Electronic Informed Consent (HRPP 6.1 Informed Consent)
Guidance / Frequently Asked Questions (FAQs)

A growing number of researchers are either conducting research at a distance or are moving to entirely computer-based models where all data and correspondence are collected and stored electronically.

The MUSC IRB has prepared this guidance along with policy wording to clarify the various approaches available to electronically obtain and document consent to participate in a research study. This guidance was developed to aid researchers who want to use an electronic process to document consent either as an alternative to or replacement of a paper-based consent process.

The MUSC policy was written to be consistent with federal regulations and joint FDA and OHRP guidance.

Q: What is electronic consent?

A: Electronic consent refers to the use of electronic systems and processes to obtain and document informed consent. An electronic consent process may be used to provide information usually contained within the paper informed consent document, to evaluate the subject's comprehension of the information presented, and to document the consent/assent of the subject or consent of the subject's LAR. It implies that researchers will use an electronic signature to document signed consent.

Q: How and where can an electronic consent process be conducted?

A: Electronic consent may take place at the study site when both the investigator and subject are at the same location, or it may take place remotely (e.g., at the subject's home or another convenient venue) where the subject and investigator are in different locations. The electronic consent materials may be used for both on-site and remote access.

Studies may use both paper and electronic documents to consent participants. An electronic version of the consent may be used for studies obtaining signed

consent, as long as the electronic signature is considered valid. Best practice is to have a back up paper-based informed consent process.

Q: What additional information should a researcher submit to the IRB if he/she wishes use electronic consent?

A: In the original application or by amendment, the researcher should provide a detailed description of the circumstances in which electronic consent will be used and a complete description of the electronic consent process (how, what, when). This information should include details concerning how the subject's signature will be obtained and documented. Also, the process for providing the participant with a signed copy of the informed consent should be outlined. The researcher will need to provide a description of the backup plan to consent subjects if the electronic consent is not available at the time of the consent process.

All studies	**Additional requirements for FDA regulated studies**
Identify the eConsent platform that will be utilized for the study.	Confirm that the study will use a Part 11-compliant license or module
Describe how the IRB-approved consent forms will be uploaded into the eConsent platform (e.g., uploading a stamped PDF, copy-pasting the exact language from the approved form, etc.).	
Confirm that the eConsent(s) will include the complete and exact contents of the most current, IRB approved study consent(s).	
Specify how consent will be conducted in-person or self-initiated remotely.	
Explain how the electronic signature is obtained (typed, written, etc.)	Confirm that the subject's identity will be verified and their signature will be captured using a method compliant with 21 CFR Part 11 requirements.
Explain how a copy of the consent will be provided to the participants	

Q: How should the researcher submit information to the IRB about the electronic consent process?

A: There is a specific Smartform in the eIRB system where researchers provide information about the informed consent process. The title of this Smartform is "Consent Process." In this Smartform, Section 5.0 is where the use of electronic consent is verified, and 6.0 is where the researcher will detail the electronic consent process that will be used. *If no changes exist between the paper consent and econsent, only one consent needs to be uploaded in section 7.0.*
If substantive changes have to be made to the consent form to allow for the electronic consent system, a copy of the electronic consent version with any format changes should be uploaded under Question 7.0.

It is the **investigator's responsibility** to ensure that the eConsent(s) will exactly match the content of the consent form approved by the IRB. If the consent form is modified over time, it is the expectation that all modifications approved by the IRB are incorporated into the eConsent. If the eConsent platform requires consent forms to be uploaded as PDFs, the investigator must ensure that the current IRB-approved consent form with the IRB approval stamp, is uploaded into the platform and utilized to obtain consent from participants.

When appropriate, the use of electronic consent should also be described in the protocol.

Q: Does the IRB allow the PI to email the fully executed consent document to the subject?

A: It is appropriate to provide the subject with a copy of the signed consent via email.

