Informed Consent for Clinical Trials: a Comparative Study of Standard Versus Simplified Forms

Terry C. Davis, Randall F. Holcombe, Hans J. Berkel, Sumona Pramanik, Stephen G. Divers*

Background: A high level of reading skill and comprehension is necessary to understand and complete most consent forms that are required for participation in clinical research studies. This study was conducted to test the hypothesis that a simplified consent form would be less intimidating and more easily understood by individuals with low-to-marginal reading skills. Methods: During July 1996, 183 adults (53 patients with cancer or another medical condition and 130 apparently healthy participants) were tested for reading ability and then asked to read either the standard Southwestern Oncology Group (SWOG) consent form (16th grade level) or a simplified form (7th grade level) developed at Louisiana State University Medical Center—Shreveport (LSU). Participants were interviewed to assess their attitudes toward and comprehension of the form read. Then they were given the alternate consent form and asked which one they preferred and why. Results: Overall, participants preferred the LSU form (62%; 95% confidence interval [CI] = 54.8%–69.2%) over the SWOG form (38%; 95% CI = 30.8%–45.2%) \( P = .0033 \). Nearly all participants thought that the LSU form was easier to read (97%; 95% CI = 93.1%–99.9%) than the SWOG form (75%; 95% CI = 65.1%–85.7%) \( P < .0001 \). However, the degree to which the participants understood the forms was essentially the same for the LSU form (58%; 95% CI = 48.6%–67.0%) and the SWOG form (56%; 95% CI = 43.8%–66.8%). Implications: These findings raise serious questions regarding the adequacy of the design of written informed consent documents for the substantial proportion of Americans with low-to-marginal literacy skills. [J Natl Cancer Inst 1998;90:668–74]

Clinicians and researchers must obtain informed consent from patients before enrolling them in clinical trials. To ensure that patients fully understand factors related to their care, the Food and Drug Administration (FDA) requires that consent documents contain detailed information regarding eight basic elements of informed consent (1). However, little attention has been given to how well patients comprehend these elements (2–10) despite the fact that health care providers have an ethical and legal responsibility to ensure that patients understand their participation in research (7).

Standard consent forms are written at too difficult a level for many patients to read and comprehend, especially those with low literacy skills (5,8,9–20). The National Adult Literacy Survey (21) found that 21% of U.S. adults are functionally illiterate, and an additional 27% have marginal literacy skills. These figures indicate that a substantial proportion of patients may not be able to read and understand the consent forms that are currently used in clinical research (11,12,18). Despite recommendations that forms be simplified to a 6th–8th grade level, most forms continue to be written at or above a 12th grade level (5,8,10–12,14–20,22,23,24).

Factors associated with decreased comprehension of informed consent include limited education, increasing age of the patient, and the readability of the consent form (2,6,8,12). Results are mixed regarding the effect of simplified patient education material and consent forms on patient comprehension (25). Lowering the readability level alone seems to have little impact (2,8). However, researchers in the field of patient education have found that the appeal and comprehension of health education material can be increased by improving the presentation through use of instructional graphics, headers, and questions, as well as use of bold text and colors (12,18,25–31). To our knowledge, the effect of improving the presentation of consent forms on comprehension has not been previously tested.

The National Cancer Institute has called for research aimed at simplifying the informed consent process, at improving comprehension, and at identifying methods to provide specific study information to diverse populations in cancer prevention and treatment trials (7). The purpose of this study was to test the hypothesis that a simplified consent form, written at a lower reading level and developed with input from patients, would improve the comprehension and attitude of participants toward the form.

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668 ARTICLES
Subjects and Methods

During July 1996, 183 adults recruited from private and university oncology clinics and a low-income housing complex were tested for reading ability and given either a standard Southwestern Oncology Group (SWOG) consent form for a phase III breast cancer clinical trial or a simplified booklet-style form developed at Louisiana State University Medical Center—Shreveport (LSU). Patients were interviewed using an oral questionnaire that assessed attitudes and comprehension of the consent form they were given. Upon completion of the interview, the patients were given time to review the alternate consent form and were asked additional questions as to which they preferred, why, and whether they would prefer to receive both forms. They were also asked to rate each consent form quantitatively by placing a vertical mark on a Likert-scale (16-cm horizontal line that was labeled “bad” at 0 cm and “good” at 16 cm).

