## 1. Introduction and Who Policy Applies To

Investigators are responsible for maintaining clinical trial records in accordance with applicable UK regulations, Good Clinical Practice (GCP) requirements, the UK Policy Framework for Health and Social Care Research, and all relevant University Hospitals of Leicester NHS Trust (UHL) policies and procedures.

Research records must remain accurate, complete, and readily accessible for review or inspection by authorised bodies, including but not limited to the Medicines and Healthcare products Regulatory Agency (MHRA), Research Ethics Committees, study sponsors or their delegates, and relevant Trust personnel. Records must be maintained in a manner that ensures full traceability and supports regulatory compliance throughout the study lifecycle.

This Standard Operating Procedure (SOP) sets out the UHL processes for the creation, organisation, maintenance, and oversight of electronic clinical trial records using the Florence Healthcare Inc. eBinders™ system (Florence). It outlines the requirements for secure management of study records, the use of electronic signatures, the responsibilities of staff involved in clinical research and the mechanisms by which Investigators can use the Florence system to delegate study related duties to appropriately trained and qualified research personnel. It also details how information on staff roles, responsibilities, and training is captured and managed to ensure accountability and oversight.

This SOP applies to all UHL research records stored and managed within Florence and all personnel engaged in the collection, creation, maintenance, and/or storage of research records within Florence.

## 2. Policy Standards and Procedures

### 2.1. Definitions

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| Certified Copy | A reproduction of original information that has been verified against the original and endorsed by the signatory as a true and accurate copy, with all of the same attributes and information as the original. |
| Binder | The key organisational concept used in Florence. An electronic Binder mirrors a traditional trial site file, and contains folders, documents, logs, and/or placeholders. One Binder will be assigned per Trial. All aspects of a clinical trial's records can be managed within the Binder. |
| Electronic Signature | Data in electronic form that is attached to or logically associated with an electronic record and used by the signatory in place of a handwritten signature. |
| Essential Records | The records, data and metadata – regardless of format – that are linked to a clinical trial and collectively allow verification that the trial was performed in accordance with GCP and all applicable regulatory requirements, and that the trial results are reliable. Please refer to ICH GCP for records that are considered essential records.<br>Good Clinical Practice (GCP) \| NIHR |
| Florence eBinders™ | A secure cloud-based electronic platform used for creation, management, storage, and oversight of essential clinical trial records. Can be used in place of paper regulatory binders (i.e. TMF, ISF). Supports electronic signatures, version control, audit trails, and remote |

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| | monitoring. |
| Role | A set of permissions that can be assigned to one or more Users. Common Roles are: Monitor, Investigator, Sub-Investigator, Coordinator, Team Admin |
| Source Data | The initial, original records in which clinical observations, findings, or activities related to a trial participant are first recorded (e.g. blood results, clinical charts, radiology reports, pharmacy records, medical consultations etc). Source data is collected to inform clinical study endpoints. |
| Study Monitor | For the purposes of this SOP, the term 'Monitor' describes any authorised individual who requires access to research records for regulatory or quality oversight of a clinical trial. This includes, but is not limited to, clinical trial sponsor representatives (e.g. CRA's, monitors, auditors) and representatives of regulatory authorities. Monitors can be internal or external to UHL. |
| Superuser | Member of the research team with additional user permissions |
| User | An authorised individual with access rights to the Florence eBinder system and an assigned Role. |

### 2.2. Access to Florence

To comply with data protection regulations and UHL governance requirements, access to Florence is strictly controlled and limited to authorised staff. Access will be granted only where it is necessary for an individual's operational responsibilities, and only after the required training has been completed. When accessing and updating Florence, staff must comply with Trust standards for record-keeping and information governance. Authorised staff must only access research records that are required to fulfil their role.

Maintenance of User Accounts, User Roles, and User access in Florence will be undertaken by the R&I Corporate Florence team. Periodic reviews will be conducted to verify the status of all Users.

The creation and termination of User accounts must be authorised by an Investigator or designated manager. The individual requesting access is responsible for verifying the User, and the purpose and scope of their access to UHL systems. R&I Admin should be notified if access is required.

Role permissions within Florence will be assigned according to delegated study tasks or operational requirements.

