

|                                                                         |                   |                 |                   |
|-------------------------------------------------------------------------|-------------------|-----------------|-------------------|
| Joint Research Management Office Standard Operating Procedure for:      |                   |                 |                   |
| <b>Use of Florence for electronic records and electronic signatures</b> |                   |                 |                   |
| SOP Number:                                                             | <b>50.0</b>       | Version Number: | <b>1.0</b>        |
| Effective Date:                                                         | <b>13.08.2026</b> | Review Date:    | <b>13.08.2027</b> |

|                                 |                                                          |
|---------------------------------|----------------------------------------------------------|
| <b>Authorship &amp; Review:</b> |                                                          |
| Author:                         | <b>Rebecca Newton, Senior GCP and Compliance Manager</b> |
| Reviewer:                       | <b>Amy Schou, Clinical Research Auditor</b>              |

|                       |                                                                                                         |
|-----------------------|---------------------------------------------------------------------------------------------------------|
| <b>Authorisation:</b> |                                                                                                         |
| Name/Position:        | <b>Mays Jawad, Associate Director of Research Quality</b>                                               |
| Signature and Date    | <b>Dr Mays Jawad</b> <div>Digitally signed by Dr Mays Jawad<br/>Date: 2026.08.13 14:51:50 +01'00'</div> |

## 1. Purpose

This Standard Operating Procedure (SOP) describes the identification, storage and management of regulatory Essential Documents for clinical research studies using Florence and establishes the process by which roles and responsibilities are delegated to applicable personnel.

## 2. Scope

This SOP applies to any electronic elements stored in Florence. It applies to all personnel involved in the collection, creation, retrieval, modification, maintenance, transmission, and/or storage of essential records, from study planning through to closeout and archiving. It excludes legacy studies.

- Legacy studies are defined as studies activated prior to Florence Implementation at Barts Health NHS Trust (Barts Health). Legacy documents will not be imported and will be maintained following the current [Joint Research Management Office \(JRMO\) Essential Documents SOP 45](#).

This SOP includes records containing patient-identifiable information governed by NHS information governance policies, such as clinical notes. which will be maintained following the organization's current SOPs

For research conducted under the new UK Clinical Trials Regulations taking effect from 28 April 2026, this SOP applies to records managed under both the existing and updated regulatory frameworks.

In alignment with ICH E6(R3), the term “essential records” is used throughout this SOP to reflect an expanded definition that includes documents, structured data, metadata, and audit trails. Terminology and related processes within this SOP will be reviewed and aligned with regulatory guidance as further updates from Medicines & Healthcare products Regulatory Agency (MHRA) become available.

### 3. Responsibilities

The table below should be read in conjunction with **Florence Training Requirements** and **Florence Governance and Compliance Guidance for JRMP Supported Clinical Research Studies**

| Function / Responsibility                                    | JRMO Superuser/Deputy                                                                                                                                                                                                                                                                                     | Research Delivery Team Champion / Deputy                                                                                      | All Users                                    |
|--------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------|
| Central organisation binders                                 | Create and oversee central organisation binders                                                                                                                                                                                                                                                           |                                                                                                                               |                                              |
| Study binders                                                |                                                                                                                                                                                                                                                                                                           | Create and oversee study binders for their area                                                                               |                                              |
| User account management                                      | Create, modify and terminate Champion/management accounts; assign roles and access dates                                                                                                                                                                                                                  | Create, modify and terminate departmental user accounts including auditors/monitors/inspectors; assign roles and access dates |                                              |
| Role & permission management                                 | Assign role permissions to Champions. Facilitate creation, approval and termination of Florence roles                                                                                                                                                                                                     | Assign permissions based on delegated responsibilities, sponsor requirements and Good Clinical Practice (GCP)                 |                                              |
| Training verification as per training instructions           | Verify complete training for Research Delivery Team Champions prior to granting access                                                                                                                                                                                                                    | Verify users complete training prior to granting access                                                                       | Complete required training before system use |
| Access reviews as per Periodic Review Process                | Undertake 6-monthly access reviews and remove/amend access as needed in response to change in employment status, job responsibilities, study allocation, or operational need.                                                                                                                             |                                                                                                                               |                                              |
| Security & account responsibility                            | Use unique NHS or Queen Mary University of London (Queen Mary) employer issued account to register in Florence, <b>shared accounts are not permitted</b> .<br>Maintain a secure password and update password should it become compromised.<br>Report suspected unauthorised access or security incidents. |                                                                                                                               |                                              |
| Binder templates                                             | Create binder structure templates                                                                                                                                                                                                                                                                         |                                                                                                                               |                                              |
| Document management                                          | Maintain central and study documents in a timely and organised fashion                                                                                                                                                                                                                                    |                                                                                                                               |                                              |
| Audit trail reviews as determined by Sponsor/JRMO Governance | Periodic risk-based review of audit trails                                                                                                                                                                                                                                                                | Periodic risk-based review of audit trails                                                                                    |                                              |

