

JERHRE NOTES

Concepts, Tools, and Resources for Solving Ethical Problems in Human Research

How Informed are Subjects by the ‘Informed Consent’ Process?

Informed consent documents have come to resemble legal contracts filled with disclaimers and technical terminology. Do such documents adequately inform and position potential subjects to decide whether to participate in a given research project? Recent research indicates that average knowledge scores of persons participating in oncology trials are as low as 69% after going through the informed consent process. In the face of such findings, the research community must question whether participants’ decisions to enroll in research are truly informed, and to consider what steps, if any, can be taken to better inform potential research participants.

Gordon Willis demonstrates that the tools of cognitive psychology may be used to assess potential subjects’ comprehension and decision-making in the informed consent process. Specifically, Willis describes three areas where cognitive psychological approaches to comprehension and decision-making—in particular, the practice of *cognitive interviewing*, as adapted from the field of questionnaire pre-testing-- can be applied usefully to the study of informed consent processes:

- (1) As *basic experimental research* on the science of informed consent;
- (2) As *applied research*: A method for pre-testing consent materials for fielded study use; and
- (3) As a *monitoring* tool: An imbedded tool for assessing comprehension and decision-making within an ongoing study.

Willis presents the results of applied research on informed consent which demonstrates that cognitive interviews are both feasible and useful for determining just how *informed* subjects are, and for preparing potential subjects to decide whether to enroll in a particular study.

Willis, G. (2006). Cognitive interviewing as a tool for improving the informed consent process. *Journal of Empirical Research on Human Research Ethics*, 1(1), 9-23.

