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It's About Time We Convene a National Working Group on Informed Consent

Joe Andrews, Assistant Dean for Regulatory Affairs and Research Integrity at Wake Forest Baptist Health, talks with Norman Goldfarb, Editor of the Journal

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

Norm, it's about time for a National Working Group to take a hard look at informed consent, identify best practices, and initiate a research program to answer the unanswered questions. We've been talking about it for ages. It's time to take decisive action.

Why now?

There are three reasons:

First, the revised Common Rule contains a new requirement for consent documents to begin with "key information" that participants will want to have when making a decision about participating in the study. This key information must be presented in a way that facilitates comprehension. This is a good idea, but there is currently no guidance on what information is considered key, nor is there any guidance on how to arrange the information to facilitate comprehension.

Second, eConsent is emerging as a legitimate improvement over paper-based consent. We need to smooth the road to adoption.

Third, there has already been a lot of research on informed consent. An authoritative body needs to review the research, summarize the valid findings, and identify the gaps in our knowledge for future research — like what Cochran does for evidence-based medicine.

What is the problem with informed consent today?

Quite a few studies have been conducted over the past decades on how to improve consent comprehension. In many studies, the level of comprehension and retention of information is shockingly low. We can't live up to our ethical obligations if we don't get informed consent right, and nobody has found the right formula yet.

What would a national working group look like?

A national working group would be composed of people who write consent forms, people who read them, people who regulate them, people who study them, and communications experts.

The working group should (1) examine the findings of previous research on consent improvement, (2) ask the public what information *they* think is important and how *they* would like to receive it; and (3) develop and test new ways to deliver that information. We need a broad reach, serious expertise, and sound empirical research. It will be a lot of work, but it's a vital objective.

Why not just wait for guidance from FDA or OHRP?

That's an option, but what we really need to do is to throw all the necessary resources and expertise we can find at this problem. Regulators should participate in the working group along with other experts from academia and industry.

Well, Joe, it sounds like a lot of work. Are you volunteering to lead the working group?

I'm not qualified for that role, but I'm ready to pitch in where I can help.

Interviewer

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