

## **Making Informed Consent Work for All**

**By Susan Brink**

The traditional process for obtaining informed consent from potential clinical trial subjects is time-consuming, expensive and not very effective. As many as one in five enrolled subjects who complete a traditional consent process have essentially zero understanding of the risks, benefits, and goals of the trial.<sup>1</sup> In a survey of subjects in 26 clinical trials, a large percentage showed a marked lack of understanding:<sup>2</sup>

- 57% did not recall that the treatment they were undergoing was part of a clinical trial.
- 75% did not recall the phase of the trial.
- 59% did not recall the level of personal effort involved in participation.
- 70% did not recall the possible alternatives to the trial treatment

Obviously, many study subjects are not fully informed when they give consent. In addition to the ethical ramifications, practical effects include problems with compliance, retention and relationships with study personnel, as well as implications for litigation if there is an injury.

### **Rethinking Informed Consent**

Traditional paper-based consent documents have positive aspects as well as drawbacks. They are familiar to candidates, patients and staff. They are inexpensive and easy to reproduce and store. On the other hand, paper consent documents are often incomprehensible to prospective subjects, provide the study team with no quantitative information about how much time the candidate has spent actually reviewing to the consent, and present paperwork problems when there are amendments.

Study candidates have difficulty understanding and remembering information in printed consent forms that give little attention to readability or explaining medical and research terminology.<sup>2,3,4</sup>

Study personnel usually supplement the informed consent document with verbal explanations. However, research suggests that study personnel tend to exaggerate the benefits and downplay the risks, discomforts and inconveniences.<sup>5</sup> They also tend to judge candidates' ability to understand various aspects of study design and implications, such as treatment alternatives, and therefore may make judgments about what information each subject can understand or wants to know.<sup>2</sup> Prospective participants thus receive inconsistent information.

We can do better. For example, prospective subjects can benefit from information presented in "layers" and in a variety of formats.<sup>6,7</sup> Candidates are more likely to remember oral than written consent information.<sup>4</sup> The use of video in addition to written documents also increases participants' long-term retention of study information.<sup>8</sup>

Multimedia presentation of information using computer technology can combine the virtues of print, audio and video while eliminating presenter bias by ensuring that all candidates are exposed to the same material.<sup>9</sup> Candidates feel less stressed and more in control when using a multimedia informed consent "document."<sup>6</sup> Candidates like a hierarchy of

information and the use of modules (distinct topic-dedicated interactive units).<sup>6</sup> Candidates find that video segments make the information easier to understand.<sup>6,8</sup>

### **Online Multimedia Consent**

The flexibility, robustness, scalability, subject-tracking potential, and transparency of Internet-based solutions have the potential to resolve the above issues.

The ideal multimedia informed consent system should have the following features:

- Interactive, modular, layered design
- Trial-specific, Institutional Review Board (IRB)-approved content
- Embedded multimedia information and interactive tools that assist with the participation decision
- Self-administered knowledge assessments (questions)
- Oral narration (optional at candidate's discretion) to accommodate a range of literacy levels
- Multilingual support
- Reporting of modules completed, time-on-task, and use of knowledge self-assessments

Online multimedia consent ensures consistent delivery of the same peer-reviewed, IRB-approved information to every candidate. Because the multimedia system does more of the work than paper documents, less time is required from study personnel, so costs are reduced. The time that the candidate spends with study personnel focuses on specific questions and self-assessments that the candidate recorded while using the multimedia consent.

### **What Do Prospective Subjects Think?**

We tested two consent forms, one paper and one multimedia, both with the exact same text and both being used in the same Phase II cancer clinical trial. The research site's IRB approved both forms. We recruited 32 adult volunteers in the Washington, DC metropolitan area for a comparative study of the two forms. We asked the subjects to review a consent form as if they were actually considering participation in the trial. Of the volunteers, 67% were female, 62% were over the age of 59, and 50% were African-American; the remainder were Caucasian. All spoke and read English. 75% percent used a computer every day. 12% used a computer rarely or never. 84% had considered participating in a clinical trial previously; 56% had, in fact, participated in a trial.

