Florence e-Consent Guidance Document

Updated May 16, 2023

This guidance document applies to any research member who utilizes Florence e-Consent for clinical research studies.

Account Registration and Training

1. If a study plans on utilizing Florence e-Consent, please send an email to Site-Admin, Sarah Ford-Trowell (strowell@mfa.gwu.edu), in order to have a user account created and registered.
2. Once the account has been registered, all research team members will be asked to register for 'E-Consent for End Users' and complete the training here: https://academy.florencehc.com/econsent-for-end-users
3. After completion of the training, a certificate will be generated- please keep this certificate in the your regulatory folders and send a copy to Sarah Ford-Trowell so she can document the completed training as well.
4. After the certificate is received by the OCR, an Attestation of Florence e-Consent Training Completion will be routed through Florence for your e-signature. Again, please download the document and save it in your regulatory files.

e-Consent Workflow

When submitting a study in iRIS, note the use of wanting to utilize e-Consent and attach the IRB memo (see Attachments) to the final page of the IRB submission.

Complete and submit the e-Consent Request Google Form https://forms.gle/rzshBCJH9TtArNwP7 **AFTER** the study has been IRB approved. The Google Form will be routed to the Site Admins for the MFA, Sarah Ford-Trowell (strowell@mfa.gwu.edu) and cc'd , Radwa Aly, PhD (raly@mfa.gwu.edu). The IRB approved ICF and the following information is required in order to submit a study for e-Consent:

- Study Status
- Study Title and Protocol ID
- Name of PI
- Name of Sponsor or if the study is Investigator Initiated
- Department
- Industry or Non-Industry
- Target Enrollment Numbers
- Screening and Enrollment IDs (if applicable)
- Study Arms (if applicable)
- Sub-Studies
- Full name and number of primary study contact (same as in ICF)

FOR SITE ADMIN USE ONLY

Once the Google Form has been received from the research team, the Site Admins will Add New Study to the Florence e-Consent system with the information provided in the Google Form.

For the Participant Identity verification questions, always use Screening or Enrollment IDs Question 1.

After the New Study has been uploaded into the Florence system, the Primary Study Contact will be notified by Site Admins that their e-Consent has been generated. The Primary Study contact will be granted access into the system and can complete, edit, and monitor the e-Consent

ATTACHMENTS

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".

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.