York Foundation Trust R&D Unit
SOP
R&D/S34

Archiving of Laboratory Research Files

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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

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	Date:	10th October 2017
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	Signature:	Signed copy held by R&D Unit
	Date:	10th October 2017

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

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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	16th October 2017	

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1 Introduction, Background and Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe the procedure for the archiving of Laboratory Research 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 Research File.

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.

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 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').
- Lab Research staff.
- Research Nurses working on research studies which involve the Laboratory Research team.
- York 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)

The Research Team and/or Sponsor should notify the Laboratory Research Team that the Study can be prepared for archiving. The Laboratory Research Team should:

- Review all documentation to ensure that there is no unnecessary duplication. It is only necessary to keep one copy of each document.
- Ensure all forms and logs are fully completed including checking that all samples have been shipped/ or ready for destruction or archive as per the study protocol.

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- Any records that are missing and not retrievable form other sources (correspondence, electronic records) should be documented in a file note. A file note template (see R&D/T20) is available for download. All file notes should be signed and dated by the individual with knowledge of the event leading 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.
- Photocopy faxes and documents which have been printed on thermal paper onto standard paper as they may deteriorate over time and become unreadable.
- Where specified by the Sponsor, ensure that copies of calibration certificates and temperature logs are filed. If this is not required, these will be stored centrally.
- Print and file relevant correspondence in appropriate sections of the Laboratory Research File.
- For studies which will not be archived at the Trusts archiving facility, ensure that any patient identifiers are redacted to maintain confidentiality.
- Remove all documents from plastic wallets as they may remove the ink from documents over time.
- Remove all documentation and use archiving clips to store. Ensure there is appropriate labelling of the file by using a cover sheet recording the study tittle, R&D number and PI.
- Inform the named archivist of any electronic media which is to be archived.
- Contact the research team to arrange for collection or delivery of the files.

Once the Research Laboratory File is given to the research team, this should be documented on the Laboratory Research Spreadsheet to ensure that there is an appropriate chain of custody. Research Team should incorporate the Laboratory Documents in the study ISF.

5 Related SOPs and Documents

R&D/S11- Archiving of Research Study Documents

R&D/T20 File Note

R&D/F59 File Note Log

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