Either the SWOG or the LSU form was presented first on alternate days. The entire interview was completed in about 25 minutes using the SWOG form or 10–12 minutes using the LSU form. Since each interview took twice as long on the day that the SWOG form was initially given, fewer people were tested in the allotted time. Sixty-nine adults were initially given the SWOG form, and 114 were initially given the LSU form. Because the study only involved assessing patient attitudes and comprehension, it received an exemption from the Institutional Review Board at LSU.

Patient Population

Of the 205 adults who were approached and asked to participate in the study, 22 refused. The reasons given for refusal were as follows: Eight patients did not want to participate, six could not see well, four could not read, and four were tired or felt ill.

Of the 183 adults tested, 18 (10%) were tested at a private oncology clinic in Shreveport, 28 (15%) at a low-income housing complex in Shreveport, and 137 (75%) at the LSU Hematology/Oncology Clinic (see Table 1). At the private and university clinics, patients or accompanying friends or family members were approached in the clinic waiting rooms. If they agreed to participate, they were taken to a private room and tested. Residents of a housing complex near LSU were recruited by the president of the residents’ council and asked to participate in a study to elicit input on consent forms used at LSU. These participants met at one of two sessions held at a community center where they were invited into a private room for testing. At the first session, 14 participating residents were initially given the SWOG form. At the second session, 14 participating residents were initially given the LSU form. While equal numbers of participants at the housing complex were tested with each form, the duration of testing when the SWOG form was supplied first was approximately double that when the LSU form was supplied first. The residents’ council was paid a stipend of $300.

Study Instruments

The Rapid Estimate of Adult Literacy in Medicine (REALM) (32) is an individually administered reading recognition test designed for use in medical settings. Reading recognition tests do not indicate the readers’ comprehension, only their ability to read aloud words in isolation (33). Reading recognition scores are accepted as useful predictors of general reading ability and are an indicator of functional literacy skills (33,34). The REALM is highly correlated with other standardized tests of reading recognition (15,16,18) as well as the Test of Functional Health Literacy in Adults (11,35). The raw scores range from 0 to 66 and can be converted into four reading grade levels: 3rd grade and below (scores of 0–18), 4th–6th grades (scores of 19–44), 7th–8th grades (scores of 45–60), and 9th grade and above (scores of 61–66). The REALM can be administered and scored in 2–3 minutes by personnel with minimal training.

A structured oral questionnaire was developed by the investigators. This questionnaire was pilot-tested over a period of 2 weeks at the LSU Hematology/Oncology Clinic to ensure that the questions were clear and understandable to patients. The final version of the questionnaire—the one used in this study—assessed patient demographics and contained 22 attitude and comprehension questions.

Description of the Consent Forms

The standard research consent form used in this study is the one developed by SWOG for protocol #8851. It is entitled, “Phase III Comparison of Combination Chemotherapy (CAF) & Chemohormonal Therapy (CAF + Zoladex or CAF + Zoladex and Tamoxifen) in Premenopausal Women with Axillary-Node Positive, Receptor-Positive Breast Cancer, Intergroup” (see “Appendix” section). The SWOG consent form is a seven-page, single-spaced document that contains 3438 words. The average sentence length is 21 words, and the form has no graphics. The readability of the SWOG form was calculated using Grammatik IV software (Reference Software International, San Francisco) (36), which revealed a Flesch–Kincaid index (37) at the 12th grade reading level and a Fog index (38) at the 16th grade level.

The LSU form was designed with input from patients. Individual patient interviews in the LSU Hematology/Oncology clinic elicited information on appeal, reading ease, and comprehension. No patient who assisted with the development of the LSU consent form or the questionnaire participated in the main study. Based on patient feedback, the form was revised twice before the study was initiated. The readability of the LSU form, calculated using Grammatik IV software, was at the 5th grade level on the Flesch–Kincaid index and at the 7th grade level on the Fog index. It was formatted as a seven-page booklet containing 524 words. The title, “Breast Cancer, You Can Help Your Doctors Find Better Treatments,” appeared on the front cover with a seal of “LSU Medical Center Shreveport.” The text had an average sentence length of 12.5 words, used colored headers, had ample white space, and included 11 culturally sensitive instructional graphics (Fig. 1).

