

LETTER TO THE EDITOR

Response[☆]

We wish to thank Dr. O'Brien for his communication regarding our review paper on methods to enhance understanding of informed consent (Dunn and Jeste, 2001). We regret the omission of the pioneering work by Grabowski and O'Brien (1979) on improving the consent process. Their original report is consistent with our overall conclusions, namely that more structured, clearly written consent documents, coupled with corrected feedback, can improve understanding of important aspects of consent. We also concur with their original report's emphasis on the importance of substance over form, and the acknowledgment that procedures may require modification to develop enhanced consent procedures.

We have recently developed a method for enhancing understanding of informed consent for research (Dunn et al., 2001). Middle-aged and older individuals with schizophrenia and other psychotic disorders considering participation in our Interventions Research Center were randomized to receive a routine or enhanced consent procedure. The enhanced procedure consisted of a PowerPoint® slideshow that retained verbatim all information from the routine, written consent form. The procedural modifications included a more structured presentation, repetition, and review of key points about consent (e.g., procedures involved, potential risks, voluntary nature of participation and the ability to withdraw at any time). A 20-question short-answer and yes/no comprehension assessment given after the consent procedure tested understanding of the fundamental aspects of informed consent. Patients who received the enhanced consent procedure demonstrated a significantly higher level of understanding of the consent information. In agreement with Dr. O'Brien, we believe it is critical to ensure that patients understand the consent form well before participating in research projects.

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