Measuring the Process and Quality of Informed Consent for Clinical Research: Development and Testing

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Purpose/Objectives: To develop and assess the reliability and validity of an observational instrument, the Process and Quality of Informed Consent (P-QIC).

Design: A pilot study of the psychometrics of a tool designed to measure the quality and process of the informed consent encounter in clinical research. The study used professionally filmed, simulated consent encounters designed to vary in process and quality.

Setting: A major urban teaching hospital in the northeastern region of the United States.

Sample: 63 students enrolled in health-related programs participated in psychometric testing, 16 students participated in test-retest reliability, and 5 investigator-participant dyads were observed for the actual consent encounters.

Methods: For reliability and validity testing, students watched and rated videotaped simulations of four consent encounters intentionally varied in process and content and rated them with the proposed instrument. Test-retest reliability was established by raters watching the videotaped simulations twice. Inter-rater reliability was demonstrated by two simultaneous but independent raters observing an actual consent encounter.

Main Research Variables: The essential elements of information and communication for informed consent.

Findings: The initial testing of the P-QIC demonstrated reliable and valid psychometric properties in both the simulated standardized consent encounters and actual consent encounters in the hospital setting.

Conclusions: The P-QIC is an easy-to-use observational tool that provides a quick assessment of the areas of strength and areas that need improvement in a consent encounter. It can be used in the initial trainings of new investigators or consent administrators and in ongoing programs of improvement for informed consent.

Implications for Nursing: The development of a validated observational instrument will allow investigators to assess the consent process more accurately and evaluate strategies designed to improve it.

More than 107,800 registered clinical trials involving human participants currently are taking place in 174 countries (National Institutes of Health, 2011), representing a small portion of ongoing clinical research worldwide. Healthcare providers rely on clinical research to advance treatments, decrease incidence of reoccurrence, and inform strategies for primary prevention and early detection, particularly in cancer care. The Clinical Trials Cooperative Group Program, sponsored by the National Cancer Institute (NCI), registers more than 25,000 clinical research participants each year from more than 3,100 institutions and more than 14,000 individual investigators in the United States, Canada, and Europe (NCI, 2009).

For most protocols, participants sign a written consent form to provide evidence that they have read about and received an explanation of the research. However, data continue to demonstrate that participants are not able to recall essential information about the studies in which they have agreed to participate (Brown, Butow, Butt, Moore, & Tattersall, 2004; Santen, Rotter, & Hemphill, 2008). After increased government regulation (Shalala, 2000), attention in the media (Foderaro, 2009), and oversight by institutional review boards, little indication exists that participant comprehension has improved (Stepan et al., 2011).

Although written consent generally is highly standardized and structured (Grossman, Piantadosi, & Cohavey, 1994; National Patient Safety Agency, 2009), less is known about the content and quality of the verbal interaction during the consent process (Brown, Butow, Butt, et al., 2004). Tools to measure informed consent focus primarily on postconsent recall (Dresden & Levitt, 2001; Ferguson, 2002; Guarino, Lamping, Elbourne, Carpenter, & Peduzzi, 2006; Joffe, Cook, Cleary, Clark, & Weeks, 2001; Lavori, Wilt, & Sugarman, 2007; Miller, O'Donnell, Searight, & Barbarash, 1996). Lindegger et al. (2006) developed and compared four alternative methods for assessing a study participant's understanding of informed consent: self-report, forced-choice checklist, vignettes, and narratives. Their study suggested that the levels of measured understanding are dependent on the methods of assessment used and