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Shorter patient consent forms, video formats improve comprehension

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When patients participate in a clinical trial, they are required—for legal and ethical reasons—to complete consent forms that are typically long, complicated and filled with technical language. Some experts fear these forms can lead some patients to enroll in studies without fully understanding them and others to miss valuable opportunities.

To improve patient comprehension, Carnegie Mellon University researchers Tamar Krishnamurti and Nichole Argo have developed approaches to simplify the process by focusing on the information that patients need most when deciding whether to enroll in a trial. They let potential trial participants determine what information is most relevant and then created written and video versions of a shortened consent form focused on that information.

Published in the journal *Medical Decision Making*, Krishnamurti and Argo found that despite being 86 percent shorter the new consent forms were equally effective at securing patient understanding and more engaging for the patients.

"This tells us that redesigning the approach to written informed consent to make it more patient-centered and patient-designed would be in the best interest of both clinical trial patients and administrators," said Krishnamurti, assistant research professor of engineering and public policy.

In the study, Krishnamurti and Argo randomly assigned 118 severe

asthma patients to review different sections of a 17-page consent form for a trial testing an experimental injectable asthma treatment. Then, they selected and ranked the information they deemed critical to their decision-making. Next, 83 asthma patients were randomly assigned to review a full informed consent document, a shortened document based on patient preferences from the first study or an animated video of the shortened consent information.

The results showed that participants who received the shorter paper form and the video reported absorbing as much information as participants receiving the long form. They also reported feeling more engaged in the consenting process than those who read the long consent form.

"There is a broad consensus in the world of clinical trials that a more patient-centered informed consent process is needed. Our challenge was to create informed consent content and formatting that would be engaging and understandable to patients, but would at the same time not hinder or bias patient judgment and decision-making. We are now proposing a patient-centered informed consent process that seems to accomplish this goal," said Argo, a research scientist in engineering and public policy and social and decision sciences.

Provided by Carnegie Mellon University