

# STRONG CHILDREN'S RESEARCH CENTER

## Summer 2012 Research Scholar

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### ABSTRACT

#### **Title: Improving Measurement of Parents' Understanding of Research Permission**

**Background:** By modifying the permission forms at the center of the understanding process, parent understanding of research studies may be improved. Furthermore, modifications of the tools used to measure understanding, such as the current gold standard, Deaconess Informed Consent Comprehension Test (DICCT), may improve our ability to measure parent understanding of research.

**Objective:** The objectives of this study were to:

- Refine a cover sheet that orients parents to the critical aspects of research studies and provides guidance for parents to find additional information in the permission form.
- Improve current tools to measure parent understanding of research permission.

This study tested the hypothesis that, among parents of potential subjects for greater-than-minimal-risk research, two modified and simplified subset of questions from the DICCT, one oral and open-ended and one written and multiple choice, would retain the test characteristics of the DICCT.

**Methods:** Subjects were asked for verbal permission to participate in the study and were informed that their child was not actually being enrolled in a study. Subjects then read sham study permission forms. Evaluations consisted of: 1) Likert Scales of subjective understanding of and satisfaction with the permission form and cover sheet, (2) either modified comprehension test followed by the DICCT, or vice versa (randomized), and (3) a demographic and exam preference questionnaire. Correlations between the full 14-item DICCT and the new measurement tool scores were measured by linear regression.

**Inclusion criteria:** Parents with infants admitted to the Strong Memorial Hospital NICU with gestational age <32 weeks at birth, parents with infants recovering from neonatal illness, parents who were English speaking

**Exclusion criteria:** Illiteracy (unable to read simple forms), parents with infants with gestational age <28 weeks at birth and age <2 weeks

**Results:** Average Likert scale ratings of the cover sheet were all greater than 5 on the Cover Sheet Questionnaire. Subjects also gave open-ended responses indicating positive opinions about the cover sheet. Eighty-eight percent of subjects preferred taking the written comprehension test compared to the DICCT, whereas equal numbers preferred the oral comprehension test vs. the DICCT. Subject scores between the DICCT and both modified comprehension tests were highly correlated ( $R = 0.9325$  for the DICCT vs. written comprehension test,  $R = 0.8722$  for the DICCT vs. oral comprehension test).

#### **Conclusion**

Subject satisfaction with the cover sheet as a part of the consent form indicates that a cover sheet may help with the understanding of research permission forms.

Open-ended surveys following the sham consent process indicated that subjects preferred the written comprehension test compared to the DICCT due to its succinctness and length.

The high degree of score correlation between the DICCT and the written comprehension test, along with subject preference for the written test, suggests that the written test may replace the DICCT as a standard test for parent understanding of research permission.