# Use of Electronic Informed Consent

For the purposes of this guidance, electronic informed consent (e-Consent) refers to using electronic methods to obtain and document informed consent. e-Consent Methods and materials may include, but are not limited to, electronic devices, digital media (e.g. websites, video) and electronic communication services.
e-Consenting can apply to either the process of consenting, the documentation of consent, or both.

This guidance provides recommendations on procedures that may be followed when using an e-Consent to:
- Ensure protection of the rights, safety, and welfare of human subjects
- Facilitate the subject's comprehension of the information presented during the e-Consent process
- Ensure that appropriate documentation of consent is obtained when e-Consenting is used to obtain informed consent

NYU Langone Health permits reseachers to use electronic processes to consent participants. There are two types of e-Consent: in-person or remote.
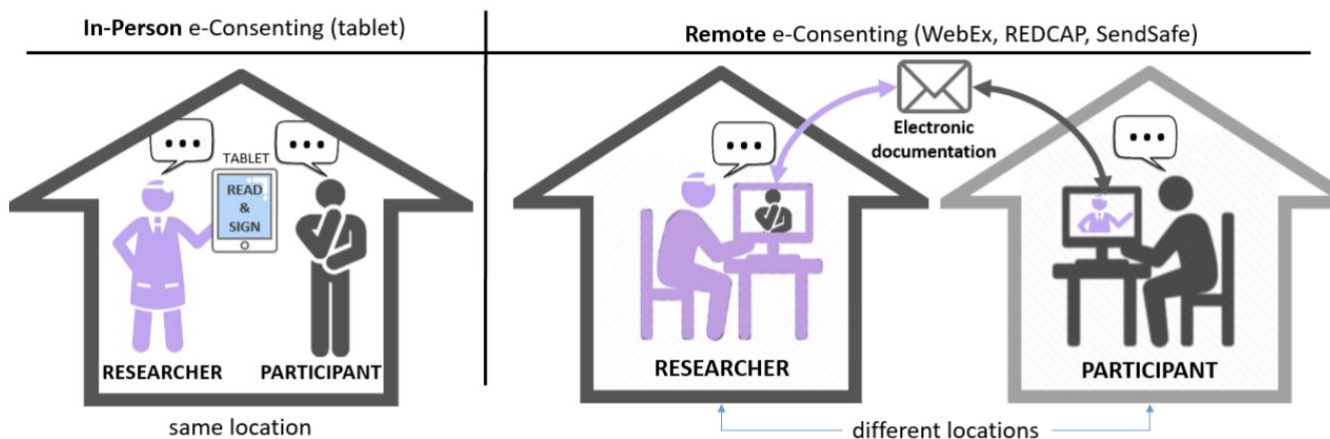
NYU Langone Health permits the following:
- In-person e-Consenting uses an electronic device such as a tablet or a computer when subjects are on-site with study personnel present.
- Remote e-Consenting takes place without the researcher witnessing any or all of the consent process in settings such as the subject's home.

The term *informed consent* is not just obtaining a handwritten signature from the subject or the subject's legally authorized representative (LAR) on a written informed consent form--it pertains to materials provided to the subject as well. The electronic informed consent process will include the same information contained within the written 'paper' informed consent document; include methods to verbally discuss the consent form; evaluate the subject's comprehension; and document the subject's or LAR's consent. Pre-recorded video, while an option for conveying information to the subject, does not replace the discussion between researcher and subject.

What is required in electronic informed consent?

PLEASE NOTE**: If you are creating an electronic consent form, such as a form in REDCap, the language in the form MUST be identical to that of the consent document approved by the IRB, and MUST contain functional signature boxes for the subject (or the subject's LAR), the personnel obtaining consent, and the witness to the consent process if the subject is a non-English speaker.

The e-Consent must contain all elements of informed consent required by federal regulations (45 CFR 46.116 and 21 CFR 50.25). The information must be in language understandable to the potential subject or the subject's LAR and conveyed in a manner that minimizes the possibility of coercion or undue influence regarding the subject's

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decision to participate in a study. The device, system, or platform used to obtain informed consent must allow enough time for completion, the ability to navigate forwards and backwards, and the option to stop and resume at a later time. Electronic methods of communication should allow the subject to contact the researcher again at any point in the process in order to ask additional questions.

Approved methods for e-Consenting

Common NYU Langone Health and HIPAA compliant methods for obtaining e-Consent, whether in-person or remote, are listed below. The informed consent process involves a discussion between the subject and the investigator (or a designee) that includes the information in the written consent form and allows the subject to ask questions.

Different combinations of in-person e-Consenting and remote e-Consenting for either the process or documentation of consent may be approved based on the merit of your research.

