

UNIVERSITY OF MINNESOTA



Standard Operating Procedure: Use of Florence for Electronic Records and Electronic Signatures

Version 2, dated 12/1/2020

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1. Purpose

- 1.1. Federal regulations require documentation of all study-related activities. Investigators are responsible for maintaining study documents in accordance with applicable federal regulations, International Conference on Harmonization (ICH) Good Clinical Practice (GCP) Guidelines, Health Insurance Portability and Accountability Act of 1996 (HIPAA) requirements, and departmental procedures.
- 1.2. At all times, study documents must be readily accessible for review and/or inspection by the regulatory agency (i.e., US Food and Drug Administration (FDA)), the Institutional Review Board (IRB) of record, study sponsor and/or sponsor's representative, and/or organizational personnel as appropriate.
- 1.3. This Standard Operating Procedure (SOP) describes the identification and storage of regulatory Essential Documents for clinical research studies and trials in Florence eBinders™, outlines how the Organizational Administrator(s) controls user access, describes how electronic documents are managed and how electronic signatures are applied to documents.

2. Scope

- 2.1. This SOP applies to all electronic records for the clinical research studies and trials where Florence eBinders™ is utilized by this organization. Documents with more than one purpose or that are applicable to more than one study (e.g., investigator professional licenses, site facility information, laboratory normal ranges, etc.) may be stored centrally, in a non-study specific location.
- 2.2. This SOP applies to departments who use Florence eBinders™, and to personnel engaged in the collection, creation, completion, maintenance, and/or storage of Essential Documents from the planning and study startup stage through study completion/archival, effective for studies starting on or after June 26, 2020.
- 2.3. Legacy studies are defined as studies that were activated prior to the use of Florence. Legacy documents may be either:
 - 2.3.1. Scanned: Legacy original paper documents will be maintained following the department's current Regulatory Binder SOP until the time period when they can be scanned, verified for completeness and signed as certified copies. As time permits, legacy documents will be uploaded into Florence at which point it will comply with this SOP.
 - 2.3.2. Not scanned (applicable to departments except MCC CTO): Legacy documents will be maintained following the department's current Essential Documents SOP.
- 2.4. This SOP excludes the following Essential Documents which will be maintained following the organization's and departments' current SOPs:
 - 2.4.1. Contracts (e.g. Clinical Trial Agreement, work order, financial agreement between the investigator/institution and the sponsor for the trial)
 - 2.4.2. Research participants' source documents, signed consent forms, and Case Report Forms
 - 2.4.3. Investigational product accountability records

3. Responsibilities

- 3.1. The study staff of each study binder are responsible for maintaining study documents in a timely and organized fashion.
 - 3.1.1. External staff (defined as external to the University and Fairview) participating in multisite studies will be responsible only for maintaining study documents in their site-specific folders.
- 3.2. The Team Owner role is assigned to one individual at the institution. The Area Manager role may be assigned to department-level managers.
- 3.3. The Team Owner, Area Manager(s) or designee develops the Binder structure template for indexing the storage of electronic study documents.
- 3.4. The Team Owner, Area Manager(s) or designee is responsible for ensuring that the appropriate Users (including external monitors and auditors), have the necessary access and permissions to conduct document management, completion, review, and archiving as detailed in the Team Access Control section below.
- 3.5. The Team Owner will have the capability to access all records in the system, except for documents identified as containing PHI based on the use of redaction and/or PHI flag assignment in the Florence multisite study folders, and provided the individual has completed UMN HIPAA training. All document views are automatically recorded in the audit trail, which is not alterable by the Team Owner.
- 3.6. External staff have sole control of site records. To ensure sole control of a site's electronic records and protect the availability of eISF documents that are created, modified, and signed in Florence, access to site designated Binder and Folder location(s) will be maintained as outlined in Section 4.9.

