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What's New in GCP?
Jurisdiction Is Big Question for Electronic Consent

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Although the Department of Health and Human Services' Office for Human Research Protections (OHRP) allows an electronic signature to be used to document informed consent or parental permission under certain circumstances, the agency "does not prescribe the method of electronic signature," Laura Odwazny, a senior attorney in the HHS Office of General Counsel told the Secretary's Advisory Committee on Human Research Protections (SACHRP) Oct. 9.

Odwazny noted that OHRP guidance (http://answers.hhs.gov/ohrp/questions/7260) last reviewed in 2011 said the agency "permits IRBs to adopt such technologies for use as long as the IRB has considered applicable issues, such as how the electronic signature is being created, if the signature can be shown to be legitimate, and if the consent or permission document can be produced in hard copy for review by the potential subject. One method of allowable electronic signatures in some jurisdictions is the use of a secure system for electronic or digital signatures that provides an encrypted identifiable 'signature.' If properly obtained, an electronic signature can be considered an 'original' for the purposes of recordkeeping."

"I would suggest that it might be prudent to think about what level of risk would be involved if a person who was not actually the person supposedly signing this document signed it," Odwazny said. "That is generally what I consider when determining what kind of electronic signature is appropriate for other types of documents, such as grants."

Whose Jurisdiction Is It?

The guidance adds that electronic signatures are allowed if such signatures are legally valid within "the jurisdiction where the research is going to be conducted." "The natural question that raises is: What jurisdiction is that? Obviously, if the investigator and the [subjects] are co-located, then it would be" that state's law, Odwazny said.

"Right now, OHRP isn't speaking to what jurisdiction the research is being conducted. This is a determination that IRBs…are making and have been making for many years," she said. "In the absence of providing OHRP guidance, the status quo would be maintained… We have deference to a reasonable interpretation of the institution or the IRB."

Joanne Less, director of FDA's Good Clinical Practice Program, noted that FDA's Part 11 regulations allowing for electronic signatures also "doesn't get into any details of jurisdiction. I agree that it is much more difficult to figure out when it is valid and when it is not. Let the IRBs figure it out."

Should OHRP Clarify Its Position?

Several SACHRP members said that if OHRP's policy is to let IRBs determine jurisdiction, the agency should state that. "With the lack of any statement at all, you don't know what OHRP is thinking," said SACHRP member David Forster. "At least if OHRP says 'we're not

designating this — it is open to broad interpretation — then people know that they have that latitude."

SACHRP Chair Barbara Bierer added that "it would be very helpful for the regulated community to know that it is an affirmative decision not to comment further rather than a 'guess what I'm thinking'" position.

However, SACHRP member Steven Joffe recommended that OHRP take a stand. "Would it be helpful to the regulated community to have a statement along the lines of 'OHRP finds that a signature is valid if it is [compliant] in the researcher's jurisdiction?' I recognize that OHRP can't speak for or pre-empt state law and in any statement we need to make that clear."

That "seems to be what IRBs are doing," Odwazny said. "They are looking at the jurisdiction of the researchers, and they are not looking at the laws in the jurisdiction where the subjects are located. So guidance such as this I don't think would be a surprise to the research community or be viewed as burdensome."

Where Is the Subject Located?

Odwazny said requiring researchers and IRBs to consider the jurisdiction of subjects would place "increased burden on the IRB and the researchers to assess whether there were any different specific or more demanding requirements in the jurisdictions of the subjects," in addition to verifying where the subjects were located. "If the investigator knows where the subjects are located, should that be a consideration?" Odwazny asked. "Should that increase the responsibility of the investigator to ensure that the electronic signature form is acceptable both in the [investigator's] jurisdiction as well as in the jurisdiction of the subject? You could structure that as saying that if the investigator does know where the subjects are located, then the investigator assesses whether the signature is valid in that jurisdiction," she added.

Odwazny noted that any OHRP guidance on electronic signatures "would only address what OHRP finds satisfies the requirements of the Common Rule. It would not pre-empt the application of any other state or local laws that might provide more restrictions or a more formal type of electronic signature."

Are You Who You Say You Are?

Another problem with electronic signatures is verifying that the person signing an informed consent form is considered an adult. "What is the expectation of the lengths to which we must go to figure out whether the person who made the eSignature is truly an adult," Bierer asked. "The ability to verify this is really quite limited."

Odwazny said "the protections afforded by the signature on the informed consent might be a little different than the protections in the regulations afforded by having the state law regarding who is or who is not authorized to consent for themselves."

SACHRP member Suzanne Rivera noted that there are electronic techniques to self-report "you really are who you say you are when you order something, for example, from Amazon. We already have paradigms for expectations about how people represent themselves in cyberspace… For the most part, the bar for how much we have to verify shouldn't have to be so high."

However, SACHRP member Lainie Friedman Ross said "medical researchers [are held] to a higher standard... So I agree that it is overkill to have to prove that someone really is 18, but" some verification is still needed.

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