All Users will be allocated a unique, secure, ID and private password, which must be kept secure and not shared. For added security, Users will also be required to activate multi-factor authentication. Florence password policies are configured at R&I Admin team level and will require reset every 180 days. Access will be periodically checked and revoked where necessary.

Written requests for new Team Accounts in Florence may be submitted to R&I Admin by any registered User. R&I Admin will forward the Team creation request to the Florence Administrator for approval and documentation prior to the creation of any new Team.

When research delivery staff access to Florence is no longer required, the relevant Department Superuser, local research manager or study investigator are responsible for ensuring that User access is promptly removed. For all other staff, responsibility for removing User access lies with the local service manager.

### 2.2.1. User Account Creation

The User must provide the following information to their Department Super User or the Florence Administrator to request account initiation:

- First Name
- Last Name
- Study Team Affiliation
- Authorised Organisation
- Email Address

The Florence Administrator, Department Superuser or designee will arrange for new Users to be trained on Florence and maintain a record of training.

### 2.2.2. User Account Initiation

The Florence Administrator or Department Superuser will initiate the new User's account.

The User's unique authorised organisation email address is added, an appropriate Role is assigned based on the organisation's approved Roles, and access dates are assigned to the new User. This will grant the User the permissions to perform delegated functions.

R&I Admin may assist in creating new Roles based on documented permission requests from the Florence Administrator in the R&I Office of Research however they may not assign Roles or access dates to specific Users. All assignments must be completed by the delegated Individual with the Team Set Up Role or designee.

The new User will receive an email notification from Florence with a link to the Florence eBinders™ URL to complete the User registration process.

### 2.2.3. User Account Modification

Upon a change in status impacting the use of Florence for a User, the Department Superuser or Florence Administrator will modify the User's Role(s) and Permissions and notify the User of the change(s).

R&I Admin may assist in modifying existing Roles based on documented requests from research teams. Written requests must include a list of all impacted Users as well as the modifications requested. R&I Admin will complete the request and provide a confirmation to the requesting team. The requesting team are responsible for verifying that Roles created and/or modified by R&I Admin are appropriate.

The Department Superuser Administrator or Florence Administrator must conduct periodic reviews of all User accounts to ensure that Users have the correct permissions and are still active.

Users are responsible for notifying the R&I Office if they change departments within R&I. This will ensure that the User has correct permissions and is active in their new department.

### 2.2.4. User Account Holds and Revocation

Temporarily inactive Users can have access dates turned off and Roles maintained without access, e.g. where Users are on temporary leave of absence, with plans to return.

Upon a change in employment status for a User that discontinues the need for specific Team access and/or all Florence use, the Department Superuser or designee removes all permissions for the User and removes the User from each appropriate Team in Florence.

#### 2.2.5. Team Termination

The requesting research team submits a written request to R&I Admin to terminate an existing Team. The request will specify any requests for record management and archiving based on local SOPs.

#### 2.2.6. Monitor, Auditor, and Inspector Access

Where required, access to Florence may be granted for the purposes of monitoring, audit, or regulatory inspection.

Access requests must be submitted by a designated UHL staff member. The requesting individual is responsible for verifying the identity of the nominated person(s), as well as confirming the purpose and scope of the requested access to the Florence system.

Monitors, auditors, and inspectors will be granted appropriate access to Florence in accordance with the procedures outlined in the Team Creation and User Access Control section of this SOP.

All User activity within Florence is recorded through the system audit trail to ensure traceability and accountability.

### 2.3. Electronic Record Management

The requirements for documentation, record keeping, and record retention apply equally to electronic records as they do to paper-based systems.

Essential records will be created, managed, stored, and presented electronically within the Florence system. Sponsors and auditors must be informed of this policy prior to study initiation and before any audits or regulatory inspections take place.

Trust-wide implementation of Florence is being introduced in phases. The initial phase focuses on the management of essential records required for trial set-up and the Confirmation of Capacity and Capability (C&C) process. This phase will be live for all applicable records from 1 April 2026.

Subsequent phases will introduce the wider functionality of the Investigator Site File (ISF) and Trial Master File (TMF) within the system.

