York and Scarborough Teaching Hospitals NHS Foundation Trust R&D Unit
SOP
R&D/S34

Archiving of Laboratory Research Files

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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: https://www.research.yorkhospitals.nhs.uk/sops-and-guidance-/ and/or Q-Pulse

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Author:	Laura Griffiths
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Approved by:	Name/Position:	Lydia Harris, Head of R&D
	Date:	27th March 2023
	Name/Position:	Sarah Sheath, SOP Controller
	Date:	27th March 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	16th October 2017		New SOP
2.0	18th July 2020		Main procedure separated out into three sections; preparing the Laboratory Site File, arranging transfer and updating of electronic records upon transfer of custody. Addition of R&D/S41 and R&D/F13 reference. Minor formatting and grammatical changes. Minor rewording to clarify information and procedures. Change of link to R&D website
3.0	24th April 2023	Laura Griffiths	Change of email address and author.

Contents

1 Introduction, Background and Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe the procedure for the archiving of Laboratory Site Files. This SOP is applicable to all studies which are sponsored by, co-sponsored by or hosted by the Trust.

Archiving is the long-term storage of essential study documentation, held in the Trial Master File (TMF) and/or Investigator Site File (ISF), Pharmacy Site File and Laboratory Site File.

The overall archiving arrangements for any study are the responsibility of the 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.

Study documents (known as 'essential documents' for CTIMPs) must be accessible after the trial has completed for further analysis if required. 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.

2 Who Should Use This SOP

This SOP is aimed at the following research personnel:

- Chief Investigators (CIs) of research studies sponsored or co-sponsored by the Trust
- Principal Investigators (PIs) of hosted studies
- Research and Development (R&D) Laboratory staff
- Research Nurses and Clinical Trials Support staff working in research teams on either sponsored or hosted studies that require R&D Laboratory support.
- York and Scarborough Teaching Hospitals NHS Foundation Trust R&D Unit staff.

3 When this SOP Should be Used

This SOP should be used when preparing a Lab Research File for archiving. This SOP should be used in conjunction with R&D/S11.

4 Procedure(s)

It is the responsibility of the Research Team and/or Sponsor should notify the R&D Laboratory Team that the Study can be prepared for archiving. Due to limited storage capacity, Laboratory Site Files can be prepared for archiving in advance once all study sampling has been completed. All study samples must have been analysed,

shipped to Central Laboratories/Biobanks or destroyed as per the study Protocol, Laboratory Manual and Laboratory SOP(s).

The Laboratory Site File must firstly be prepared for archiving. The R&D Laboratory Team should complete the following;

- Ensure all forms and logs are fully completed including checking that all samples have been shipped/analysed or destroyed as per the study Protocol. If the Laboratory Site File has been created locally, then it may be appropriate to complete a file audit using the Laboratory Site File Audit (R&D/F13) form. The audit should be documented on the '*Lab Site File Audits*' sheet of the '*Deviations & QA*' spreadsheet located on the X drive (*Laboratory M (X:) > Biochemistry > 01.Trials Info > Quality Assurance*).

- Review all documentation to ensure that there is no duplication. It is only necessary to keep one copy of each document.

- Account for any absent or incomplete data. Any records that are missing and not retrievable form other sources (correspondence, electronic records) should be documented in a file note (R&D/T20). All file notes should be signed and dated by the individual with knowledge of the event that led to the file note, and authorised by the study PI (where appropriate). File notes should be referenced in a file note log (see R&D/F59) within the study file. Cross referencing file notes indicating the location of documents within the study file do not require PI authorisation.

- Make copies of documents if applicable. It may be appropriate to photocopy documents that have been printed on thermal paper onto standard paper as the originals may deteriorate over time and become illegible.

- Where specified by the Sponsor, ensure that copies of calibration certificates and temperature records are filed. These records are also retained electronically by the R&D Laboratory Team. Please refer to the R&D Laboratory Tutela Temperature Monitoring System SOP (R&D/S41) for further details.

- Print and file relevant correspondence in appropriate sections of the Laboratory Site File.

- For studies that will not be archived at the Trusts archiving facility, ensure that any patient identifiers are redacted to maintain confidentiality. It is the responsibility of the Research Team to communicate this to the R&D Laboratory Team.

- Inform the Research Team or named archivist of any electronic media which is to be archived.

Once the Laboratory Site File has been prepared, the R&D Laboratory Team should;

- Contact the Research Team to arrange collection or delivery of the file(s). Research Teams should retain the Laboratory Site File with the main ISF or incorporate the laboratory documents into the main study ISF.

On the day of Laboratory Site File transfer, the R&D Laboratory Team should;

- Document the Laboratory Site File transfer of custody on the '*Archiving Audit*' sheet of the '*Deviations & QA*' spreadsheet located on the X drive (*Laboratory M (X:) > Biochemistry > 01.Trials Info > Quality Assurance*) to ensure that there is an appropriate chain of custody.

- Transfer the electronic study specific folder, located on the X drive (*Laboratory M (X:) > Biochemistry > 01.Trials Info > Studies RESEARCH SPECIALITY*), to the '*Studies CLOSED*' folder (*Laboratory M (X:) > Biochemistry > 01.Trials Info*).

- Transfer the study specific email correspondence folder, located in the yhs-tr.labresearch@nhs.net inbox to the '*STUDIES CLOSED*' folder.

- Update the '*Clinical Trials Summary Spreadsheet*' located on the X drive (*Laboratory M (X:) > Biochemistry > 01.Trials Info > Clinical Trials Summary Spreadsheet*); cut the relevant row from the '*YORK OPEN*' or '*SGH OPEN*' sheet and paste it in the '*YORK CLOSED*' or '*SGH CLOSED*' sheet respectively. It is also advisable to add a comment in the notes section to document the transfer of custody.

5 Related SOPs and Documents

R&D/S11 Archiving of Research Study Documents

R&D/S41 R&D Laboratory Tutela Temperature Monitoring System

R&D/T20 File Note

R&D/F59 File Note Log

R&D/F13 Laboratory Investigator Site File (ISF) Audit