### POLICIES & PROCEDURES –ELECTRONIC DOCUMENT MANAGEMENT

- 4.1. Requirements for documentation, record keeping, and record retention apply to electronic records as they do for paper systems in accordance with UK General Data Protection Regulation (GDPR) and Regulatory Expectations.
- 4.2. Key study documents will be managed, stored, and presented electronically. Sponsors and auditors should be notified of this policy prior to study initiation and before any audits or inspections.
- 4.3. Documentation of Florence's electronic security controls, secure backup schedule, and routine vulnerability testing are available on request and maintained by Florence Healthcare, Inc in the Florence Compliance Team.
- 4.4. Essential records will be retained for a minimum of 25 years from the end of the study, unless a different period is required by the sponsor, funding body, or regulatory authority. This includes audit trails, certified copies, version history, and all associated metadata necessary to support inspections and GCP compliance.
- 4.5. Documentation will be downloaded from Florence and maintained per Investigator Site Agreement and JRMO procedures.
- 4.6. Electronic certified copies
  - 4.6.1. The **User** making a certified copy of the Document will upload an electronic copy of the Document into Florence eISF, review and verify the uploaded Document for completeness and readability and then sign the Document as a Certified Copy.
  - 4.6.2. The audit trail will track and record the timestamp, reason, and author for authenticity and responsibility.
- 4.7. Documents and General File
  - 4.7.1. Documents that will be used across studies can be maintained centrally.
  - 4.7.2. Document duplications or shortcuts may be utilised allowing Users to access central documents as appropriate based on the User's access controls assigned.
  - 4.7.3. Central documents may include, but are not limited to training, United Kingdom Accreditation Service certificates, lab normal ranges, SOPs.
- 4.8. Document Version Control
  - 4.8.1. Version tracking within Florence can be utilised for draft documents, completed forms, logs, redacted documents, etc.
- 4.9. Protected Health Information (PHI)

Applicable electronic Records may be marked as PHI to prevent certain users (e.g. Sponsor) from any unintended/accidental visibility of records containing PHI. Documents containing PHI data must be:

- Uploaded by delegated study personnel only
- Tagged using Florence's PHI flagging tool
- Redacted where necessary prior to upload
- Restricted to authorised users in line with NHS Information Governance Policy

A redaction audit trail must be preserved within Florence for any altered files.

## 5. Policies & Procedures – Electronic Signatures

5.1. Electronic signatures used within Florence must comply with UK law and MHRA expectations. All users utilising electronic signatures shall ensure the following:

- Credentials are unique, secure, and remain confidential (i.e. not reused by, not reassigned to, and not shared with other individuals).
- Their user profile is complete to ensure their signature manifestation includes all components required.
- Signatures are performed only by the authenticated user.

5.2. This section applies to all documents and clinical research studies and research where Florence is utilised by Barts Health/Queen Mary and where electronic signatures and handwritten signatures executed to electronic documents are intended to be equivalent to paper records and handwritten

signatures.

