JOURNAL OF CLINICAL RESEARCH BEST PRACTICES

Vol. 14, No. 7, July 2018 "Happy Trials to You"

It's About Time We Get Serious about eConsent

Betsy Fallen, Clinical and Regulatory Process & Technical Consultant, talks with Norman Goldfarb, Editor of the Journal

Betsy, what do you think it's about time for the clinical research enterprise to start doing?

We need to stop dabbling with electronic informed consent — eConsent — and jump in with both feet.

How does eConsent work?

"eConsent" requires only that the information be presented electronically, rather than on paper. It could, therefore, take the form of something as simple as a .pdf file on a laptop, or as sophisticated as a highly interactive, multimedia experience. A .pdf file can be emailed and signed electronically, but the big payoff is with a highly interactive, multimedia experience, so that's what I call "eConsent."

What are the advantages of eConsent?

eConsent is much more flexible and engaging than paper-based consent. Text, images, audio, videos and animations can provide information in the best manner possible, in multiple ways, and in the way the potential study participant wants to see it. Reading levels can be adjusted.

eConsent can ensure that people see all the essential information and it can quiz them to identify areas that need more explanation or verbal follow-up by the investigator. eConsent can make lots of other information available that would not be found in a paper consent form, while allowing the person to focus on the most important material. People can get instant definitions of unfamiliar or technical terms. They can flag topics for clarification by the investigator.

eConsent can analyze quiz results, track the amount of time people spend on each step, and collect other data about the process for each individual and in aggregate, for verbal follow-up by the investigator and to improve presentation and process.

Investigators can make an online eConsent "form" available to people in their homes. For virtual trials, eSignatures can be obtained remotely (assuming robust identity verification), after a follow-up telephone or video conversation with the investigator. Regulators, including the FDA, recognize eSignatures.

When an eConsent form is revised, the previous, outdated version can no longer be used. The version signed by a participant is recorded in the audit trail.

Sounds great, so what's holding us up?

Leaving aside all the other urgent priorities that eConsent must compete with, there are five main obstacles:

First, creating an eConsent form is complex, expensive and time-consuming. Someone has to create the multimedia content, the quizzes, and the flow through the material. Over time, libraries of standard modules will be developed that can easily be plugged into a consent framework and adapted for a specific study.

Second, IRB review of an eConsent form — and any changes — might be more complex and time-consuming, although this issue should resolve over time with experience.

Third, how do you ensure that study personnel and participants understand the eConsent process? Technology is not everyone's strong suit. Experience, education and user-friendly user systems will help.

Fourth, if the eSignature is obtained remotely, how do you verify that the study participant is the person who completed the eConsent process and signed the form? One approach is for the participant to hold up his or her ID next to his or her face in a video call.

Fifth, it's not entirely clear what the participant's copy of an eConsent form and the site's archival copy should look like. Do you give them a packaged, electronic version of the entire eConsent? Do you include all the material, or just what the participant viewed? Does the participant sign a paper version of the consent form? If you print out a paper version of the eConsent material, what about the video files?

Those sound like daunting challenges.

Well, Norm, research shows that paper-based consent processes simply don't work — even the highest comprehension levels are shockingly low.

We are moving to an online world in which paper is increasingly archaic. Millennials — and whatever generation comes next — will not accept paper consent forms any more than consent forms chiseled on stone tablets.

Interviewer

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