If there is any uncertainty regarding the current stage of Florence implementation, staff should consult with the Florence implementation team for clarification.

Electronic security controls, secure backup schedules, and routine vulnerability testing are described in QMS-002 Florence Healthcare, Inc. Security Overview and the QMS- 006 Florence Healthcare Disaster Recovery Plan (DRP), both provided and maintained by Florence Healthcare, Inc.

Retention and/or destruction of electronic records in Florence at the conclusion of the study is performed in accordance with regulatory requirements and local policies and procedures.

Electronic records maintained within Florence must comply with data integrity principles (ALCOA+: attributable, legible, contemporaneous, original, accurate, complete, consistent, enduring, and available).

Electronic records stored in Florence are protected through system backup and disaster recovery procedures to ensure continued availability and protection against data loss.

Should an external sponsor not want to utilise Florence, this should be escalated to the R&I Deputy Director of Operations at the earliest opportunity.

Trial records should be uploaded to Florence in a timely manner to ensure the study records remain current and inspection-ready.

### 2.4. Electronic Certified Copies

Electronic records may consist of a combination of original records and certified copies.

An electronic certified copy is defined as a reproduction of original information that has been verified against the original and confirmed as an accurate and complete copy. The certified copy must preserve the context, content, and structure of the original record.

Electronic certified copies may be created where the original record exists in paper form and is required to be maintained within the Florence electronic system. The individual who has access to the original record and is responsible for its filing may create the electronic certified copy.

To create an electronic certified copy, the User will:

- Upload an electronic copy of the original document into Florence.
- Review the uploaded record to confirm it is complete, legible, and an accurate reproduction of the original.
- Apply a digital signature within Florence to certify that the uploaded document is a true and accurate copy of the original.

Florence maintains an audit trail that records the identity of the User, date and time of certification, and any associated actions taken on the document. This audit trail provides evidence of authenticity, traceability, and accountability.

### 2.5. Central Documents

Records that are applicable across multiple studies may be maintained centrally within the Central Binders section of Florence.

Links (shortcuts) may be used to allow Users to access central documents, as appropriate, based on the User's assigned access permissions. Shortcuts are intended for viewing and reference purposes only and should not be relied upon as part of the official study records required for archiving.

For archiving purposes, all documents relevant to a specific study, including all versions generated during the conduct of the trial, must be maintained within the protocol-specific eBinder or designated Archiving folders to ensure the completeness of the study record and appropriate documentation of trial activities.

Users should note that shortcuts always reflect the current version of the central document and will automatically update when a new version is issued.

Central documents may include, but are not limited to:

- Curriculum Vitae (CVs)
- Normal laboratory ranges
- Standard Operating Procedures (SOPs)
- Training records and certificates

### 2.6. Document Version Control

Version tracking within Florence can be utilised for draft documents, completed forms, logs, redacted documents, etc. Designated "Archive" folders can be used for version tracking of approved documents such as Informed Consent Forms, Protocols, Investigator Brochures, etc.

To verify compliance, the version tracking tool maintains each version of a document and logs modifications made by authorised Users, including data and time stamps.

### 2.7. Electronic Signatures

To be considered equivalent to handwritten signatures, electronic signatures must be unique to an individual, attributable, and linked to the electronic record with an audit trail, within a validated system. Since Florence meets this requirement, using Florence to apply electronic signatures to electronic research record is the legally binding equivalent of a handwritten signature on paper document.

The following requirements apply to the use of electronic signatures in Florence:

- Users are responsible for regularly reviewing their Florence accounts for any pending signature requests.
- The Principal Investigator (PI), or delegated individual, will verify the identity of each Florence User in accordance with the Team Creation and User Access Control section of this SOP. Where applicable, identity verification may also occur through the email-based User registration process for non–Single Sign-On (SSO) Users.
- The Department Superuser Administrator, or designee, is responsible for ensuring that Users are assigned appropriate permissions and access levels to request signatures and/or sign documents within Florence.
- Electronic signatures may be used for documents stored in Florence, including clinical trial agreements (CTAs) and contracts processed through the R&I Contracts Office. Where required, Users may also utilise alternative signature processes such as DocuSign or wet-ink signatures in accordance with organisational requirements.
- Electronic signatures must be unique to the individual User. Within Florence, the User's UHL email address serves as the unique identifier associated with their electronic signature.
- When a document is signed in Florence (via Addendum or Stamp signature), the details of each electronic signature are recorded on the signature addendum page, which can be included when the document is downloaded. When the Stamp signature option is used, the signature is also visible directly on the document.
- Electronic signatures apply only to the specific version of the document being signed. If a new version of the document is created, signatures from previous versions will not carry forward. Any updated version requiring review, acknowledgement, or approval must be signed by the appropriate Users.
- The Addendum (invisible) signature option and the Stamp (visible) signature option are considered equivalent and may be used interchangeably. Both signature types retain the required signature metadata and audit trail information to meet UK regulatory and Good Clinical Practice (GCP) requirements.