Analysis of Data

A chi-squared test was used to determine the differences in attitude and comprehension between the two forms, as well as to compare education and reading levels between the two study groups. The Kruskal–Wallis one-way analysis of variance was used to compare the participants’ comprehension of forms across reading levels. The Mann–Whitney rank-sum test and the Wilcoxon signed-rank test were used to determine differences in patient preference between the SWOG and LSU forms. All P-values were derived from two-sided tests; 95% confidence intervals (CIs) were determined for all points estimates.

Results

Of the 183 adults interviewed, 102 (56%) were African American, 81 (44%) were white, and 139 (76%) were female (Table 1). The median age of the participants was 48 years (range, 19–85 years). Fifty-three (29%) of the adults tested had cancer, but none were candidates for participation in the clinical trial for which the consent forms were prepared. Patients had completed an average of 11.9 years in school. The mean raw

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Table 1. Demographics of study population by participant who received the LSU* or the SWOG† form first

<table>
<thead>
<tr>
<th></th>
<th>LSU form (n = 114)</th>
<th>SWOG form (n = 69)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No.</td>
<td>%</td>
<td>No.</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female (n = 139; 76%)</td>
<td>86</td>
<td>53</td>
</tr>
<tr>
<td>Male (n = 44; 24%)</td>
<td>28</td>
<td>16</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Black (n = 102; 56%)</td>
<td>64</td>
<td>38</td>
</tr>
<tr>
<td>White (n = 81; 44%)</td>
<td>50</td>
<td>55</td>
</tr>
<tr>
<td>No. of participants per clinic site</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LSU Cancer Clinic</td>
<td>91</td>
<td>46</td>
</tr>
<tr>
<td>Housing projects</td>
<td>14</td>
<td>14</td>
</tr>
<tr>
<td>Private</td>
<td>9</td>
<td>9</td>
</tr>
<tr>
<td>Years of schooling</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (standard deviation)</td>
<td>11.8 (2.6)</td>
<td>12.1 (2.1)</td>
</tr>
<tr>
<td>Median</td>
<td>12</td>
<td>12</td>
</tr>
<tr>
<td>Raw REALM‡ score</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (standard deviation)</td>
<td>50 (19.6)</td>
<td>54 (14.2)</td>
</tr>
<tr>
<td>Median</td>
<td>60</td>
<td>59.5</td>
</tr>
</tbody>
</table>

*LSU = Louisiana State University Medical Center—Shreveport.
†SWOG = Southwestern Oncology Group.
‡REALM = Rapid Estimate of Adult Literacy in Medicine.

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ARTICLES 669
score on the REALM was 52, which indicates that the patients were reading, on average, at a 7th–8th grade level. Forty-six (25%) scored below 45, which indicates that they were reading on a 6th grade level or below and that they could be considered marginally literate. Education levels and reading raw scores were slightly higher in the group that was initially given the SWOG form but did not differ significantly from the group initially given the LSU form (Table 1).

Overall, participants preferred the LSU form (62%; 95% CI = 54.8%–69.2%) over the SWOG form (38%; 95% CI = 30.8%–45.2%) \( (P = .0033) \). Nearly all participants thought the LSU form was easy to read (97%; 95% CI = 93.1%–99.9%) in contrast to the SWOG form (75%; 95% CI = 65.1%–85.7%) \( (P < .0001) \). Participants reported they felt less comfortable with the SWOG form (20%; 95% CI = 10.6%–30.0%) compared with the LSU form (6%; 95% CI = 1.6%–10.6%) \( (P = .0099) \). They were more frequently frightened by the SWOG form (30%; 95% CI = 19.3%–41.5%) than the LSU form (13%; 95% CI = 6.9%–19.5%) \( (P = .0079) \). They thought that the SWOG form was more likely than the LSU form to discourage them from participating in the breast cancer clinical trial (12% [95% CI = 3.9%–19.3%] versus 2% [95% CI = 0%–4.3%] respectively; \( P = .0135 \) (Fig. 2). Very few participants were insulted by either form: Only 2% given the SWOG form first and 1% of those given the LSU form first indicated that they were insulted. A majority of the participants reported that they would read the entire form if given to them by a physician (86% SWOG form [95% CI = 77.0%–94.0%] versus 90% LSU form [95% CI = 84.9%–95.9%]). While 75% (95% CI = 69.0%–81.8%) of the participants thought the form that they had read contained the right amount of information, 17% (95% CI = 8.3%–26.5%) initially given the SWOG form thought it contained too much information, and 22% (95% CI = 14.2%–29.6%) initially given the LSU form felt it contained too little information.