4. Policies and Procedures – Team Creation and Access Control

- 4.1. The process of maintenance of Team Accounts, User Accounts, User Roles, and User access in the Florence eBinders™ system, including how to create or delete a Team Account as well as how to create, modify, or revoke a User Account.
- 4.2. Team Owner will approve the creation and termination of all new Teams and delegate which Users will be the Area Manager(s).
- 4.3. The Team Owner will determine Role permissions based on designated study related tasks.
- 4.4. The Team Owner, Area Manager(s), or designee will create, modify, and terminate User accounts, assign Roles, manage access dates, and conduct periodic reviews to verify the status of all Users.
- 4.5. The Team Owner may submit a written request to Florence Support to assist with creating new User accounts.
- 4.6. End users or supervisors should notify the Team Owner or Area Manager(s) about any change of employment status, including holds (e.g., termination of employment or leave of absence).
- 4.7. All end users with a UMN account will use Single Sign-On for authentication and will comply with UMN password requirements. All non-UMN users are required to maintain a unique, secure, and private password. . For users using Single Sign-On (SSO) for authentication, Florence signing personal identification numbers (PINs) are used to sign documents. Florence Password and PIN reset policies are configured at the Team level.

- 4.8. Written requests for new Team Accounts in Florence eBinders™ may be submitted to Florence Support by any registered organization User. Florence Support will forward the Team creation request to the Team Owner for approval and documentation of the delegated Team Owner prior to the creation of any new Team.
- 4.9. User accounts may be created for external staff (defined as external to the University and Fairview) participating in UMN-led multisite studies. Upon study closure, external staff members' access to their site-designated Binder and Folder location(s) will be updated to permit view and download capabilities only.
- 4.10. User Account Creation:
 - 4.10.1. Prospective end-user makes access request via online form.
 - 4.10.2. HIPAA Training is required for eBinders access. UMN Staff must complete HIP019 HIPAA Training. Non-UMN staff must submit proof of equivalent HIPAA training or complete the above course as well.
 - 4.10.3. The Supervisor or Organization Approvers (where identified) will approve or deny access via the online request form and will indicate the appropriate access level.
 - 4.10.4. The Team Owner, Area Manager(s) or designee will arrange for the new User to be trained on Florence eBinders™.
 - 4.10.5. Upon completion of the training, the new User shall submit acknowledgment of completed training to the Team Owner, Area Manager(s) or designee as outlined in the organization's policy to receive access to Florence eBinders™. *Note: The Florence Training Attestation form serves as additional that a user's specific electronic signature is the legally binding equivalent of the signer's handwritten signature.*
- 4.11. User Account Initiation:
 - 4.11.1. The Team Owner, Area Manager(s) or designee will initiate the new User's account.
 - 4.11.2. The User's unique authorized organization email address is added, an appropriate Role is assigned based on the organization's approved Roles, and access dates are assigned to the new User. This will grant the User the permissions to perform delegated functions.
 - 4.11.2.1. When user's access to study binders is to correspond with the user's OnCore assignments, the OnCore integration will grant the user access to the appropriate binders and roles, based on their OnCore assignments.
 - 4.11.2.2. When user's access is not to correspond with their OnCore assignments, the user will to be manually added to the binder with appropriate role(s).
 - 4.11.3. Florence Support may assist in creating new Roles based on documented permission requests from the Team Owner, Area Manager(s) or designee however they may not assign Roles or access dates to specific Users. All assignments must be completed by the delegated Team Owner, Area Manager(s) or designee.
- 4.12. User Account Modification:
 - 4.12.1. Upon a change in status impacting the use of Florence eBinders™ for a User, the Team Owner, Area Manager(s) or designee modifies the User's Role(s) and Permissions and notifies the User of the change(s).

4.12.2. Florence Support may assist in modifying existing Roles based on documented requests from the Team Owner, Area Manager(s) or designee. Written requests must include a list of all impacted Users as well as the modifications requested. Florence Support will complete the request and provide a confirmation to the Team Owner, Area Manager(s) or designee. The Team Owner, Area Manager(s) or designee are responsible for verifying that Roles created and/or modified by Florence Support are appropriate.

