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Preparing Certified Copies for Research Studies
STANDARD OPERATING PROCEDURE

Introduction and Aim

This SOP has been compiled to provide guidance to staff who intend on creating a certified copy of a paper document. The generation and maintenance of essential records are a critical aspect of ensuring accuracy of the metadata attributed to the document, data integrity, regulatory compliance and patient safety. With the increasing adoption of electronic systems and the need for efficient document management, certified copies serve as verified and accurate reproductions of original documents that can be relied upon for regulatory and legal purposes. This SOP outlines the process for the creation, verification, and use of certified copies within clinical research activities to meet Good Clinical Practice (GCP), Medicines and Healthcare products Regulatory Agency (MHRA) and regulatory standards.

The use of certified copies is increasingly important in the transition to electronic investigator site files (eISFs), remote monitoring practices, and centralised document management systems. Properly managed certified copies will allow Cardiff and Vale UHB and sponsors to maintain compliance while improving efficiency in document handling, auditing, and archiving processes.

The aim of this SOP is to define the standardised process for creating, verifying, and managing certified copies of original documents used in clinical trials. It ensures that certified copies are handled in a consistent manner that upholds the integrity and credibility of the trial data.

Objectives

- to define the standardised process for creating, verifying, and managing certified copies of original documents used in clinical trials.
- to ensure certified copies are handled in a consistent manner that upholds the integrity and credibility of the trial data.
- to describe the procedure for creating certified copies using the Florence system e.g. consent forms.

- to describe the procedure for creating certified copies using Adobe for storage outside the Florence system. This procedure should be followed when creating certified copies of source documents produced on thermal paper (e.g., ECG printouts, telemetry strips and similar outputs) which may deteriorate or become illegible during the required retention period.

Scope

This SOP applies to all personnel involved in the generation, certification, or use of certified copies in research studies.

Approved by Joint Research Governance Group

Accountable Executive or Clinical Board Director	Medical Director
Author(s)	Florence Project Manager

Disclaimer

If the review date of this document has passed please ensure that the version you are using is the most up to date either by contacting the document author or the Governance Directorate.

Summary of reviews/amendments

Version Number	Date of Review Approved	Date Published	Summary of Amendments
1	22/10/2026	10/11/2026	Not applicable, new SOP

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GLOSSARY OF TERMS

Term	Definition
Certified Copy	A copy of an original record that has been verified and certified by an authorised individual as an exact and complete representation of the original document.
eISF	Electronic Investigator Site File.
Florence	Digital platform used to manage studies and their relevant essential records within the Florence system.
GCP	Good Clinical Practice
Meta Data	Metadata are data that describe, explain, or provide context for clinical trial data, including information such as who created the record, when it was created or modified, and the history of any changes made.
MHRA	Medicines & Healthcare Products Regulatory Agency.

1.0 RESPONSIBILITIES

This SOP applies to any member of staff who intends to create a certified copy of an original paper document for use in research studies.

2.0 PROCEDURE FOR SCANNING OF ORIGINAL DOCUMENTS FOR PRODUCTION OF CERTIFIED COPIES

Key considerations:

It is not acceptable to use the scanning process to remove or add material to the image.

A certified copy may be stored in electronic format if required but must retain the metadata and audit trail to ensure that the full meaning of the data is kept and its history may be reconstructed.

2.1 Preparing Document(s) for Scanning

Before scanning a document to create a certified copy, the authenticity completeness and condition of the original paper document is to be checked

- Confirm the document is the original source look for a wet ink or other indicators of authenticity
- Check document for completeness, if there are multiple pages, confirm all are present and in the correct order
- Check condition of document and remove staples, clips or obstructions that may interfere with the copy quality.
- Confirm the document is clearly readable by reviewing signature, dates/times, handwritten notes.
- Check if the document is single- or double-sided before scanning.

2.2 Scanning the Document

To scan the original document

- Ensure the photocopier is clean and functioning properly.
- Set up the scanner to ensure scanning a 1:1 ratio
- Scan in black and white. Only scan the document in colour if the colour elements are critical to the interpretation of the content of the record;
- The person responsible for checking confirming the authenticity and completeness of the document should scan the document into their own' my scans' folder.
- The pages should be scanned straight upright and not on an angle.

