Procedure Name: Use of Florence eConsent for Electronic Informed Consent (eConsent)	**Number:** SOP 16 v1.0
Subject: Clinical Research	**Effective Date:** April 06, 2023
Linked Policy: Clinical Research Operations & Compliance Policy	**Revised Date:** April 06, 2023

PURPOSE:

The George Washington University (GWU) and GWU Medical Faculty Associates (MFA) are utilizing Florence Healthcare Inc.'s eConsent platform to sign and store all applicable electronic forms that are involved in the consenting process. Florence Healthcare is US Food and Drug Administration (FDA) 21 CFR 11 Compliant for eSignatures.

Investigators are responsible for ensuring that the informed consent form is signed and personally dated by the subject or by the subject's legally acceptable representative, and by the person who conducted the informed consent discussion prior to a subject's participation in the trial; 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 GWU MFA Informed Consent Guidance Document.

At all times, the informed consent forms must be readily accessible for review and/or inspection by the regulatory agency (i.e., US Food and Drug Administration (FDA)), and/or organizational personnel as appropriate.

SCOPE:

For general use of Florence, refer to ADM-104 Use of Florence eBinders for Electronic Records and Electronic Signatures. For eConsent use of Florence, this Standard Operating Procedure (SOP) applies.

This SOP describes the signing, distribution and storage of all applicable electronic forms that are involved in the consenting process for clinical research studies where the Florence eConsent platform is being utilized.

Refer to the GWU MFA Informed Consent Guidance Document for details on how Informed Consent is obtained at the Study Center

Procedure Name: Use of Florence eConsent for Electronic Informed Consent (eConsent)	**Number:** SOP 16 v1.0
Subject: Clinical Research	**Effective Date:** April 06, 2023
Linked Policy: Clinical Research Operations & Compliance Policy	**Revised Date:** April 06, 2023

Refer to GWU MFA Informed Consent Guidance Document if the participant will be utilizing a paper Informed Consent for the trial

RESPONSIBILITY:

This SOP sets forth the responsibilities for research team members conducting clinical research at GWU/MFA/GWUH. The PI retains all clinical research responsibility unless the investigator has expressly delegated specific duties to research team members and the delegation (s) is documented on a study specific Delegation of Authority Log.

PROCEDURES:

Responsibilities

- Authorized individuals, the Site Admins are responsible for creating the study in Florence eConsent, and specifying any applicable identification verification questions.
- An authorized individual, the Form Manager, is responsible for maintaining correct versions of informed consent forms and updating all forms as required.
- Upon completion of required training, authorized individuals, the Site Admins, are responsible for specifying which users have access to Florence eConsent.
- An authorized individual, the Study and Staff Editor, is responsible for assigning and maintaining user-specific access control (e.g., access levels).
- All users must have the appropriate training, education, experience, and access (e.g., access levels) to perform their assigned tasks.
- Authorized individuals, the Site Admins, are responsible for periodically reviewing the level of access granted to all users (including internal and external users) to ensure all users are authorized to perform the available task(s).
- Each user's identification code (e.g., email address or username) and password/PIN must be periodically checked, recalled, or revised.
- All users utilizing electronic signatures shall ensure the following:
    a. Credentials are unique, secure, and remain confidential (i.e., not reused by, not reassigned to, and not shared with other individuals).
    b. Signatures are performed only by the authenticated user.

Procedure Name: Use of Florence eConsent for Electronic Informed Consent (eConsent)	**Number:** SOP 16 v1.0
Subject: Clinical Research	**Effective Date:** April 06, 2023
Linked Policy: Clinical Research Operations & Compliance Policy	**Revised Date:** April 06, 2023

c. 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.

- An authorized individual, the Participant Manager, is responsible for educating participants regarding participant responsibilities to provide accurate identification; and ensuring all participants are trained on the eConsent platform. Any training materials provided to the participant should be approved by the IRB prior to their use.
- An authorized individual, the Participant Manager and Primary Study Contact, are responsible for ensuring that participants understand how to execute an electronic signature prior to requesting their signature.

