of archived study documents:

- The Named Archivist should be contacted prior to destruction
- When the agreed date of destruction arrives the Named Archivist will contact the study Sponsor or team for written authorisation for the destruction.
- Destruction must not take place without written authorisation from the Sponsor. If there is no longer an identifiable Sponsor the Head of R&D and the Named Archivist will authorise destruction on the agreed date (only after every effort has been made to contact a new data owner and for CTIMPs, MHRA have declined to accept the data).
- For CTIMPs only, a certificate of destruction must be issued and the reasons for destruction documented and signed by a person with appropriate authority (Head of R&D or Named Archivist).
- For all studies destruction will be noted on the R&D database (EDGE) against that studies record.

A copy of the record of destruction together with any written authorisation for destruction will be retained by the R&D Unit for a further 5 years from the date that the study documents were destroyed.

4.11 Archiving trial data on computers

It is the responsibility of the CI/PI to notify the Named Archivist as soon as it is known that electronic study data will need to be archived.

Electronic study data should be encrypted and copied onto a read-only media device for archiving with the study documents as described above. Study data held on computer servers should then be permanently deleted as soon as the study has been reported and the participants notified of the results. This is the responsibility of the CI/PI.

It is important to consider the most appropriate media for archiving of electronic documentation. The selected medium should be unlikely to become obsolete during the planned period of storage and a regular check should take place to ensure that the data remains readable. Archived data should be transferred to a newer or more appropriate media format if necessary. Consideration must also be given to the software or hardware requirements in order to maintain readability of the data for the planned archive period.

5 Related SOPs and Documents

R&D/F11 TMF/ISF Contents

R&D/F56 Archive Box Label

UK Clinical Trial Regulations
http://www.legislation.gov.uk/uksi/2004/1031/contents/made

6 Appendix 1 – Contact Details

Details of the current R&D Unit Named Archivist are found at:

https://www.research.yorkhospitals.nhs.uk/about-us1/meet-the-team/

01904 726996
Research.governance@york.nhs.uk subject “FAO Named Archivist”

Trust Archiving Facilities

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