#### 2.7.1. Signature Requests

Signature requests can be made by individuals with the appropriate permission and access to do so within Florence. The individual requesting an electronic signature is required to specify:

- Document that requires the electronic signature(s)

- User(s) who need to sign the document
- Reason/meaning of the signature (Approval, Acknowledgment, Authorship, Certified Copy, Responsibility, or Review)
- Optional Signature Type, either Addendum (invisible on the document) or Stamp (visible on the document).
- Optional Sign by Date to specify the date by which the document must be signed.

#### 2.7.2. Signing Documents

The individual signing the document reviews the document and the requested reason for their signature in Florence. If they agree, the username (authorised organisation email address) and password (or signing PIN) are entered, and the system confirms that they match the User's verified secure credentials. The signature addendum page and audit trail for the document are updated to reflect the new electronic signature, its reason/meaning, and the date and time of execution.

#### 2.7.3. Signature Log

The purpose of the Signature Log is to have a record of the handwriting sample of every individual involved in study-related activity. An individual Signature Log should be maintained for each team member who participates on a study or trial that uses wet-ink handwriting. At a minimum, the Signature Log will include:

- Printed name
- Signature
- Initials
- Date when the signature log was completed

The Department Superuser or requesting research team will initiate the Signature Log with each new User. Each Team member should provide a complete handwritten copy of the Signature Log to the Department Superuser or the requesting research team. Each completed Signature Log will be uploaded and stored in Florence. In case of a name change for a Team member, a new Signature Log must be created and uploaded to Florence.

### 2.8. Email Correspondence

In accordance with UHL and sponsor requirements, all relevant study- and trial-related correspondence with participants, sponsors, research locations, and study team members must be retained to ensure appropriate documentation of trial activities and for review during monitoring, audit, or inspection.

Users may forward emails and any associated attachments to the appropriate location within Florence using the 'Import via Email' function, provided they have the necessary system permissions.

Key trial correspondence must be stored within Florence as part of the study documentation.

Once emails are imported into Florence, authorised Users may rename the email records for organisational purposes, provided that the content and integrity of the original correspondence remain unchanged.

### 2.9. Signature and Delegation of Authority Logs

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 Electronic Investigator Site Files (eISF) documents as well as the Delegation of Authority Log (DoAL).

#### 2.9.1. Delegation of Authority Log (DoAL)

The purpose of the study-specific DoAL includes:

- Documentation of the roles and responsibilities of those on the study team
- Evidence of PI authorisation of delegated duties
- Notification to study team members of their responsibilities
- Record of duration of study involvement

A DoAL must be maintained for all clinical research, with a separate DoAL for each study. Prior to initiation and for the duration of the study, the PI is responsible for reviewing study requirements and determining assigned duties in the DoAL.

The PI is responsible for ensuring that all applicable regulations, institutional policies, and any protocol-specific requirements are followed when delegating study-related duties.

All individuals with delegated study responsibilities must be listed on the DoAL, including the PI. The DoAL must be kept up to date, with delegated duties clearly recorded and updated as they change. If an individual leaves, an end date must be recorded and signed by the PI.

#### 2.9.2. Initiation of the DOAL on Florence

The Research Coordinator or designee for each study will initiate the DOAL on Florence, as directed by the PI. The appropriate columns for each team member should be completed at the initiation of the DOAL and uploaded to Florence. The Research Coordinator or designee will request an electronic signature from each study team member listed on the DOAL as acknowledgment of their assigned duties. The Clinical Research Coordinator or designee will then request an electronic signature from the study Investigator as approval of assigned duties, indicating its effective date.