Site Personnel Training

- Upon completion of the training, the new User shall submit acknowledgement of completed training to the Site Admins to receive access to Florence eConsent. *Note: The Florence Training Attestation form serves as additional evidence that a user's specific electronic signature is the legally binding equivalent of the signer's handwritten signature.*
- All training records should be stored and maintained in the regulatory binder for any individual accessing the Florence eConsent system.

Electronic Signatures

- All Florence eConsent Users will be responsible for maintaining secure passwords and updating them at the interval specified by their governing organization.
- Users are responsible for reviewing their accounts for pending signature requests on a regular basis.
- The Study and Staff Editor or designee is also responsible for ensuring that the appropriate individuals have the necessary User access levels to sign forms in Florence eConsent.
- Clinical trials regulated by the FDA:
  a. Use of electronic signatures, archiving, and retention of electronic consent materials must meet the FDA "Part 11" requirements.
  b. The Primary Study Contact or designee will complete and submit a non-repudiation letter to the FDA prior to the use of electronic signatures on any

Procedure Name: Use of Florence eConsent for Electronic Informed Consent (eConsent)	**Number:** SOP 16 v1.0
Subject: Clinical Research	**Effective Date:** April 06, 2023
Linked Policy: Clinical Research Operations & Compliance Policy	**Revised Date:** April 06, 2023

clinical trial document attesting to the fact that their electronic signatures are legally binding equivalents of their traditional hand-written signatures.

c. Use of electronic signatures, archiving, and retention of electronic consent materials must meet the FDA "Part 11" requirements.

IRB Approval

- The reviewing IRB should review and approve the use of electronic informed consent prior to its use. This approval is needed in addition to the standard IRB approvals needed for paper informed consent.
- IRB approval of Florence eConsent for each study will be stored with the IRB approval for the study and paper consent forms in the regulatory binder and on the department shared drive in the appropriate study file.
- Any IRB utilized to govern a clinical trial at the site will have the option of two methods for reviewing and approving the use of Florence eConsent:
  a. IRB review of Florence eConsent system, not each eConsent form.
  b. To be used when an IRB considers a PDF version of a form to be identical to the paper consent form and only wants to view the function and usability of the system one time
  c. The reviewing IRB should specify the requested/required Florence eConsent information, access or training materials in order to review and approve the system.
  d. IRB review of the Florence eConsent forms for every study.
  e. To be used when an IRB wants to review the electronic version of the consent forms each time
  f. The reviewing IRB should specify the requested/required Florence eConsent information in order to review and approve the system and forms.

Review and Revision

The SOP Review Committee shall review this SOP every 2 years. This SOP may be reviewed more frequently if it does not reflect current operations.

Procedure Name: Use of Florence eConsent for Electronic Informed Consent (eConsent)	**Number:** SOP 16 v1.0
Subject: Clinical Research	**Effective Date:** April 06, 2023
Linked Policy: Clinical Research Operations & Compliance Policy	**Revised Date:** April 06, 2023

Attachments
IRB Memo

REFERENCES:

21 CFR 312.60	General responsibilities of investigators.
21 CFR 312.62	Investigator recordkeeping and record retention.
21 CFR 312.64	Investigator reports.
21 CFR 312.66	Assurance of IRB review.
21 CFR 812.40	General responsibilities of sponsors.
21 CFR 812.100	General responsibilities of investigators.
21 CFR 812.110	Specific responsibilities of investigators.
21 CFR 812.140	Records.
21 CFR 812.145	Inspections.
21 CFR 812.150	Reports.
ICH E6 (R2)	Integrated Addendum to International Council for Harmonization (ICH) E6 (R1): Guideline for Good Clinical Practice E6 (R2)
GWU MFA Clinical Research SOPs	SOP 02: Research Team Responsibilities

