Legalese creates consent 'conundrum' in clinical trials

When the social networking site Facebook recently updated its privacy policy, the lengthy documentation associated with the changes set off a deafening uproar. Web users bemoaned that the new policy surpassed even the US Constitution in length. Ultimately, their criticisms prompted the site to switch to a simpler format for privacy settings. In the world of research, meanwhile, participants must continue to navigate complicated 'legalese' in consent forms.

Granted, clinical trial consent forms have come a long way since the US National Research Act of 1974 codified the concept of Institutional Review Boards (IRBs) and required informed consent from study subjects. Early consent forms were sometimes only a paragraph or two long and sparse on details; in contrast, present-day files are often meticulous tomes of information that include all the potential risks and benefits of participating in the research. But even though the forms are now more complete, recent incidents suggest that the added details often come at the cost of clarity.

"The longer and more complicated the form, the less it probably accomplishes the goal of informed consent," says Christine Grady, acting chief of the bioethics department at the US National Institutes of Health Clinical Center in Bethesda, Maryland.

To gauge the extent of the problem, a team led by Paul Appelbaum, a psychiatrist at Columbia University in New York, compared 25 years' worth of consent forms and protocols from the New York State Psychiatric Institute's IRB. Reporting in the May–June issue of *IRB: Ethics & Human Research* (**32**, 7–11, 2010), the researchers found that documents nowadays contain all of the relevant risk information, unlike earlier consent forms, which were riddled with inconsistencies. But in the process of improving accuracy, the forms ballooned from slim two-page brochures to wordy, five-page booklets that are now about as unreadable as most other everyday contracts, such as agreements with telephone or electricity companies.

"It really underscores the conundrum here," says Appelbaum, who has studied informed consent issues for decades. "We rely on consent forms to inform subjects, yet the more complete we are, the less likely they will be to read and understand the forms we rely on." Laura Beskow, a health policy researcher at the Duke Institute for Genome Sciences and Policy in Durham, North Carolina, agrees. "It undermines the whole process of informed consent if people aren't reading the thing, let alone comprehending it."

Arizona State University officials learned this lesson the hard way, when the university settled a lawsuit in April with the Havasupai Native American tribe after investigators used blood samples originally donated for diabetes research to study mental illness and geographic origins. The consent form stipulated that the blood would be used to "study the causes of behavioral/medical disorders," but the tribe members had allegedly been told that the blood would be used only for a specific project on diabetes.

Length and clarity are not just problems in English-language forms either. Last year, Ola Berger and his colleagues at St. Olavs Hospital in Trondheim, Norway examined the length and content of consent forms for 87 cancer trials conducted in central Norway from 1987 to 2007. Over the two decades, the forms had grown from around one page to more than four pages, the researchers found, and the amount of text dealing with legal, financial and insurance issues had increased substantially (*Ann. Oncol.* **20**, 379–385, 2009). A study published in May showed that French consent forms have similarly become long winded and convoluted (*PLoS One* **5**, e10576, 2010).

Standardization hope

"What we're asking in the current system is ridiculous," says Ezekiel Emanuel, a bioethicist and special advisor for health policy to the director of the White House Office of Management and Budget. He notes that clinical investigators are not typically professional writers or communicators, and so "part of the solution is to try and get more standardization and more templates" to make consent forms more comprehensible across the board.

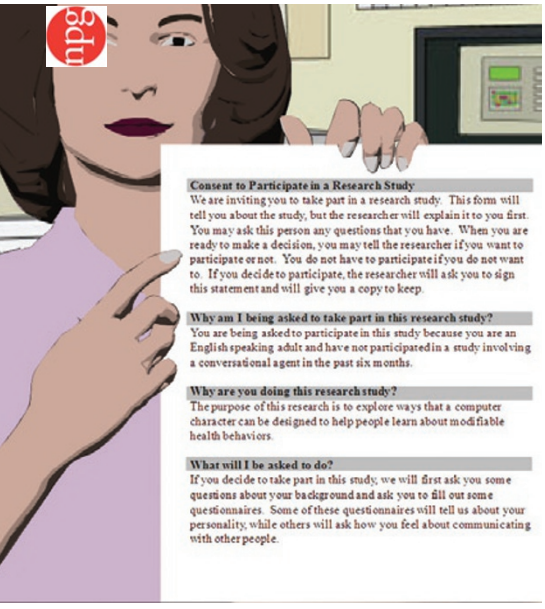
Michael Paasche-Orlow, a physician who studies health literacy at Boston University School of Medicine, was involved in one such effort: the US Agency for Healthcare Research and Quality's 'Informed Consent and Authorization Toolkit for Minimal Risk Research', released last September. However, even these guidelines for what to include in consent forms remain encumbered by the legal mumbo jargon required by legislation such as the Health Insurance Portability and Accountability Act (HIPAA). "Understanding on the part of the participant is a different goal and often at odds with making sure that every legal protection is listed," explains Grady.

To better inform study subjects, Paasche-Orlow, together with Timothy Bickmore, a computer scientist at Northeastern University in Boston, has been working on an animated character that carries out a virtual conversation with study subjects about the consent process. On the basis of theoretical protocols, the researchers found that participants were more likely to ask questions of the computer character and were thus more informed and comfortable with the trial design. As a result, enrollment and retention were higher in their hypothetical scenarios involving the cartoon. "Ultimately, informed consent is a process and not just a document," says Paasche-Orlow.

Written documents, however, will probably remain the mainstay of informed consent. So, to help cut through the judicial and technical jargon, Holly Taylor and Nancy Kass at the Johns Hopkins Bloomberg School of Public Health in Baltimore helped develop two-page, large-font, bullet-pointed summaries to complement the complete informed consent forms, which they are now evaluating in a series of active trials. "This is not innovative," admits Taylor. "Why doesn't everybody do that? Maybe it's because no one's shown that that's actually made a difference."

Emanuel applauds such efforts for helping cut through the legal boilerplate. "What is institutional boilerplate?" he asks. "It tends to be 'protect your ass', not 'inform the patient of salient information.'"

Elie Dolgin, New York



Timothy Bickmore

Virtual reality: Consent gets animated.