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

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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 study. 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...