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Concise consent forms are effectively understood by clinical trial participants

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Shortening consent documents makes no significant difference to how well potential research participants understand a clinical study, according to a study published April 26, 2017, in the open-access journal *PLOS ONE* by Christine Grady from the NIH Clinical Center, US, and colleagues.

Informed consent is a central tenet of ethical clinical research, but over time the documents used to obtain informed consent from participants have grown longer, more complex, and harder to read. Grady and colleagues developed a "concise" alternative to consent documents used in the multinational START trial, which was shorter by almost 70 percent at 1,821 words. The new document also contained bullet points and tables, and had a simpler reading level. The authors tested these documents with 4,229 HIV-positive participants at 77 sites across the world seeking enrollment in the START trial between 2009 and 2013. The sites were randomly allocated to either the concise or the standard consent documents for participants to review.

Participants who reviewed the concise version showed no significant difference in their comprehension, satisfaction, or willingness to volunteer compared to participants who reviewed the standard form. However, comprehension was better when sites mailed the consent forms in advance and when site leaders explained the study to participants in person. One potential advantage of shorter, more concise consent forms, is that they could be reviewed more quick by an ethics committee. This could allow site leaders more time to discuss the

important points of the study with their patients before enrollment in the trial, but this theory needs testing.

Whilst the study only examined one type of concise document in the context of a single clinical trial, the authors state that it is the largest test to date of modified clinical research consent forms among patients in a real clinical trial setting. They note that their results support continued efforts to make consent forms more efficient.

More information: Grady C, Touloumi G, Walker AS, Smolskis M, Sharma S, Babiker AG, et al. (2017) A randomized trial comparing concise and standard consent forms in the START trial. *PLoS ONE* 12(4): e0172607. DOI: 10.1371/journal.pone.0172607

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