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Ways to improve informed consent are testable, study says

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New ways to make sure people are adequately informed about the risks and benefits of taking part in a clinical trial can be field-tested for effectiveness as vigorously as new medical treatments themselves, a study led by a Johns Hopkins bioethicist suggests.

Informed consent, a mainstay of ethical clinical trials, is the process by which potential research subjects are asked to decide whether to participate in research. The bedrock components of the process include gaining an understanding of the study's goals and benefits, as well as the risks and roles of the subjects themselves.

"Many clinical researchers believe that the informed consent process and documents need to be better and that people often consent without understanding that the research is not intended to benefit them personally," says Jeremy Sugarman, professor of bioethics and medicine at the Berman Institute of Bioethics at The Johns Hopkins University.

"Although numerous improvements have been suggested, no sound objective method existed to test them, leaving the process open to costly or time-consuming interventions that could ultimately have no effect," he adds.

Writing in the December 2007 Clinical Trials, Sugarman and his colleagues, Philip W. Lavori of Stanford University School of Medicine and Timothy J. Wilt of the Minneapolis VA Center for Chronic Disease Outcomes Research, describe a questionnaire tool they developed and

tested at 30 study sites in five ongoing clinical trials for medical treatments that include from administering selenium and vitamin E to prevent cancer and giving female veterans therapy for post-traumatic stress disorder.

Though the tool ultimately proved ineffective in improving informed consent in this experiment with its use, Sugarman says the evaluation method they developed is helpful in ruling out what doesn't work.

Sugarman and his colleagues started with the idea that if those seeking informed consent from potential subjects were armed with reminders of the steps needed to adequately educate them, participants would be more likely to receive and understand the information they need to make good decisions.

Consequently, the investigators put together a short, self-monitoring questionnaire for researchers to fill out after each time they obtained informed consent. This questionnaire is a checklist of 18 questions that review critical parts of the informed consent process designed to help ensure that potential participants understand what is being asked of them.

In an experiment to test the questionnaire, clinical trial administrators used it at half of the study sites so that they could compare its impact.

Volunteers at a phone bank spoke with study subjects who minutes before had agreed to join a clinical trial at all the study sites, asking a series of questions to assess how much the subjects understood about the trial, their role in the research and what the trial's benefits would be. The callers didn't know which subjects had joined the trials at sites that used the questionnaire and which did not.

When the researchers compared results from the calls to participants at

all of the sites, they found similar results, suggesting that the questionnaire did nothing to improve informed consent. A significant number of patients did not fully understand the purpose of the research, that the research may not benefit them or that agreeing to participate was completely voluntary.

“Implementing changes to the informed consent process is like taking new medicine - you wouldn’t want to take a drug if it was too expensive or burdensome unless it’s really helpful,” Sugarman says. “This study shows that we can do rigorous clinical testing of informed consent, just like we can do rigorous testing of drugs in clinical trials.”

Source: Johns Hopkins Medical Institutions