On the Likert scale, the LSU form was rated significantly better (11.8; standard deviation [SD] = 4.1) than the SWOG form (10.2; SD = 3.5) \( (P < .0001) \). While participants tended to prefer the consent form they were first asked to read, those first given the LSU form preferred it to a greater degree than those first given the SWOG form. Among adults who read below a 9th grade level, the majority preferred the LSU form even when they were given the SWOG form first; 46% (95% CI = 34.0%–58.0%) of those first given the SWOG form preferred it, and 79% (95% CI = 71.4%–86.6%) of those first given the LSU form preferred that form.

A total of 115 participants (63%; 95% CI = 55.9%–70.1%) said they would prefer to be given both forms. Participants were more likely to say they would prefer both forms if they were first given the SWOG form. Preference of form did not vary by race, since identical proportions (59%) of black (95% CI = 49.3%–68.7%) and white (95% CI = 48.1%–69.9%) participants preferred the LSU form. However, participant preference did vary

Fig. 1. Example of a page from the simplified Louisiana State University Medical Center—Shreveport consent form.

Fig. 2. Participant attitudes concerning the Louisiana State University Medical Center—Shreveport (LSU) and Southwestern Oncology Group (SWOG) forms. Bars show the mean percentages of participants who responded affirmatively to questions that are shown on the x-axis. Error bars represent 95% confidence intervals. Participants responded to the first question concerning which form they preferred after they had also reviewed both forms. Participants responded to remaining questions after they had reviewed only one form (either the LSU or SWOG)
by reading and education level: Those with lower literacy levels preferred the simplified LSU form. Participants reading at an 8th grade level and below preferred the LSU over the SWOG form (70% [95% CI = 61.8%–79.2%] versus 30% [95% CI = 21.8%–39.2%]). Those reading at a 9th grade level or above also preferred the LSU form but to a lesser extent (52% [95% CI = 41.1%–62.9%] versus 48% [95% CI = 37.1%–58.9%]). Overall, participant comprehension was the same for both forms—58% for the LSU form (95% CI = 48.6%–67.0%) and 56% for the SWOG form (95% CI = 43.8%–66.8%)—with no significant differences on any of the 10 individual questions used to assess this. The participants’ scores on the comprehension questions were related to their reading ability. Participants reading at or below a 3rd grade level had an average comprehension score of 21% (95% CI = 1.3%–40.7%), those reading at a 4th–6th grade level averaged 39% (95% CI = 20.6%–57.4%), those at a 7th–8th grade level scored 54% (95% CI = 40.4%–67.6%), while those reading at or above a 9th grade level scored 72% (95% CI = 62.2%–81.8%) (P = .038 for trend). Adults reading at or above a 9th grade level had significantly higher comprehension of both the SWOG form (71%; 95% CI = 61.1%–80.9%) and the LSU form (73%; 95% CI = 63.3%–82.7%) than those reading on or below an 8th grade level (SWOG form, 43% [95% CI = 33.0%–53.0%] versus LSU form, 45% [95% CI = 35.0%–55.0%]; P < .0001).

Results of the 10 comprehension questions are shown in Table 2. Of note, the participants’ comprehension of basic treatment information was very low. For example, less than a third of the participants tested understood the differences in the three treatments for the breast cancer protocol (14% [95% CI = 10.8%–25.2%] for the SWOG form versus 25% [95% CI = 16.9%–33.1%] for the LSU form) or what determines which treatment you get (23% [95% CI = 12.9%–33.1%] for the SWOG form versus 18% [95% CI = 10.8%–25.2%] for the LSU form).

**Discussion**

Informed consent is an interactive, multifaceted process, of which one important element is the informed consent document.

In clinical research, participants must be given informed consent documents that they can understand (6,7,28), yet participants in this study comprehended just over half of the information in the standard SWOG consent form (56%) or in the simplified LSU form (58%). Making the form more suitable by using suggestions from the literature (12,16,18,24–30) and eliciting participant input made the consent document easier to read and less frightening to the participants but did not improve comprehension of the elements contained within it.