No study related duties may be performed until both the PI and the study team member have signed the DOAL. The DOAL must be updated whenever a new member of staff joins the study team, when a delegated individual's role in the research changes, when an individual's employment status changes, if the individual is no longer a member of the research team and/or the study closes.

## 3. Training Requirements

Before accessing Florence, study personnel must have completed all relevant Florence training required for their role, and all mandatory UHL Information Governance training.

Mandatory Florence Study Team Training is provided by the R&I Florence Team through the Florence learning platform (Flo University) and is delivered as an online, self-directed training package. Details of how to access the training and the required learning modules are communicated by the R&I Florence Team.

Upon successful completion of the Florence Study Team Training, Users must download the training completion certificate generated by Flo University. The certificate must be uploaded to the appropriate training section within the Central Binder in Florence as evidence of training completion. In-person

training sessions, demonstrations and refresher training may also be provided upon request by the R&I Digital Transformation Lead or their nominated delegate, where appropriate.

As new features or functionality are introduced, additional guidance will be issued by the R&I Florence Team in the form of R&I templates, available through the R&I SOP Library.

## 4. Monitoring Compliance

| What will be measured to monitor compliance | How will compliance be monitored | Monitoring Lead | Frequency | Reporting arrangements |
|---|---|---|---|---|
| Review of User accounts to ensure access is appropriate to User role and removed when no longer required | Internal audit of current Users | R&I Deputy Director of Operations | Ongoing, as part of routine audit plan | Non-compliance reported to R&I Governance Meeting |
| Verification that all Users have completed required training and evidence of completion available within the Central Binder | Internal audit of training records against User lists | R&I Deputy Director of Operations | Ongoing, as part of routine audit plan | Non-compliance reported to R&I Governance Meeting |
| Confirmation that required records are present in Florence Trial Master Files and Investigator Site Files within Florence and maintained in an inspection-ready state. | Check of file structure and contents against GCP and regulatory requirements | R&I Deputy Director of Operations | As part of study monitoring plan | Non-compliance reported to R&I Governance Meeting |

## 5. Equality Analysis Assessment

The Trust recognises the diversity of the staff and local community it serves. Our aim therefore is to provide a safe environment free from discrimination, harassment and victimisation and treat all individuals fairly with dignity and respect and, as far as is reasonably possible, according to their needs.

As part of its development, an Equality Analysis on this policy has been undertaken and its impact on equality has been reviewed and no detriment was identified.

### EDI Statement

We are fully committed to being an inclusive employer and oppose all forms of unlawful or unfair discrimination, bullying, harassment and victimisation.

It is our legal and moral duty to provide equity in employment and service delivery to all and to prevent and act upon any forms of discrimination to all people of protected characteristics: Age, Disability (physical, mental and long-term health conditions), Sex, Gender reassignment, Marriage and Civil Partnership, Sexual orientation, Pregnancy and Maternity, Race (including nationality, ethnicity and colour), Religion or Belief, and beyond.

We are also committed to the principles in respect of social deprivation and health inequalities.

Our aim is to create an environment where all staff are able to contribute, develop and progress based on their ability, competence and performance. We recognise that some staff may require specific initiatives and/or assistance to progress and develop within the organisation.

We are also committed to delivering services that ensure our patients are cared for, comfortable and as far as possible meet their individual needs.

## 6. Supporting references

SOP J-5001 - Managing Essential Research Documentation, the TMF and the ISF

SOP J-5014 - Archiving of Essential Research Documentation

SOP S-1007 - UHL Monitoring

SOP S-1036 - UHL Audit

ICH-Good Clinical Guidelines E6 (R3)

## 7. Key Words

Research, Innovation, Florence, eBinders, Electronic Records, Trial Master File, Site File

| CONTACT AND REVIEW DETAILS | |
|---|---|
| **Policy Lead:**<br>Jen Boston<br>R&I Deputy Director of Operations | **Executive Lead:**<br>Professor Nigel Brunskill<br>Director of Research & Innovation |
| **Details of changes made during review:**<br>N/A | |