2.3 Quality control (QC) check

Review the scanned document against the original

- Check document for completeness, if there are multiple pages, confirm all are present and in the correct order
- Check legibility confirming the document is clearly readable by reviewing signature, dates/times, handwritten notes.
- Check image quality including the document alignment.

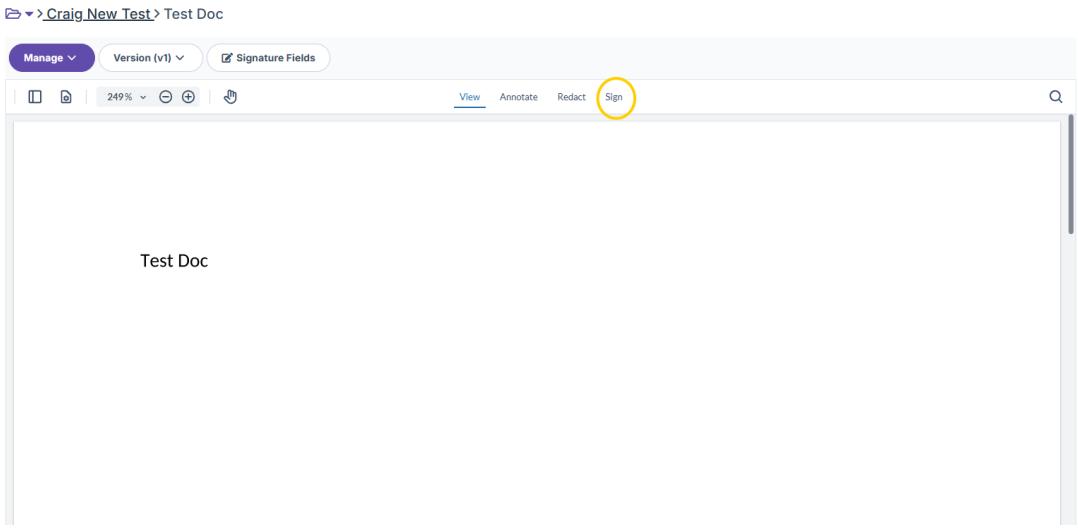
On completion of QC checks the scanned document may progress to be certified

If the scanned document fails any of the QC checks the original document is to be rescanned.

