Procedure Name: Use of Florence for Electronic Records and Electronic Signatures	**Number:** SOP 24 v1.0
Subject: Clinical Research	**Effective Date:** 22FEB2024
Linked Policy: Clinical Research Operations & Compliance Policy	**Revised Date:** 22FEB2024

PURPOSE:

- 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.
- At all times, study documents must be readily accessible for review and/or inspection by the Food and Drug Administration (FDA), approving Institutional Review Board (IRB), and/or organizational personnel as appropriate.
- This Standard Operating Procedure (SOP) describes the identification and storage of regulatory Essential Documents for clinical research studies and trials in Florence Electronic Investigator Site File (eISF) and establishes the process by which roles and responsibilities are delegated to applicable personnel.

SCOPE:

- This SOP applies to all electronic records for the clinical research studies and trials being conducted at George Washington University where Florence eISF is utilized. Documents with more than one purpose or that are applicable to more than one study (e.g., CV's investigator professional licenses, site facility information, laboratory normal ranges, etc.) may be stored centrally, in a non-study specific location.
- This SOP applies to personnel engaged in the collection, creation, retrieval, modification, maintenance, transmittal and/or storage of Essential Documents from the planning and study startup stage through study completion/archival, effective for studies starting on **22 FEB 2024**This SOP does not apply to legacy studies.
    - Legacy studies are defined as studies that were activated prior to the use of Florence. Legacy documents will be:
        - Imported: Legacy documents will be maintained following the organization's current Essential Documents SOP (reference: SOP 3) until the time period when they can be imported, verified for completeness and signed as certified copies.
        - Not imported: Legacy documents will be maintained following the organization's current Essential Documents SOP 3

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- If legacy studies choose to be uploaded into Florence, a Note to File should be added to the regulatory binder noting documents are now stored electronically in Florence. .

- This SOP excludes the following Essential Documents which will be maintained following the organization's current SOP 3
  - Original wet-ink signed contracts-if an essential document is wet inked, a copy will be scanned and uploaded in Florence and the original wet ink document will be maintained in a separate binder on site
- This SOP includes the following records with Protected Health Information (PHI), which will be maintained following the organization's current SOP 6
  - Documents with PHI may include, but are not limited to, e-Consent/scanned informed consent forms

RESPONSIBILITY:

All Users must have the appropriate **training, education, experience, and access** (e.g., roles and permissions) to perform their assigned tasks.

- User Accounts and Access:
  - The Site Admin or designee is responsible for ensuring new Users (including any external auditors, monitors or inspectors) are trained on Florence eISF prior to granting access to the system.
  - The Site Admin or designee is responsible for **assigning** Role permissions based on designated study related tasks.
  - The Site Admin or designee is responsible for the **creation, modification, and termination** of User accounts for all Users (including any external auditors, monitors or inspectors) assigning Roles and managing access dates in Florence eISF.
    - The User requesting a new account will provide the Site Admin with the their first name, last name, organizational email address, documented HIPAA training (for GWU personnel), and proof of completion of eBinders training prior to an account being created.
    - Upon a change in employment status for a User that discontinues the need for specific Team access and/or all Florence eISF use, the Site Admin or designee is responsible for removing all permissions for the User and removing the User from each appropriate Team in Florence eISF. The User or the User's supervisor should notify the Site Admin about any change in

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employment status that would necessitate a change in role or removal from Florence eBinders.

- Temporarily inactive Users can have access dates turned OFF and Roles maintained without access. Examples of temporarily inactive Users include Users on a leave of absence, with plans to return.
- The Site Admin or designee is responsible for **periodically reviewing** all roles and permissions to ensure that all Users (including any external auditors, monitors or inspectors), are authorized to perform the available task(s).

- All Users are responsible for maintaining a **unique, secure, and private password.**
  - All Users with a GWU account will use Single Sign-On (SSO) for authentication. For Users using Single Sign-On, Florence signing personal identification numbers (PINs) are used to sign documents. Passwords and signing PINs are to be periodically checked, recalled, and revised as necessary. Password and PIN policies are configured at the team level. Passwords and PINs will require reset every 180 days.
- Each User's identification code (e.g., email address or Username) and **password/PIN** must be periodically checked, recalled, or revised.
- When granting external Sites with access to Florence (Review Florence Monitor Access Guidance Document), Site Users have sole control of their site records. To ensure sole control of a site's electronic records and protect the availability of the site's records that are created, modified, maintained and/or signed in Florence, the **Site Admin** or designee will ensure that an agreed-upon procedure is in place with each site if and when the site no longer has access to Florence (e.g., sites retain ongoing access to view and download and/or sites are trained to export/download records at study closeout/completion/closure, etc.).
- <u>Team, Binder Structure, and Document Management:</u>
  - The Site Admin is responsible for facilitating the creation, approval, and termination of any new Team member. The request will specify any requests for document management and archiving based on any applicable organizational SOP's
  - The Site Admin or designee is responsible for developing the Binder structure template for indexing the storage of electronic study documents. A User with the Site Admin role will have the ability to access all records in the system; all document views are recorded in the audit trail, which cannot be altered.

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- The **research team members** or designee is responsible for maintaining study documents in a timely and organized fashion.

- All Users utilizing **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 assure their **signature manifestation** includes all components required per applicable governing regulatory bodies.
  - Signatures are performed only by the authenticated User.
  - For clinical trials regulated by the US FDA, GWU has submitted 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.
  - Responsibility
    - This SOP serves as documentation to hold individuals accountable and responsible for actions initiated under their electronic signatures, in order to deter record and signature falsification.

REFERENCES:

- Florence Compliance Team Key Training Resources: FDA (Part 11 Predicate Rules) ICH, GCP EU/UK GDPRand More!
- US FDA 21 CFR Part 11 Electronic Records; Electronic Signatures
  - General Principles of Software Validation; Final Guidance for Industry and FDA Staff
  - Part 11, Electronic Records; Electronic Signatures – Scope and Application
  - Use of Electronic Records and Electronic Signatures in Clinical Investigations Under 21 CFR Part 11 - Questions & Answers
- US FDA 21 CFR Part 312.62(c) – Investigational New Drugs – Drugs for Human Use
- US FDA 21 CFR Part 812 – Investigational Device Exemption
- US FDA Industry Guidelines and Information Sheets

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- FDA Compliance Policy Guidance Programs
- E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1), Guidance for Industry