Q: What types of electronic consent systems are currently available at MUSC for researchers' use and how do I know if electronic consent is a good fit for my study

A: There are many electronic consent systems that are commercially available. For a system that has not previously been used at MUSC, the MUSC IRB would have to evaluate the system upon review of study. This review may entail the investigator working with other MUSC departments or divisions to ensure information security, HIPAA compliance, and other requirements are adequately met.

If a study is FDA regulated and records data or consent electronically, the study must use a 21 CFR Part 11 compliant platform for electronic records and/or electronic signatures. Software systems must be compliant with all requirements under FDA 21 CFR Part 11 (e.g., restricted access, administrative controls, training, identity verification, etc.). Generally, there is no "out of the box" software solution as the customer is responsible for setting features, demonstrating compliance, providing/documenting training, and administering operational policies and procedures. It is the **investigator's responsibility** to ensure that the chosen platform is set up and validated to meet 21 CFR Part 11 regulations.

NOT Food and Drug Administration (FDA) 21 CFR Part 11 Compliant:

- REDCap eConsent -The REDCap eConsent template for creating an eConsent database is available from the Template List on the "New Project" page within REDCap. The template is called MUSC eConsent Project Template and is designed to be customized by the investigator to mirror the study consent document. Both regulatory and REDCap assistance are strongly suggested -to ensure data integrity for documenting informed consent. Request these services via the SCTR SUCCESS Center by submitting a SPARCRequest and requesting the appropriate consultation(s).

- Doxy.me- The MUSC Biomedical Informatics Center supports a video based telemedicine platform capable of facilitating teleconsent that is available for use by MUSC researchers.. To receive information regarding the use of the Doxy.me system for electronic consent, please submit a SPARCRequest or contact one of the below individuals:

    - Trevor Faith: faitht@musc.edu
    - Jihad Obeid: jobeid@musc.edu or 834-792-0273

FDA Regulated Research

- eReg (*limited to Hollings Cancer Center studies*)
  If an investigator wants to use eReg for an oncology related trials, contact one of the below individuals:
  - Tricia Bentz
  - Catherine Busch

- External or industry sponsors may provide a 21 CFR Part 11 compliant electronic consent. You may request a statement from the sponsor or vendor of the electronic system used for obtaining the electronic signature that the system meets the relevant requirements contained in 21 CFR Part 11 and maintain documentation that your site has fulfilled applicable customer requirements such as training, password controls, etc.

  The following will be accepted as verification of Part 11 compliance:

  - A letter/email from the system "owner" verifying that the system is Part 11 compliant
  - An official product descriptor of the e-consent system (i.e. from the e-consent system's official website) verifying it is Part 11 compliant
  - An email from an IT professional at the host institution verifying the system is Part 11 compliant
  - Documentation from the sponsor that the system is Part 11 compliant.

  ○

Q: Are there certain aspects of electronic consent that a researcher should consider when proposing to use this as a means to consent subjects?

A: Yes. At a minimum, the researcher should consider:

- The type of technology participants will be required to have in order to engage in the electronic consent process.
- Whether the jurisdiction in which the research is taking place allows for the use of electronic signatures. For South Carolina, electronic signatures are permitted with certain stipulations.

- The privacy of the participant and whether the participant has the capability to be in a private area during the consent process.

This information should be included in the description of the electronic informed consent process that is submit to the IRB.

Q: What if the MUSC researcher is the lead PI of a multi-site study with sites in other states? Can they use electronic consent?

A: It depends. If the researcher is working with an institution in another state, it is important for the researcher to receive from the other institution information regarding any state laws or institutional restrictions prohibiting electronic signatures at the remote sites.

Q: Can HIPAA Authorization be obtained through the same electronic process? If so, what and how should the researcher submit to the IRB?

A: Yes. There is a specific Smartform in the eIRB system where researchers summarize the procedures to be used when obtaining HIPAA Authorization.

The title of this Smartform is "HIPAA Research Authorization." Item 2.0 of this Smartform is where the researcher will summarize the procedures to be used when obtaining authorization through an electronic process.