4.12.3. The Team Owner, Area Manager(s) or designee must conduct periodic reviews of all Users in Florence eBinders™ to ensure that all Users have the correct permissions and are still active.

4.13. User Account Holds and Revocation:

4.13.1. Temporarily inactive Users can have access dates turned OFF and Roles maintained without access. Examples of temporarily inactive Users includes Users on a leave of absence, with plans to return.

4.13.2. Upon a change in employment status for a User that discontinues the need for specific Team access and/or all Florence eBinders™ use, the Team Owner, Area Manager(s) or designee removes all permissions for the User and removes the User from each appropriate Team in Florence eBinders™.

4.14. Team Owner Modification:

4.14.1. The Organizational Administrator submits a written request to Florence Support to modify the Florence eBinders™ Team Owner. Florence Support will make the modification and provide confirmation of the update to the Organizational Administrator.

4.15. Team Termination:

4.15.1. The Organizational Administrator submits a written request to Florence Support to terminate an existing Team. The request will specify any requests for document management and archiving based on the Team's established SOP.

5. Policies & Procedures –Electronic Document Management

5.1. Requirements for documentation, record keeping, and record retention apply to electronic records as they do for paper systems.

5.2. 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.

5.3. User access control to electronic documents is described in the Team Creation and User Access Control section above.

5.4. Electronic security controls, secure backup schedule, and routine vulnerability testing are described in the Florence eBinders™ Security Overview provided and the Florence Healthcare Disaster Recovery Plan, both provided and maintained by Florence Healthcare, Inc.

5.5. Retention and/or destruction of electronic documents in Florence eBinders™ at the conclusion of the study is performed in accordance with local institution/IRB/IEC policies and procedures as established in U.S. Federal regulations.

5.6. Electronic certified copies

5.6.1. Electronic documents may include a blend of original and certified copies. Electronic certified copies are defined as copies that have been created and verified against the original and tracked with a dated signature. Electronic signatures with an audit trail demonstrate evidence of authenticity. Per ICH E6(R2), the data is to include the context, content, and structure, as the original. For studies regulated by the US FDA, the copy is to have all of the same attributes and information as the original.

5.6.1.1. For consent forms, refer to Fairview's SOP on creating the Electronic Certified Copy in EPIC.

5.6.2. Only the User who possesses the original copy may create the Electronic Certified Copy.

5.6.3. The User who possesses the original copy of the Document will upload a electronic copy of the Document into Florence eBinders™, review and verify the uploaded Document for completeness and readability and then sign the Document as a Certified Copy.

5.6.4. The audit trail will track and record the timestamp, reason, and author for authenticity and responsibility.

5.7. Central Documents and General Files

5.7.1. Documents that will be used across studies can be maintained centrally. This can be a combination of a single central file binder across all departments and department-specific central file binders.

5.7.2. Links, or shortcuts, will allow Users to access central documents as appropriate based on the User's access controls assigned. Shortcuts are to be used for viewing purposes and not as part of the official study records needed for archiving. Note: Shortcuts reflect the document's current version and are updated with each new version.

5.7.3. Central documents may include, but are not limited to CVs, medical licenses, CAP/CLIA, lab normal ranges, SOPs, CITI training, and HIPAA training.

5.8. Monitor, Auditor, and Inspector Access

5.8.1. Monitors, auditors, and inspectors will be given access to Florence eBinders™ by following the guidelines described in the Team Creation and User Access Control section above.

5.8.2. All access is monitored via the audit trail.

5.9. Document Version Control

5.9.1. Version tracking within Florence eBinders™ can be utilized for draft documents, completed forms, logs, redacted documents, etc. Alternatively, per Team's preference, designated "Archive" folders can be used for version tracking of approved documents such as IRB approved Informed Consents, Protocol Versions, etc.

5.9.2. The version tracking tool maintains each version of the document and the audit trail logs, the action of modification by authorized Users, date of modification, as well as the time stamp of modification to verify compliance with GCP.

