Introduction/Background: Consent form readability is one aspect of the informed consent process often overlooked by researchers. Most IRBs suggest that these documents be written in lay language at a sixth to eighth grade reading level so that intended subjects may easily comprehend the information being conveyed. There is a general concern, however, that patient consent forms utilize much higher reading levels that subsequently impede the average patient's ability to understand these documents.

Methods/Intervention: Data were obtained from 10 randomly selected IRB approved consent documents from research conducted at an army medical center. Two protocols from each year were randomly selected from 2008-2012, for a total of 10 protocols. Grade-level standards (at or below an eighth grade reading level) were assessed using three different readability scales: Flesch-Kincaid, Fry, and SMOG calculations. A t test was used to compare readability scores with readability grade level standards. All P values were derived from two-sided tests; 95% confidence intervals (CI) were determined for all means.

Results/Outcomes: Each method produced means above the recommended eighth grade reading level: Flesch-Kincaid: 12.3 (95% CI 11.7-12.9; P = <0.001); FRY: 13.0 (95% CI 11.6-14.3; P = <0.001); and SMOG1: 11.2 (95% CI 10.1-12.4; P = <0.001). A combined mean reading level of 12.2 was calculated for the approved IRB consent documents.

Conclusion/Discussion: The three readability scales suggest that the 10 consent documents analyzed were written at reading levels three to five grades higher than the suggested standard. Despite general guidance that forms be simplified to a sixth to eighth grade level, most consent forms are written at or above an 11th grade reading level. Readability of the informed consent process is crucial to the underlying issue of volunteer comprehension. Without an appropriate level of readability, the informed consent document is inadequate and ineffective. The informed consent document must be written at a level so volunteers can truly understand all aspects of the research study. There is a need for effective changes that will provide subjects with a consent form that is clear, concise, and comprehensible.