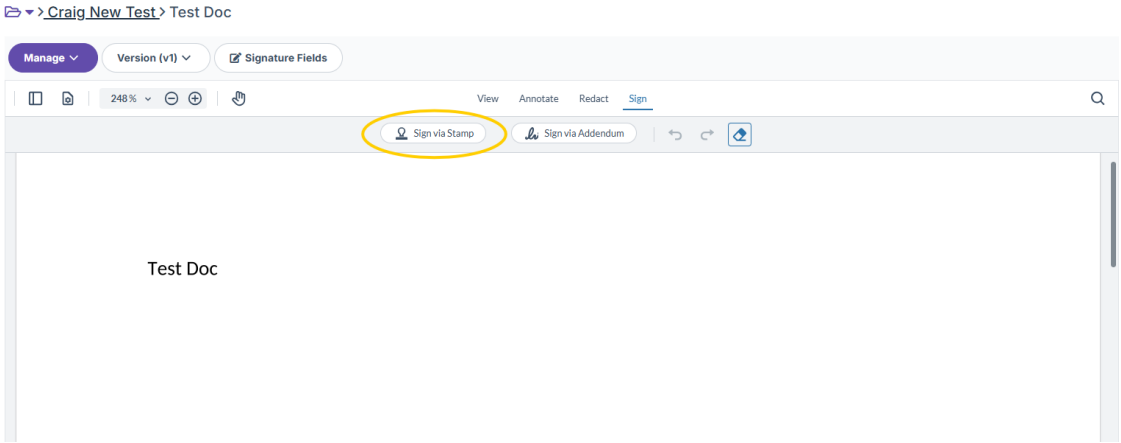
3.0 FLORENCE CERTIFICATION PROCESS

3.1 Open the document requiring certification within Florence.

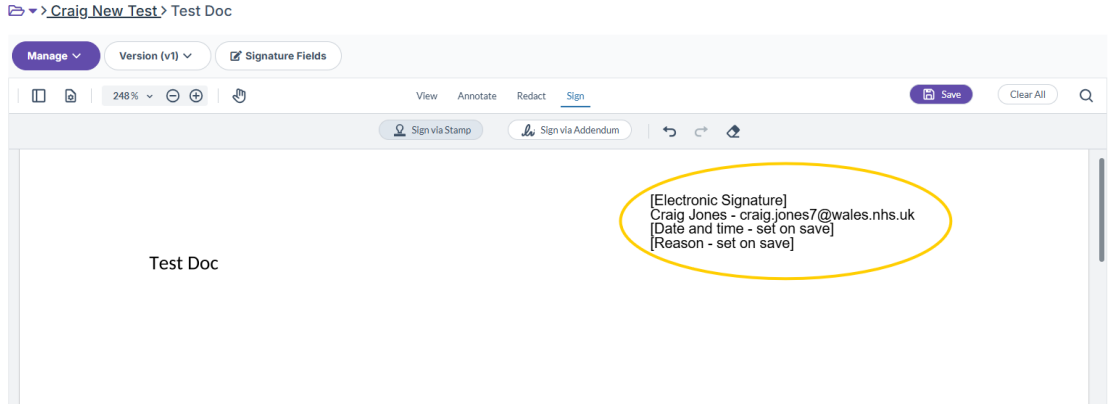
3.2 Once all document checks have passed, select the sign button above the document