6. Policies & Procedures – Electronic Signatures

6.1. This section applies to all documents and clinical research studies and trials where Florence eBinders™ is utilized by this organization and where electronic signatures and handwritten

signatures executed to electronic documents are intended to be equivalent to paper records and handwritten signatures.

- 6.2. For clinical trials regulated by the US FDA, the Organizational Administrator, or other delegated individual will complete and submit a non-repudiation letter to the FDA prior to the use of electronic signatures on any clinical trial document attesting to the fact that their electronic signatures are legally binding equivalents of their traditional hand-written signatures.
 - 6.2.1. Study staff at organizations other than the University of Minnesota will be permitted to use electronic signatures for FDA-regulated studies upon providing documentation that their department or institution has submitted a letter of non-repudiation to the FDA that either specifically includes the use of Florence eBinders™ through the University of Minnesota or covers the use of Florence eBinders™ as part of a blanket statement.
- 6.3. Users are responsible for reviewing their accounts for pending signature requests on a regular basis.
- 6.4. The Team Owner, Area Manager(s) or designee will verify the identity of each Florence eBinders™ User per the Team Creation and User Access Control section and if applicable, via the email-based User registration process for non-SSO Users. The Team Owner, Area Manager(s) or designee is also responsible for ensuring that the appropriate individuals have the necessary User permissions and access to request signatures and/or sign documents in Florence eBinders™.
- 6.5. Electronic signatures may be used for all documents stored in Florence eBinders™. Each electronic signature shall be unique, using the individual's organization email address as the unique identifier in Florence eBinders™.
- 6.6. When a document is signed in Florence (via Addendum or Stamp), the details of each electronic signature is listed on the signature addendum page, which can be included when the document is downloaded. If the Stamp signature option is used, the signature is also visible on the document itself.
- 6.7. Signatures only apply to the version of the document signed. Any updates to a version of the document do not carry over signatures from the previous version. Any updates which require review, acknowledgment, and/or approval must be signed by the appropriate Users.
- 6.8. Use of the Addendum (invisible) signature option and the Stamp (visible) signature option are seen as equivalent and can be utilized on all electronic documents interchangeably as both signature types maintain the details required by US FDA 21 CFR Part 11.
- 6.9. Signature Requests
 - 6.9.1. Signature requests can be made by individuals with the appropriate permission and access to do so within Florence eBinders™.
 - 6.9.2. The individual requesting an electronic signature is required to specify:
 - 6.9.2.1. Document that requires the electronic signature(s)
 - 6.9.2.2. User(s) who need to sign the document
 - 6.9.2.3. Reason/meaning of the signature (Approval, Acknowledgment, Authorship, Certified Copy, Responsibility, or Review)
 - 6.9.2.4. Optional Signature Type, either Addendum (invisible on the document) or Stamp (visible on the document).

6.9.2.5. Optional Sign by Date to specify the date by which the document must be signed.

6.10. Signing Documents

6.10.1. The individual signing the document reviews the document and the requested reason for their signature in Florence eBinders™.

6.10.2. If s/he agrees, the username (authorized organization email address) and password (or signing PIN) are entered, and the system confirms that they match the User’s verified secure credentials.

6.10.3. 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.

7. References

7.1. Florence eBinders™ V2 User Guide

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

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

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

7.2.3. Use of Electronic Records and Electronic Signatures in Clinical Investigations Under 21 CFR Part 11 - Questions & Answers ([here](#))

7.3. US FDA 21 CFR Part 312.62(c) – Investigational New Drugs – Drugs for Human Use ([here](#))

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

7.5. US FDA Industry Guidelines and Information Sheets ([here](#))

7.6. FDA Compliance Policy Guidance Programs ([here](#))

7.7. E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1), Guidance for Industry ([here](#))

7.8. IHC GCP Essential Documents for the Conduct of a Clinical Trial ([here](#))

8. SOP History

Version	Changes/Reason	Approval Date	Effective Date
1	N/A – Initial Version	7/1/2020	7/1/2020
2	Added provisions to allow external site staff access to multisite study binders.	12/1/2020	12/1/2020