Electronic Informed Consent

Electronic Informed Consent (e-Consent) is an evolving platform for consenting research participants, either on-site or remotely, using a computer-based consent process. As with traditional paper-based informed consent, e-Consent is not only a form, it’s also a process. Any e-Consent process conducted on-site or remotely should include an opportunity for subjects to ask questions and receive answers prior to providing their consent to participate in the study. The consent process can be implemented on a number of electronic systems such as computers, tablets, and phones. These platforms may also use multiple media types (e.g., text, graphics, audio, video, podcasts, and interactive web sites, biological recognition devices, and card readers, etc.) to convey information related to the study and to obtain documented informed consent. Additional considerations should include the process to validate identity and how the consent form will be signed electronically (e.g., Adobe e-sign). Investigators must receive IRB approval for the e-Consent process, even if they already have IRB approval for a paper version of the consent process.

Below are model statements investigators may adapt to describe the technology-specific risks in e-Consent.

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Sample: Reading the Informed Consent

On the next screens, you will view the informed consent document. Please read all sections of the informed consent document. After each section, you may be asked to answer some questions before continuing onto the next section. After you have read all sections, you will be given the opportunity to go back and review all sections.

Swipe the screen from bottom to top with your finger to scroll through each section of the informed consent document. When you reach the end of a section, you will be able to touch the Continue button.

If there is a word or group of words that you do not understand, touch and hold your finger on the word until a small box appears, then tap the "unfamiliar term" selection. This will highlight the word and allow your physician to explain the meaning to you during your discussion.

Please touch the "Continue" button below to read the informed consent document.

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