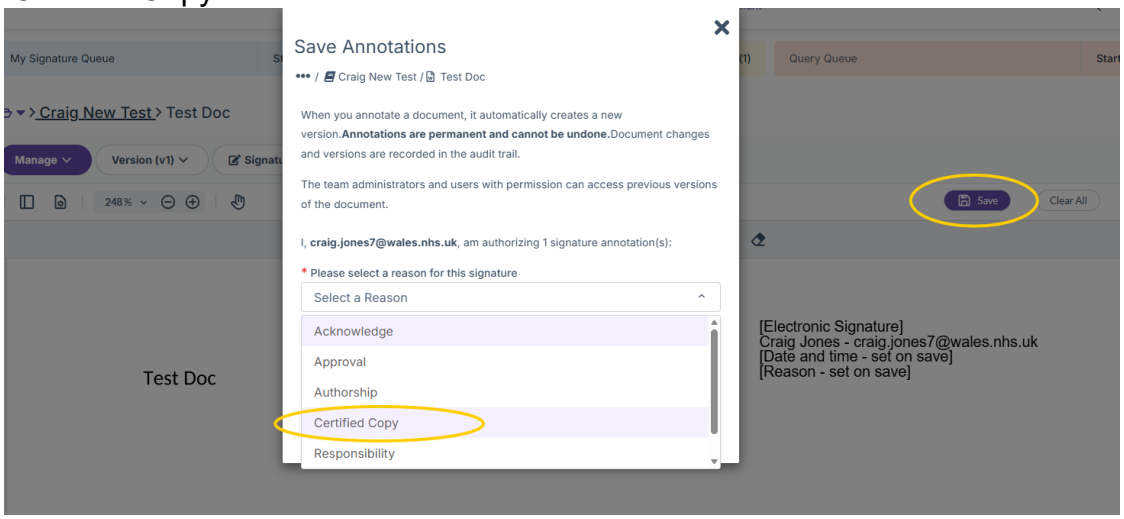
3.3 Select sign via stamp



3.4 Using the mouse, place the electronic signature on the document

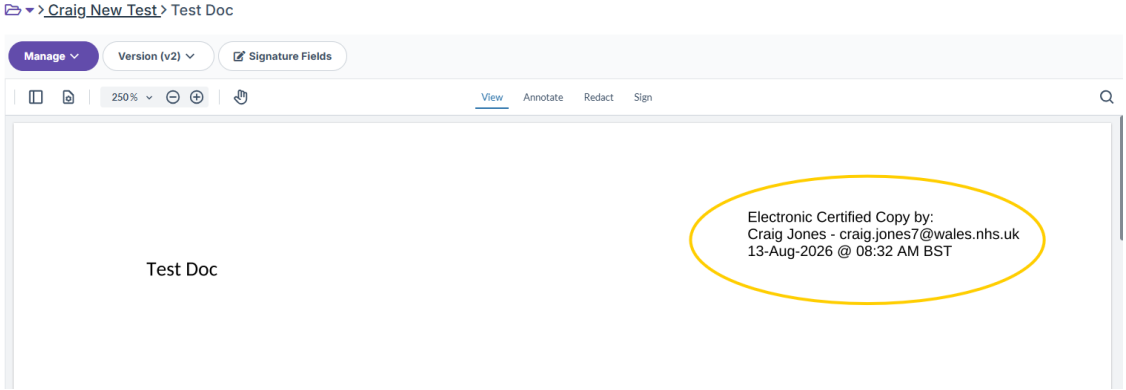


3.5 Select 'Save' and then select the reason for the signature as 'Certified Copy'



3.6 Enter your Florence password and select Save.

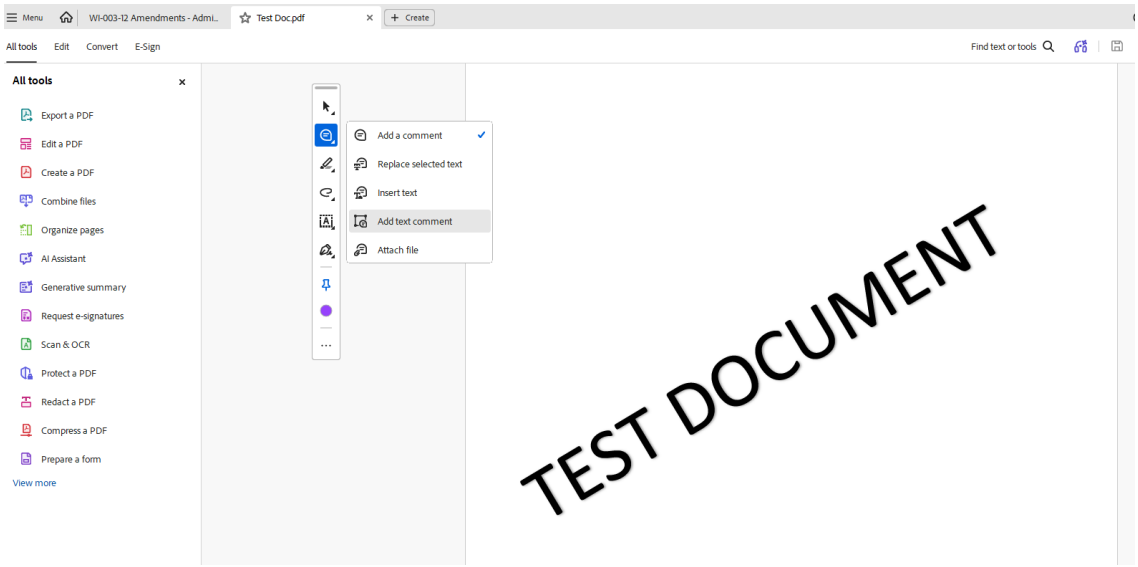
3.7 The Document will now show your electronic signature certifying the document