Procedure Name: Use of Florence eConsent for Electronic Informed Consent (eConsent)	**Number:** SOP 16 v1.0
Subject: Clinical Research	**Effective Date:** April 06, 2023
Linked Policy: Clinical Research Operations & Compliance Policy	**Revised Date:** April 06, 2023

	SOP 03: Regulatory Binder and Study File Maintenance
	SOP 04: Research Team Communications/Interactions with IRB
	GWU MFA eConsent Guidance Document
	GWU MFA eConsent Workflow
Florence Resources	• FDA Information Sheet - Informed Consent • FDA Use of Electronic Informed Consent - Q&A • Florence eConsent reference guides and/or ZenDesk articles

Office of Clinical Research | School of Medicine & Health Sciences
THE GEORGE WASHINGTON UNIVERSITY

Procedure Name: Use of Florence eConsent for Electronic Informed Consent (eConsent)	**Number:** SOP 16 v1.0
Subject: Clinical Research	**Effective Date:** April 06, 2023
Linked Policy: Clinical Research Operations & Compliance Policy	**Revised Date:** April 06, 2023

Office of Human Research

eConsent Memo for Clinical Research

Florence eConsent

Florence eConsent is designed to mimic the look and flow of paper-based informed consent to make the transition from paper to electronic consenting easy for participants. Participants can navigate and sign their informed consent forms from any internet enabled device, anywhere in the world, and access all studies and associated consents. Built-in compliance features include identity verification, IRB approval and expiration tracking, audit trails, version control and user permission options. All signatures completed within Florence eConsent are 21 CFR Part 11 compliant Advanced Electronic Signatures.

Risk Language

Risks to research participants using electronic signature consent documentation (or "eConsent") will be minimized by the eReg Support and Florence teams by using procedures which are consistent with sound research design, and which do not unnecessarily expose research participants to risk. Use of eConsent signatures carries the probability and magnitude of harm or discomfort anticipated in the research that is not greater in and of themselves than those ordinarily encountered in daily life or with wet-ink signature documents. We ask the IRB to consider that the benefit of eConsent signatures allows for wider access and greater utility by potential participant populations, and this benefit outweighs the potential risks. Use of eConsent will always be optional and voluntary, and participants will always have the option to use paper signature forms if they wish; the choice to decline using eConsent signatures will not affect participant enrollment eligibility. The principal risk would be potential harm resulting from a breach of confidentiality. Florence eConsent and the George Washington University Medical Faculty Associates and Cancer Center CRS eReg Support team have worked together to ensure that potential risks will be minimized to the highest extent through various features, including participant email address verification, in-person or telehealth conversations to confirm understanding and ask questions, comprehension questionnaires, and unique identity verification questions that can be customized for each study. In addition, eConsent risk language will be included in written consent forms and included for IRB review of the ICF, such as the example language below: You will have the option to sign this consent form electronically using an "e-signature".

Procedure Name: Use of Florence eConsent for Electronic Informed Consent (eConsent)	**Number:** SOP 16 v1.0
Subject: Clinical Research	**Effective Date:** April 06, 2023
Linked Policy: Clinical Research Operations & Compliance Policy	**Revised Date:** April 06, 2023

You will be given a unique user account to access, sign, and view the consent form. We will only keep information that could identify you long enough to match your responses your medical records, and for the duration of the study. This signed form may also become part of your personal medical record. We do not plan to share this information with anyone who is not connected to this research study. We will take steps to protect your confidentiality, but there is a small risk that your information could be accidentally disclosed to people not connected to the research. If you have any questions about using electronic signatures, you can email the Office of Clinical Research at: clinicalresearch@mfa.gwu.edu

Signature Lines

Florence eConsent allows users to customize the look and feel of their signature lines based on how their paper-based form is structured. Electronic signature manifestations completed within Florence eConsent contain the printed name of the signer, date and time of signing and meaning of the signature.