

Florence Governance and Compliance Guidance for JRMO Supported Clinical Research Studies

1. Purpose

This guidance document outlines the principles, responsibilities, and compliance requirements for the use of Florence in the management of essential study records for clinical research studies. It is intended to support the associated Barts Health NHS Trust (Barts Health) & Queen Mary University of London (Queen Mary) Florence eBinders Standard Operating Procedures (SOPs), which provides operational instructions for users.

The guidance establishes expectations for the creation, maintenance, storage, review, and electronic signing of study documentation within Florence to ensure compliance with applicable regulatory, legal, and organisational requirements.

2. Scope

This guidance applies to all personnel involved in the conduct and management of clinical research studies that utilise Florence for the management of essential study documentation and records.

It applies to all study-related documentation maintained within Florence, including documents, structured data, metadata, study correspondence, and electronic logs.

3. Regulatory and Compliance Framework

The management of study records within Florence must comply with applicable legislation, regulations, and guidance, including:

- ICH E6(R3) Good Clinical Practice (GCP).
- UK General Data Protection Regulation (UK GDPR).
- UK Policy Framework for Health and Social Care Research.
- Applicable sponsor, organisational, and study-specific requirements.
- Any additional regulatory requirements applicable to the study.

All study-related activities and records must be documented and maintained in a manner that supports data integrity, traceability, accessibility, and inspection readiness.

4. Roles and Responsibilities

4.1 Coordinating Investigators and Principal Investigators

Coordinating Investigators and Principal Investigators retain overall accountability for ensuring that essential records are maintained throughout the study lifecycle in accordance with applicable regulatory and organisational requirements.

While document management activities may be delegated to appropriately trained study personnel, accountability for oversight of study records remains with the Investigator.

4.2 Florence System Oversight

The JRMO Florence Superuser, or appropriately delegated individual, is responsible for providing system oversight and ensuring that appropriate risk-based user acceptance testing

has been completed before system implementation or significant changes. This oversight is intended to provide assurance that Florence meets defined user requirements and is fit for its intended purpose.

4.3 Florence Users

Individuals using Florence are responsible for:

- Maintaining the accuracy and completeness of records under their control.
- Using system functionality in accordance with approved procedures.
- Protecting their individual system credentials.
- Ensuring that actions performed within Florence are attributable to the authorised user.
- Maintaining compliance with organisational policies and applicable regulatory requirements.

5. Management of Study Records

5.1 Accessibility and Inspection Readiness

Study documentation maintained within Florence must remain readily accessible for review, monitoring, audit, inspection, or regulatory assessment throughout the required retention period.

Records may be reviewed by:

- Study Sponsors.
- Organisational oversight personnel.
- Regulatory authorities, including but not limited to:
 - Medicines and Healthcare products Regulatory Agency (MHRA).
 - European Medicines Agency (EMA).
 - United States Food and Drug Administration (FDA).
 - Other applicable regulatory authorities.

5.2 Electronic Documents and Certified Copies

Records maintained within Florence may consist of a combination of original electronic records and certified copies.

Electronic certified copies should:

- Be created from the original source document.
- Be verified against the original record.
- Include documented evidence of verification.
- Preserve the context, content, and structure of the original record.

Electronic signatures and associated audit trails provide evidence supporting the authenticity and integrity of certified copies.

5.3 Version Control

Appropriate version control must be maintained for all controlled documents.

Where Florence functionality is used:

- The **Duplicate** feature creates a separate, version-specific copy of a document.
- The **Shortcut** feature creates a linked document reference that always displays the current approved version of the source document.

Users should understand the distinction between these functions and select the most appropriate option based on the intended use.

5.4 Audit Trails

Florence provides audit trail functionality to support regulatory compliance and data integrity requirements.

Audit trails record, as applicable:

- Document version history.
- User actions.
- Date and time of activities.
- Record modifications.
- Electronic signature events.

Audit trail information must be retained and available to demonstrate compliance with GCP and applicable regulatory requirements.

6. Study Correspondence

Florence's email import functionality may be used to retain study-related correspondence and associated attachments within the relevant study record.

Examples of correspondence that may be retained include communications with:

- Study participants.
- Sponsors.
- Research sites.
- Study teams.
- Regulatory bodies.
- Other study stakeholders.

Users should ensure correspondence is stored within the appropriate study location and managed in accordance with applicable information governance requirements.

7. Electronic Logs (eLogs)

Florence eLogs may be used to create and maintain study logs that have traditionally been maintained as paper records.

Examples may include:

- Screening logs.
- Enrolment logs.
- Training logs.
- Delegation logs.
- Investigational Medicinal Product (IMP) accountability logs.

The suitability of using eLogs should be determined during study setup by the Research Delivery Team.

Access to eLogs must be controlled through appropriate user permissions to ensure that only authorised individuals can create, amend, review, annotate, or electronically sign records.

8. Electronic Signatures

Electronic signatures applied within Florence are considered attributable to the authorised user and must only be applied by the individual to whom the credentials have been assigned.

Users must not share usernames, passwords, signing PINs, or other authentication credentials.

For studies regulated under UK legislation, Florence audit trails and system controls provide evidence of user identity, signing intent, and record integrity. A separate non-repudiation agreement is not required unless specified by sponsor or study-specific requirements.

9. Electronic Signature Principles

When a document is electronically signed within Florence:

1. The signer reviews the document and confirms the purpose of the requested signature.
2. The signer authenticates using their approved Florence credentials.
3. The system verifies the user identity through the configured authentication controls.
4. The electronic signature record is applied to the document.
5. The associated audit trail is updated to record:
 - The identity of the signer.
 - The meaning or purpose of the signature.
 - The date and time of execution.

Electronic signatures must only be applied where the signer has reviewed the content and agrees to the associated statement, approval, or attestation.

10. Related Documents

This guidance should be read in conjunction with:

- Barts Health & Queen Mary Florence eBinders SOP
- Florence Document eSignatures Workflows and Guidance

- Records Management Policy.
- Data Protection and Information Governance Policies.
- Clinical Research Governance Framework.
- Applicable Sponsor Requirements.
- ICH E6(R3) Good Clinical Practice.