Q: Does the electronic consent policy apply to all studies?

A: There may be studies and subject populations where electronic consent would not be appropriate. The IRB will review the request to use electronic consent per study.

Q: The policy states that electronic consent should be an easy process for the subject to navigate. Is there one process that works for all studies?

A: Not necessarily. The process will be protocol-specific and will depend on the subject population being enrolled in the study.

Q: When using electronic consent platforms will the electronic informed consent form and HIPAA authorization look different from a standard paper consent?

A: Possibly. The elements of consent should have the same IRB approved wording, however the mechanism/language by which a choice must be indicated on the consent may differ from the standard paper consent based on features/capabilities of the platform being used (e.g. use of radio buttons instead of initial lines, directing participant to scroll to the bottom of the page).

Q: What are the regulatory and policy requirements for electronic consent?

If the research is FDA regulated (includes drugs or devices) and does not meet the criteria for a waiver of documentation of consent (i.e., the study poses more than minimal risk to the participants), the FDA requires written informed consent. FDA considers signatures drawn with a finger or an electronic stylus on a mobile platform or other electronic system to be a handwritten signature. The handwritten signature should be placed on the electronic document just as it would appear on a printed document to link the signature to the respective electronic record.

21 CFR Part 11 applies to any records that are required by the FDA that are being maintained electronically instead of on paper. When electronic signatures or recordkeeping systems are utilized to support research involving drugs, biologics, and devices regulated by FDA, the research is subject to an additional set of requirements found at **21 C.F.R. Part 11 (often referred to as FDA "Part 11")**. It is the **investigator's responsibility** to ensure that the chosen platform is set up and validated to meet 21 CFR Part 11 regulations.

To determine whether you may use e-signatures for your documentation, check with your study sponsor or sponsor-investigator to confirm the protocol's compliance requirements and if documents must be Part 11 compliant. Some sponsors may request or require wet ink signatures over esignatures, or the reverse.

Q: What is a valid signature for econsent?

To have a valid signature, your econsent process must have:

- The ability to prove that the actual signer is the intended signer;
- The inability of the signer to deny the signature; and
- An assurance that neither the record nor the signature has been altered since the moment of signing. To achieve this, the electronic signature and date should be linked to the document so that it cannot be modified or tampered with. (Having the individual type their name on a word document or other format that allows the signature to be tampered with is not valid.)
- The application of the electronic signature to the electronic record must be a deliberate act.
    - Participant agreement to use electronic signature must be recorded

FDA 21 CFR Part 11 describes two types of signatures:

- Electronic signature - a computer data compilation of any symbol(s) executed, adopted, or authorized by an individual to be a legally binding equivalent of the individual's handwritten signature.
    - Methods include computer-readable ID cards, biometrics, digital (cryptographic) signatures, and user/password combinations.
    - Electronic signatures must comply with 21 CFR 11.5 & 11.7 signature requirements:
        - The printed name of the signer;
        - Date and time when the signature was executed;
        - Meaning (i.e., consent); and
        - Linked to their respective electronic records to ensure that they cannot be excised, copied, or otherwise transferred (i.e., tampered with).
- Handwritten signatures executed to electronic records - hand-scripted signatures executed to electronic records by signing with a stylus, finger, or cursor drawing.
    - These may be used in a hybrid process where the only electronic component is the documentation (signature) of informed consent.
    - Handwritten signatures executed to electronic records must comply with 21 CFR 11.7:

        - Linked to their respective electronic records to ensure that it cannot be copied, or otherwise transferred (i.e., tampered with).
    - In situations where electronic signatures cannot be placed in a specified signature block, a statement of testament (e.g., “I consent to participate”) should be placed elsewhere in the document to state the meaning of the signature and link the signature to the electronic informed consent.

References:

Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations: Questions and Answers

https://www.fda.gov/media/116850/download

https://www.fda.gov/media/75414/download