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Future World Without Paper Consent Could Be Here Sooner Than Imagined

Remember when the IRB submission process was entirely on paper? In 2027, someone might ask the same thing of informed consent: "Remember informed consent paper documents?"

Electronic consent has great potential for growth, says **David Forster**, chief compliance officer with WIRB-Copernicus Group in Princeton, NJ.

"But the process needs to be more administratively efficient and affordable," Forster says.

Forster says WIRB-Copernicus sees some e-consent forms from sponsors, but the percentage still is quite low.

"Ten to 15 years ago, everyone was converting from paper forms to EDC [electronic data capture], and now every study is EDC instead of paper. We will see the same change with e-consent," says **Anthony Costello**, vice president of mobile health with Medidata Solutions in Davis, CA. Costello was the founder of Mytrus, which developed Enroll, an e-consent process. Mytrus was purchased by Medidata in April 2017.

"Over the next five years or so, I believe that the paper-to-electronic-consent movement will mirror what we saw with paper to the electronic data capture movement," Costello adds.

"My prediction is we'll see a much more rapid adoption of e-consent in the next year or two," says **Kyle Maeda**, vice president of information technology at Kinetiq, a division of Quorum IRB in Seattle.

Others say that within seven years, most clinical trials will use an electronic consent process. These won't be costly e-consent and patient educational tools, but a more streamlined version that works better for standard pharmaceutical and device trials.

The nonprofit Sage Bionetworks of Seattle has used e-consent on some research projects. The organization created its e-consent using Apple's ResearchKit software and also consulted with other first adopters of e-consent, says **Christine Suver,** PhD, director of research governance for Sage Bionetworks. ResearchKit is an open source framework for creating a medical research tool. *(For more information on ResearchKit, see the story "Smartphone Apps Are a New Frontier for Minimal Risk Studies" in the May 2015 issue of* IRB Advisor*.)*

"Our studies were different from traditional clinical trial studies," Suver notes. "They were designed to be self-managed and self-implemented."

The e-consent took about six months to create, from the first concept to design, to coding, and to working with the IRB, Suver says.

Participants can download an app and view information about the research study. If desired, the participant then could view the e-consent and sign it electronically from their cellphone. Participants also would do the study on their own.

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"Those studies were designed to be implemented, self-paced, and have participants be able to do it on their own outside of a clinical study site," Suver explains. "Because the study was self-administered, we needed to design a consent process that was similarly self-paced and administered within the application."

E-consent has a few drawbacks before wide adoption is a reality.

For instance, the systems often are difficult to present to the IRB in the same format the subject sees, and the electronic signatures need to be compliant with 21 CFR Part 11, Forster says.

"And amendments, likewise, can be difficult to process. Also, paper is cheap in comparison to electronic platforms, and that can be an issue," Forster says.

International regulations also can pose an obstacle to e-consent because it is challenging for research sites and IRBs to know of a nation's related data privacy laws, data storage, electronic signature process, and other rules that differ from country to country, Costello says.

One of the benefits of an electronic consent process is that it can prevent the human errors and omissions that slow down the research process.

"It's very easy to miss signature lines, datelines, and an electronic consent would eliminate those deviations," says **Raymond Nomizu**, JD, co-founder of Clinical Research IO of Cambridge, MA.

IRBs and research sites should seriously consider moving to paperless processes, including e-consent, Nomizu says.

"The real reason why people should go electronic is because of the impossibility of managing current protocols on paper forms," he says. "It's really hard to manage that complexity, and trials are getting more complex every year."

E-consent can do things paper consent documents cannot, says **Mitchell Parrish**, JD, RAC, CIP, vice president of legal and regulatory affairs for Kinetiq.

"With e-consent, you actually have the ability to reduce compliance risks," Parrish says. "You have the smart form approach, so you will know the form is not complete until it's completely filled out."

The e-consent process locks in the correct version of the informed consent, so everyone signs the correct form. It has built-in mechanisms that ensure compliance from the site's perspective, he adds.

"E-consent is not just meant for remote, online consenting," Parrish says. "You see it as the standard for how you consent. It's a best practice."

Another time-saver is in how trial amendments and repeat consenting are handled. When a study amendment results in a revised informed consent for research participants to sign, it can cause delays. With an e-consent process, this can be handled more efficiently.

"If the IRB had approved remote consent, then study participants can review and approve the revised informed consent remotely," says **Tom Favillo**, president and chief operating officer of Quorum IRB.

E-consent is something the human research protection industry has been trying to push for the last four years, Favillo says.

There is interest in paperless consenting processes, but there have not been great tools available on the market. And the tools that were available often required investment in hardware and software, he says.

"Most tools have come from an educational perspective, versus a consent perspective," Favillo says. "When they came to market, they did bring positive elements of engagement and retention."

But the drawback was that the time spent on designing these electronic consent tools added months to the research process, he says. "The benefit of paperless consent did not offset that expense."

That was then, and this is now: E-consent tools can be adapted to most studies. If research sites wish to add explanatory videos or other visual or auditory aides, they can.

"But it's not something you have to have if you don't need it for your study," Favillo says.

Another benefit of an e-consent platform is it gives sites real-time metrics.

"You can see who has consented," Parrish says. "You can see how the site is doing on enrollment, and which version of the informed consent was used in enrollment."

Sponsors and clinical research organizations have real-time access, and it can reduce costs, he adds.

"People can access the electronic consent from any internet-enabled device," he says.

As these tools become better known, there will be more like them. Soon — perhaps within 18 months — there will be quick adoption of e-consent, Favillo predicts.

"The biggest benefits of e-consent are about getting this information in a place and platform that

participants can interact with when they need to," Favillo says. "It secures data, allowing data to be used across multiple studies."

Another e-consent benefit is the prospect of participant engagement.

"With electronic consent, you're giving people an opportunity to interact with the document in a way they're more familiar with — online," Parrish says. "You can interact with the research staff, principal investigator, or clinical research associate."

With paper consent, participants might take it home, jot down questions and notes, and then return to the research site to learn more. With e-consent, they can type in questions and send them automatically to the site. Then the research site can respond through the e-consent platform with questions or answers.

"It's an easier way to have participants engage with research sites and to make sure all questions are answered," Parrish says.

Sage Bionetworks was motivated to design an e-consent so that it would increase engagement and allow research participants to be more autonomous in their decision-making, Suver says.

E-consent makes it possible to add multimedia functions, including visual tools, graphics, and other technology.

"We inform participants in a multimedia approach with words, video, icons," Suver explains. "Then we guide them through what the study is about and what the risks and benefits are."

All of the traditional informed consent topics are addressed in an e-consent form. The difference is the information provided electronically is more accessible, and it can be easier for some types of learners to understand, she adds.

The e-consent app developed by Sage Bionetworks is available on the Apple iTunes store for download. "We welcome any feedback on improving the process," Suver says. "We are continuing to really try to evolve this e-consent process to make it more engaging."

There are some challenges to switching to an electronic consent process, including ensuring cybersafety.

But the benefits outweigh the risks, according to Parrish, Favillo, and others.

E-consent is very efficient and will become the industry standard, Parrish predicts.

"It will maximize clinical trials. There are industry work groups working on it, and people will put out new products," Parrish adds. "All signs are pointing toward wide adoption, and that's why these are exciting times." ■