The results of this study confirm those of previous studies that showed comprehension of informed consent documents poses problems for many participants. Williams et al. (11) found that fewer than half of participants in public hospitals in Atlanta and Los Angeles could comprehend the standard consent document used for invasive procedures at the Atlanta hospital. Cassileth et al. (24) found that 60% of patients participating in a study conducted in Philadelphia understood the purpose and nature of medical procedures to which they had signed written consent just 1 day before and that only 40% of the participants reported they had read the form carefully. Cassileth et al. (24) concluded that the difficulty of the material and its legalistic wording imposed barriers to the patients’ comprehension of information intended to facilitate informed decisions.

To improve comprehension, consent forms should be brief and direct. They should avoid legal jargon and should be written at appropriate reading levels using plain English (12,19). Following these recommendations and those in the participant education literature, we developed a more suitable form written on a 7th grade level. This form was rated as being easier to read than the SWOG form (16th grade level) by the participants in the study, yet their comprehension of the content was not improved. These findings support the results of another study (2), which showed that simplifying informed consent materials alone does not significantly improve participant comprehension. On the other hand, Young et al. (8) reported significantly (P < .05) higher participant comprehension using a simplified form (6th grade level) compared with a standard form (16th grade level). While the differences reported by Young et al. reached statistical significance, they seem to be of marginal clinical importance: They

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**Table 2. Comprehension of informed consent assessment by reading grade level**

<table>
<thead>
<tr>
<th>Question</th>
<th>Standard form, % correct</th>
<th>LSU† form, % correct</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>≤8th grade</td>
<td>≥9th grade</td>
</tr>
<tr>
<td>What is the purpose of the consent form?</td>
<td>46</td>
<td>84</td>
</tr>
<tr>
<td>Why is the breast cancer research study being done?</td>
<td>19</td>
<td>47</td>
</tr>
<tr>
<td>What is chemotherapy?</td>
<td>57</td>
<td>81</td>
</tr>
<tr>
<td>What are the differences between treatments I, II, III?</td>
<td>8</td>
<td>22</td>
</tr>
<tr>
<td>What determines which treatment you get?</td>
<td>5</td>
<td>44</td>
</tr>
<tr>
<td>List three side effects of the drug in these treatments that make you feel sick.</td>
<td>65</td>
<td>84</td>
</tr>
<tr>
<td>What happens to most side effects of these drugs when you stop taking them?</td>
<td>35</td>
<td>75</td>
</tr>
<tr>
<td>Why is it important to tell your doctor if you have any side effects while taking these drugs?</td>
<td>23</td>
<td>97</td>
</tr>
<tr>
<td>Can you be in this research if you are pregnant?</td>
<td>70</td>
<td>94</td>
</tr>
<tr>
<td>Can you take birth control pills during your treatment?</td>
<td>51</td>
<td>78</td>
</tr>
</tbody>
</table>

*Data are organized by the form participants were first given and by the participants’ reading grade level based on testing by Rapid Estimate of Adult Literacy in Medicine.
†LSU = Louisiana State University Medical Center—Shreveport.
found a mean difference of only 0.6 more questions (of the 21 questions) answered correctly on the “low reading level consent form.” Research is lacking as to the methods by which participant comprehension of informed consent documents can be increased to a clinically acceptable level or even what a clinically acceptable level might be.

Our previous research (11,18,25), as well as other research, indicated that participants with very low literacy would probably not be able to adequately comprehend either standard or simplified consent form. Williams et al. (11) suggested that simplifying the text to an approximately 6th grade level might allow marginally literate participants to comprehend the documents. We hypothesized that a form written on a 7th grade level would be better understood by participants with both adequate and marginal literacy levels in comparison to a standard form written on a 16th grade level. We further hypothesized that those who would benefit most from the simplified form would be participants with marginal literacy skills. In actuality, participants with adequate literacy levels (i.e., those reading at or above a 9th grade level) comprehended both forms at marginally adequate levels: 73% the simplified LSU form and 71% the standard SWOG form. Participants with marginal literacy skills (i.e., those reading at a 7th–8th grade level) understood approximately half of the information on either form. Although comprehension was higher with the simplified form, the difference was not statistically significant.

Participants with inadequate literacy skills understood only a minimal amount of the content of either form. Those reading at a 4th–6th grade level comprehended 41% of the LSU form and 35% of the SWOG form. The 17 participants with the lowest literacy, (0–3rd grade reading level), who could be considered functionally illiterate, comprehended only 20% of the LSU form and 10% of the SWOG form. These findings indicate that 1) standard forms do not adequately inform participants (particularly those with marginal and inadequate literacy skills) and 2) simplified forms, when used alone, do not significantly improve the comprehension of participants—at any reading level.

