Clinical trials abroad: Making non-English language consent forms readable

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The first study to look at simplified English-language consent forms translated into another language calls into question the common belief that a translated consent form meets readability standards. The study appears in *IRB: Ethics & Human Research*.

Nearly half of all U.S.-based clinical trials are now conducted overseas, many in countries where the native language is not English and whose population has low literacy - factors that present challenges to getting informed consent. But ethics review committees around the world generally assume that if an English language consent form is simplified, then the translated version will resemble the original form in its readability.

The authors used a readability formula called the cloze procedure, which measures a reader's ability to make sense of the text. For the study, volunteers in Kenya read 10 consent forms written in simplified English and the same forms translated into Kiswahili—which, with English, is one of the two official languages of Kenya. Seven out of 10 translated versions had a significant mean difference, suggesting they were less comprehensible in Kiswahil than in English. Using a "cloze pass mark" as a score of above 38 percent, for six of the 10 forms a greater percentage of respondents "failed" the Kiswahili form than the English version.

The findings raise questions about the quality of the translations of consent forms used in clinical trials. "Ethics review committees should

pause before asking only for simplified English language forms without scrutinizing the language or translation approach that will be used to translate those forms into the local language," the authors wrote.

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