	In-person e-Consenting		Remote e-Consenting	
	Discussion of consent	Documentation of consent	Discussion of consent	Documentation of consent
"Face-to face"	On-site discussion takes place between study personnel and subject.	Signed ICF can be obtained on-site with a digital consenting device such as a tablet or computer.	*See "video conferencing" in the last row of chart*	
Email (SendSafe) *Instructions on utilizing SendSafe here*	On-site discussion takes place between study personnel and subject.	The subject may receive and return consent remotely via SendSafe. A signature can be captured electronically on the document provided, or the subject may print and sign a physical copy that is scanned and returned via SendSafe or later in person.	An initial telephone call or video conference takes place between study personnel and the remote subject.	The subject may receive and return consent remotely via SendSafe. A signature can be captured electronically on the document provided, or the subject may print and sign a physical copy that is scanned and returned via SendSafe.
RedCap *Instructions on setting up RedCap for e-Consenting here*	On-site discussion takes place between study personnel and subject.	Signed ICF is obtained through REDCap displayed on a tablet or other device.	An initial telephone call or video conference takes place between study personnel and the remote subject. The subject received a link to the ICF.	The subject can remotely receive, sign, and return documentation through a link to REDCap.
Video conference (WebEx only*)	A video conference takes place between study personnel and the remote subject.	After video screening, the subject may come for an on-site visit and consent through a tablet or other device.	An initial video conference takes place between study personnel and the remote subject.	The subject can remotely receive, sign, and return documentation through SendSafe or REDCap.
NEW FDA e-Consenting App a.k.a. "COVID MyStudies" *Additional instructions here*	On-site discussion takes place between study personnel and subject.	Via "COVID MyStudies" app, PI sends the ICF electronically to participants or his or her legally authorized representative (LAR). Participants or LAR will receive an electronic copy upon signing. PI can securely access the signed ICF and print it or transfer the file electronically.	An initial telephone call or video conference takes place between study personnel and the remote subject.	Via "COVID MyStudies" app, PI sends the ICF electronically to participants or his or her legally authorized representative (LAR). Participants or LAR will receive an electronic copy upon signing. PI can securely access the signed ICF and print it or transfer the file electronically.

Services such as Skype, FaceTime or Zoom are not HIPAA compliant and are prohibited. If you are not using WebEx or Redcap contact MCIT for clearance of any other services.

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The IRB must review all forms (electronic and paper) and other informational materials, including any videos and Web-based presentations, which the subject will receive and view during e-Consenting. The IRB will also review any optional questions or methods used to gauge subject comprehension of key study elements. During its review, the IRB will review the proposed e-Consent process to determine the usability of the e-Consent materials. If the program uses hyperlinks to convey study-related information, the IRB will review the online materials in order to ensure that the study-related information is accurate and appropriate.

Examples of allowed methods of e-Consenting

1. The subject meets study personnel on-site for a discussion. Comprehensive materials and the ability to sign may be provided through a device such as a tablet.
2. The subject is screened remotely by study personnel through a WebEx conference before they receive a REDCap link that allows them to read comprehensive materials and sign remotely on a personal computer.
3. The subject is screened remotely through a telephone call before they receive a SendSafe email containing consent materials. They may print the document at home, sign it, scan it, and return it to the study personnel through the SendSafe portal.

In-person e-Consenting versus remote e-Consenting

While e-consenting is allowed face-to-face using a tablet or other electronic device, NYU Langone Health will also allow the consent process to take place remotely (e.g., at the subject's home or another convenient venue). In this case, the subject reviews the consent document in the absence of study personnel. The e-Consent materials may be provided for both on-site and remote access. In some cases of remote e-consenting, it may be required that the electronic system has a method in place to ensure that the person electronically signing the informed consent is the subject who will be participating in the research study or is the subject's LAR.

Researchers should have methods in place to ensure that the e-Consent process provides the opportunity to consider whether or not to participate, and to ask questions about the study before they sign consent, as well as at any time during the subject's involvement in the research study. This may be accomplished by a discussion between study personnel and the subject, whether it is in-person, a telephone call, or a video conference. When video conferencing is used during the e-Consent process, study personnel should remind subjects to conduct the e-Consent discussion in a private location. Additionally, the signed documentation of consent from the subject, whether a scanned paper document returned electronically or a digital form with electronic signature, must be obtained.

Additional information

- Subjects must be instructed how and when they will receive answers to questions, and they must be provided information on how to contact an appropriate individual for pertinent questions about the research and their rights and whom to contact in the event that they sustain a research-related injury.
- Subjects may have difficulty navigating or using electronic systems because of a lack of familiarity with electronic systems, poor eyesight, or impaired motor skills. In such cases, e-Consenting processes should be ADA compliant to meet the needs of these subjects. A paper-based informed consent should be also available to subjects.
- The e-Consent may use interactive electronic-based technology, which may include diagrams, images, graphics, videos, hyperlinks, and narration. The e-Consent should be appropriate for the intended audience, taking into consideration the subject's age, language, and comprehension level.
- Regulations require identity verification before study personnel establishes, assigns, certifies, or otherwise sanctions an individual's electronic signature.
- The e-Consent process can be used to obtain assent from pediatric subjects (when applicable) and parental permission from their parent(s) or guardian.
- Subjects should receive a copy of their e-Consent and have easy access to the materials and information presented to them during the consenting process.
- The electronic system used in e-Consent must be secure with restricted access and should include methods to ensure confidentiality regarding the subject's identity, study participation, and personal information after informed consent has been obtained. Depending on the electronic system, additional clearance from MCIT Security may be needed before IRB approval can be granted.
- HIPAA authorizations may be obtained electronically, provided that the signature of the subject (or the subject's LAR) is a valid electronic signature under applicable laws and regulations.
- Any changes to the e-Consent materials and processes require IRB approval prior to their use.