Given that approximately 90 million adults in the United States have inadequate literacy skills (21), our findings raise ethical and legal questions about the ability of informed consent documents to aid all individuals in the decision-making process for study participation. These adults may not be able to read and understand the forms they are signing, and they may not let clinicians or researchers know their problem since most participants who have reading difficulties are embarrassed to admit it (39). Clinicians should also be aware that patients with inadequate literacy skills may be anxious about being expected to read and sign documents and to communicate with physicians (18,34,39). Patients with low literacy may also have problems with basic physician/participant communication. Recent studies (40,41) have shown that participants with extremely limited literacy skills may have limited health knowledge and may not understand basic health concepts such as the purpose of a mammogram. Such individuals often do not understand what the physician has said and may not be willing to ask physicians for clarification of information (18,39).

In an attempt to sufficiently inform patients so they can make a rational decision about participating in a research study, the Department of Health and Human Services (1) developed detailed regulations concerning the minimum information that consent forms should contain. Subsequently, consent forms have expanded in length (19,23). However, in our study and in other studies, consent forms that are longer and more detailed did not improve the readability of the form or its comprehension by participants (19,23). In this study, participants preferred the shorter, easy-to-read material and found it less frightening. Perhaps long forms written on a college level, though intended to provide complete information for informed consent of a clinical trial, may inadvertently be frightening and overwhelming, especially for low-level readers.

In our study, even those participants who read on at least a 9th grade level were not offended by the simple form. Only seven of 183 participants reported that they were insulted by either form, and none were offended by the simplicity of the LSU form. This observation supports earlier findings (25,26) that neither highly literate nor high-income participants are offended by simple material.

Ethicists and patient educators (8,17,24,42–46) are recommending that patients be included in the development of patient education materials and forms to ensure that the materials include information important to them and are more understandable, appealing, and culturally sensitive. Reid et al. (45) found that patients and physicians differed in what they thought was important to include in written material. This may also be true for informed consent. Turner et al. (46) found that physicians did not identify the outcomes that were most important to cancer patients. For example, patients indicated that acute side effects were as important as long-term side effects. Side effects that were not routinely emphasized, such as energy loss or change in appearance, were more important to patients. Cassileth et al. (24) found that 80% of participants viewed consent forms as a protection for physicians.

In developing the LSU simplified consent form we elicited individual patient feedback on various versions of the form and modified it over a 2-week period based on this input. While patients liked the information presented in booklet form, they felt it was important for a consent form to look official and they requested a formal cover page and legally detailed signature page. A one-page insert was added as a supplement to the booklet.

There are several limitations to this study. First, although the different consent forms were administered on alternate days, the study was not randomized in the traditional sense. More participants were initially given the LSU form because more questionnaires could be completed in each testing period when the shorter, simplified LSU form was reviewed by participants first. Second, none of the participants were candidates for the phase III breast cancer trial for which the consent form was designed. Therefore, neither the SWOG nor the LSU consent form was specifically relevant to them, and none of the participants were dealing with an actual recent diagnosis of cancer. They did not have to truly consider participation in a clinical trial and, as such, did not have associated anxiety that might interfere with comprehension of both verbal and written communication. Third, in a standard clinical encounter, a written informed consent document is supplemental to an interactive, “face-to-face” consent process. The design of our study did not include this active
continuing process. Comprehension was limited to what the participant could understand from reading the document.

Another potential problem is that, although the questionnaire was pilot-tested for comprehension, the validity of the questionnaire was not extensively tested to determine the appropriateness of the questions. In addition, the questions did not assess the participants’ comprehension of all eight essential elements of informed consent as outlined by the FDA. The Deaconess Informed Consent Comprehension Test (3), published after this study was conducted, provides 14 questions that could be used to assess all eight elements of informed consent. The design of the study also does not control for previous knowledge and does not distinguish between recall and true comprehension. However, there is no published standard that defines a coherent methodology to test comprehension in a similar setting.

In conclusion, our findings indicate that simplifying informed consent material alone makes the forms more appealing and easier to read but will not improve comprehension. Research is needed to determine the methods to increase comprehension, especially for participants with inadequate or marginal reading skills. Input from participants and recognition of hidden illiteracy will be critical in the development of better informed consent.

References