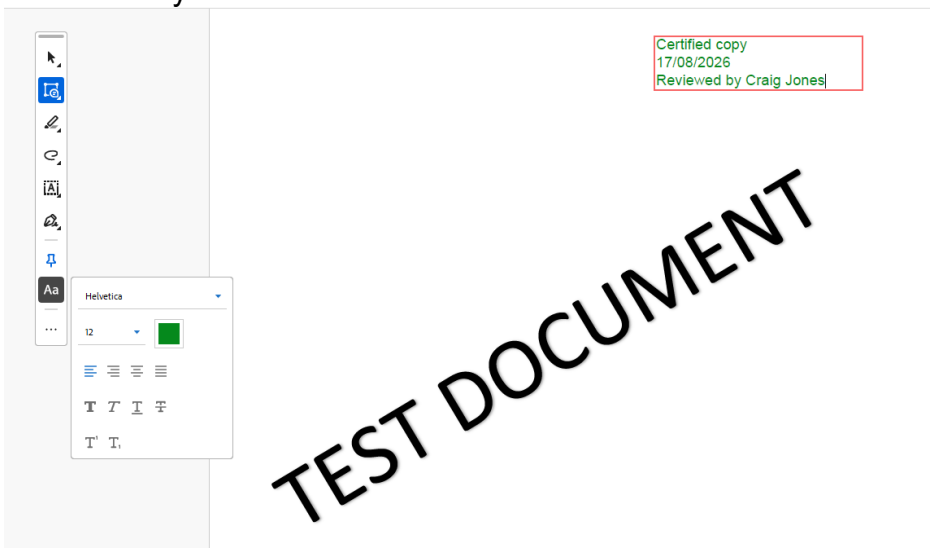
4.0 ADOBE CERTIFICATION PROCESS

4.1 Open the document in Adobe

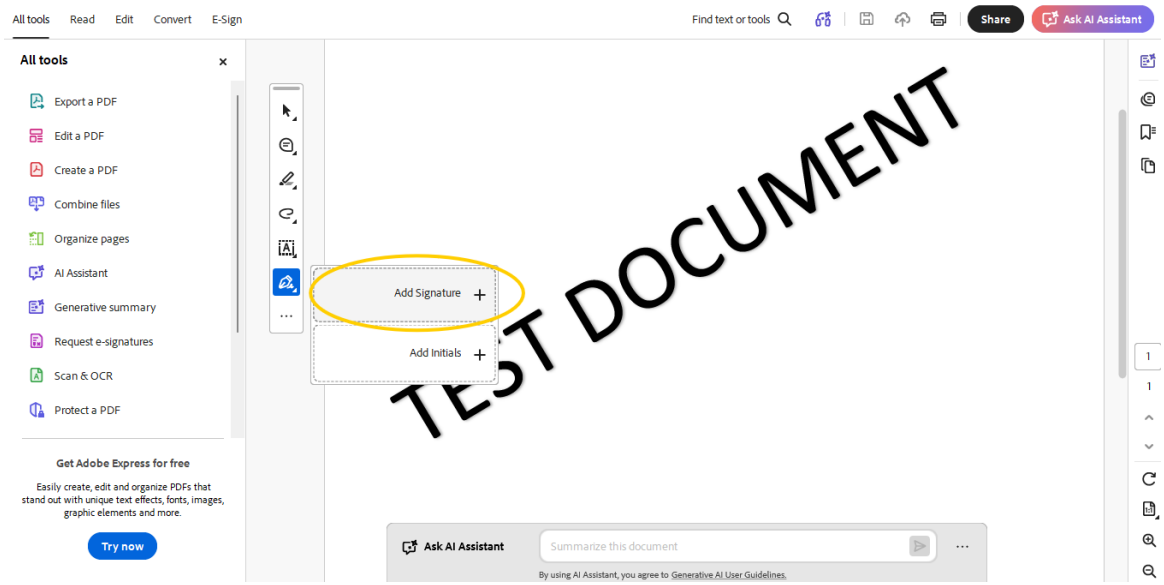
4.2 Add a text comment to the document:

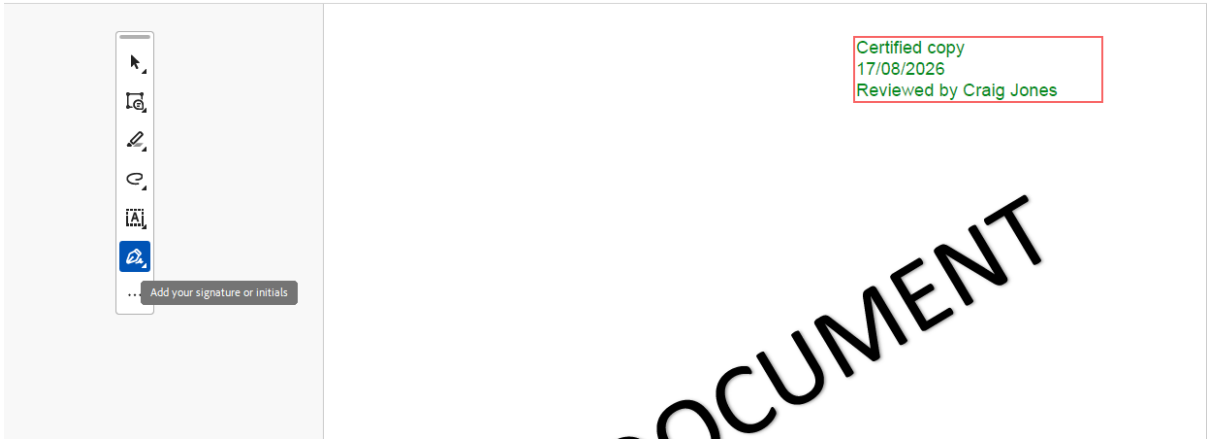


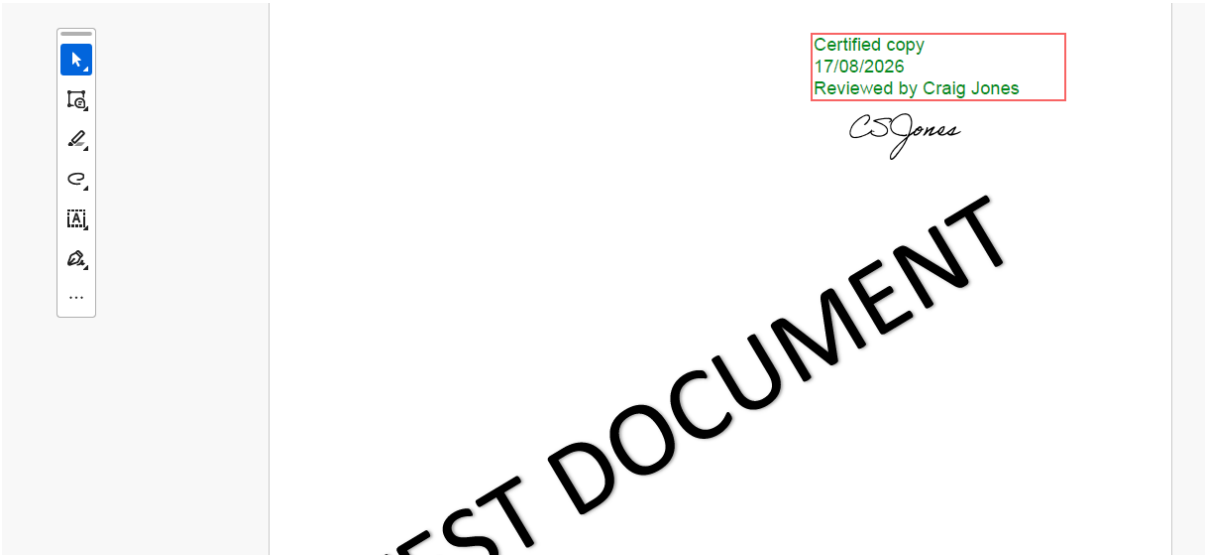
Enter the text:
Certified copy
Date
Reviewed by:



4.3 Add the electronic signature under the comment box. To Create a signature:







Save the PDF.

5.0 Review and Quality Check

Ensure that your certified stamp does not cover any of the information on the document.

Compare the certified copy against the original document to ensure it is a true and accurate reproduction. Pay attention to small details like page numbers.

6.0 Retention of the Original Paper Record

Any associated risk of destruction of the original record should be carefully considered. It should be agreed with the study sponsor at study set up which documents need to be retained as original wet ink paper documents and where certified copies would not be deemed acceptable. The ethical approval of a study may include instruction on the retention of original paper documents.

You should also clarify with the sponsor whether the document can be;

a) Archived electronically
b) Whether or not the original paper document can be destroyed and if so at what time point (for example after the original consent form has been reviewed by the CRA or at end of study)

If a sponsor would like the paper document archived, this should be charged for in the set-up of a trial.

You should save evidence of the sponsor requirements via email and file in the ISF. If in doubt, you should speak to study sponsor before making a decision.

7.0 References

MHRA (2018). Medicines & Healthcare products Regulatory Agency (MHRA) 'GXP' Data Integrity Guidance and Definitions. [online] Available at:

https://assets.publishing.service.gov.uk/media/5aa2b9ede5274a3e391e37f3/MHRA_GxP_data_integrity_guide_March_edited_Final.pdf

ICH E6(R3) Good Clinical Practice
The Medicines for Human Use (Clinical Trials) Regulations 2004, as amended
UK Policy for Health and Social Care Research
UK General Data Protection Regulation (UK GDPR 2018)
Data (Use and Access) Act 2025 (DUAA)

8.0 Related documents

The following SOPs should be read in conjunction with this SOP to ensure alignment with broader research governance processes:

SOP-010-02 UHB 449 - Data Management for Clinical Trials
SOP- 003-04 UHB121 - Archiving of Clinical Trial and Research Study Data
SOP- 004-02 - Use of Florence for Electronic Records and Electronic Signatures

Appendix 1

Flow diagram of process

