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.

***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 the where the researcher will detail the electronic consent process that will be used. A copy of the electronic consent should be uploaded under Question 7.0.

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?***

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.

A few examples of electronic systems that have been vetted for use include the REDCap eConsent template developed at the SUCCESS Center, Doxy.me and the FDA COVID MyStudies app.

See below for information regarding the use of the REDCap eConsent template :

* The REDCap eConsent template for creating an eConsent database is available from the Template List on the “New Project” page within [REDCap](https://redcap.musc.edu/).  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 intergrity for documenting informed consent. Request these services via the SCTR SUCCESS Center by submitting a [SPARCRequest](https://sparc.musc.edu/) and requesting the appropriate consultation(s).
* The MUSC Biomedical Informatics Center supports a video based telemedicine platform capable of facilitating teleconsent that is available for use by MUSC researchers. This platform is called Doxy.me. To receive information regarding the use of the Doxy.me system for electronic consent, please submit a [SPARCRequest](https://sparc.musc.edu/) or contact one of the below individuals:
  + Trevor Faith: [faitht@musc.edu](mailto:faitht@musc.edu)
  + Jihad Obeid: [jobeid@musc.edu](mailto:jobeid@musc.edu) or 834-792-0273

***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/capabilitites 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 doducment just as it would appear on a printed document to link the signature to the respective electronic record.

**References:**

[*https://www.fda.gov/media/105557/download*](https://www.fda.gov/media/105557/download)

[*https://www.fda.gov/media/116850/download*](https://www.fda.gov/media/116850/download)

[*https://www.fda.gov/media/75414/download*](https://www.fda.gov/media/75414/download)