- 5.3. Users are responsible for reviewing their accounts for pending signature requests on a regular basis.
- 5.4. Electronic signatures may be used for all documents stored in Florence
  - Signatures only apply to the version of the document signed.
  - When the version of a document is updated, signatures from the previous version are no longer valid due to the changes made.
  - Any updates which require review, acknowledgment, and/or approval must be signed by the appropriate Users.
  - All required fields required for initiation of study activities must be completed by the end user before signing an eLog row. The electronic signature attests to row accuracy and completeness at the time of signing.
  - In Delegation Logs, the end date is the only row that may be completed after signatures have been obtained on the row. Addition of end dates does not invalidate previous row signatures
  - eLog signatures will be cleared when row details are changed. Any updates which require review, acknowledgment, and/or approval must be signed by the appropriate Users.
- 5.5. Documents can be signed as documented in the eSignature Document Workflow using **Addendum signatures**: Logged in the audit trail but not visible on the document face
- 5.6. Signature requests can be made by individuals with the appropriate permission and access to do so within Florence

## 6. POLICIES & PROCEDURES – SIGNATURE LOGS

- 6.1. This process includes the completion and maintenance of the Signature Log for any clinical research studies and/or trials that include wet-ink handwriting for documents.
  - 6.1.1. The purpose of the Signature Log is to have a record of the handwriting sample of every individual involved in study-related activity.
  - 6.1.2. Signature Logs will be maintained as follows:
    - A central Signature Log will be maintained for all members of the Research Delivery and Governance teams. This avoids the need for duplicate logs across multiple studies and will be stored centrally within Florence.
  - 6.1.3. For external personnel or staff outside of the core research teams, a study-specific Signature Log must be completed and uploaded into the respective study binder
- 6.2. An individual Signature Log should be maintained for each team member who participates on a study or research that uses wet-ink handwriting.
- 6.3. The Signature Log will include:
  - Printed name
  - Signature
  - Initials
  - Numbers 0-9
  - Date when the signature log was completed
- 6.4. The JRMO Superuser, Champion or designee will initiate the Signature Log with each new user.
- 6.5. Each Team member should provide a complete handwritten copy of the Signature Log to the JRMO Superuser, Research Delivery Team Champion or designee.

6.5.1. Each completed Signature Log will be uploaded and stored in Florence by the JRMO Superuser, Research Delivery Team Champion or designee

6.5.2. In case of a name change for a Team member, a new Signature Log must be created and uploaded to Florence.

## 7. Business Continuity

### 7.1. System Updates

**The Superuser or designee** will review system updates and ensure they follow a risk-based change control process, with validation as needed to confirm the change does not impact system performance or data integrity.

### 7.2. Florence System Downtime

In the event of a temporary outage or loss of access to the Florence system (e.g. technical failure, scheduled downtime, network disruption, or cybersecurity incident), procedures must be followed to ensure the continuity of research activities and compliance with GCP.

7.2.1. During system downtime:

- Essential research activities that rely on Florence (e.g. delegation logs, consent tracking, document reviews) must be **temporarily documented using paper-based or local secure formats**.
- These temporary records must be dated, signed, and stored securely until the system is restored.
- Research teams must **inform the Florence Super User** of the incident and document any impact on study conduct or timelines.
- The Superuser or Designee will ensure the incident is recorded and Corrective Actions/ Preventative Actions actioned as appropriate.

Once system access is restored:

- All offline records created during the outage must be **scanned, uploaded, and certified** in Florence.
- A comment should be included on each uploaded record (or study file note) to document the circumstances of the downtime and restoration.

Florence Healthcare, Inc. maintains:

- Encrypted backups
- Validated disaster recovery plans
- System performance monitoring and support escalation

A formal review of any significant downtime incident will be undertaken by the Florence Superuser in collaboration with JRMO Governance to ensure learning and any necessary preventive actions are documented.

## 8. References

Florence Compliance Team Key Training Resources: FDA (Part 11 Predicate Rules) ICH, GCP  
Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025

EU/UK GDPR and More! ([here](#))

US FDA 21 CFR Part 11 Electronic Records; Electronic Signatures ([here](#))

General Principles of Software Validation; Final Guidance for Industry and FDA Staff ([here](#))

Part 11, Electronic Records; Electronic Signatures – Scope and Application ([here](#))

Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations:  
Questions and Answers ([here](#))

US FDA 21 CFR Part 312 – Investigational New Drugs([here](#))

US FDA 21 CFR Part 812 – Investigational Device Exemption ([here](#))

E6(R3) Guideline for GCP ([here](#))

### Related Resources:

1.1. [JRMO SOPs](#) ([here](#))

## Supporting Documents

| Document ref.         | Document name                                                     |
|-----------------------|-------------------------------------------------------------------|
| Associated Document 1 | Florence Governance & Compliance Guidance for JRMO Hosted Studies |