Each subject reviewed both the paper and multimedia forms in order of random assignment. Regardless of which version was given first, the multimedia version elicited greater time-on-task, with first-time multimedia consent users spending 28.4 minutes with the form and first-time paper consent readers spending 17.7 minutes. Time spent with the multimedia form ranged from 10 to 60 minutes. Time spent with the paper form ranged from 2 to 20 minutes, not an unusual range in clinical trials.

After the subjects reviewed the first assigned form, they were asked both specific factual questions and more general questions of perceived understanding. We asked them eight factual true/false questions about the study. For example, did they know that the chemotherapy would be given in three-week cycles? On average, there was no difference in the scores by type of form – paper or multimedia. However, in response to a 14-item scale developed from the Deaconess Informed Consent Comprehension Test<sup>10</sup>, in which the questions were of a more general nature regarding the trial, there was 8.4% higher overall

self-reported understanding with the multimedia form than with the paper form ( $t = 2.479$ ,  $p = .019$ ). Individual items that contributed the most to significance were:

- Understanding that the treatment involved research ( $t = 1.974$ ,  $p = .058$ )
- Understanding how the trial may benefit future patients ( $t = 3.155$ ,  $p = .004$ )
- Understanding that participation in the trial was voluntary ( $t = 2.145$ ,  $p = .040$ )

All differences were significant in the direction of greater understanding with the multimedia form.

After the subjects answered questions about the first form, we gave them the other form to review as if it were the first form they were seeing. After the reviewing both forms, 65% of the subjects stated a preference for the multimedia form. As shown in Table 1, subjects indicated that the multimedia version compared to the paper version better helped them understand what would happen (37%), better presented and helped them identify risks (47%), and better explained trial medical procedures (44%).

**Table 1. Subject Preferences for Presentation Format**

|                                    | <b>Computer</b> | <b>Paper</b> | <b>Neither</b> |
|------------------------------------|-----------------|--------------|----------------|
| Preference, overall                | 21 (65%)        | 8 (25%)      | 3 (10%)        |
| Preference by perceived benefit:   |                 |              |                |
| Understanding of what would happen | 12 (37%)        | 6 (19%)      | 14 (44%)       |
| Identifying possible risks         | 15 (47%)        | 5 (15%)      | 12 (37%)       |
| Explaining procedures              | 14 (44%)        | 6 (6%)       | 15 (47%)       |

In response to open-ended questions, subjects preferring the multimedia form said that it was:

- Easier to read and understand
- More interesting and exciting
- More informative and effective in getting points across

They found the paper document:

- Boring, more clinical, and more "boiler-plate"
- Wordy, but providing less explanation
- More time-consuming
- Daunting with respect to the number of pages

These perceptions are especially interesting because both forms included exactly the same text and the average subject spent more time with the multimedia version than with the paper version.

In response to open-ended questions, subjects preferring the paper form said:

- The paper form was familiar and more comfortable
- It was easier to look back at previous pages
- They liked holding the paper document
- They felt more in control

They found the multimedia form:

- Not as easy to read
- Uncomfortable to navigate at first

- Too public if audio was played without earphones

In general, subjects with relatively more computer experience preferred the multimedia form while subjects with relatively less computer experience preferred the paper form. Both groups liked the media elements and explanations found in the online version.

Three screenshots from the multimedia consent form are at [http://www.firstclinical.com/journal/2006/0612\\_Multimedia.zip/](http://www.firstclinical.com/journal/2006/0612_Multimedia.zip/)

## Conclusions

Multimedia informed consent forms are clearly preferred by many prospective subjects. This preference is not just a reflection of entertainment value; it also correlates with better comprehension than with paper informed consent forms.

Given their many advantages to the informed consent process, multimedia consent forms will probably soon be widely accepted as a viable alternative to paper forms. They will not substitute for face-to-face time with trial staff, but rather as a method of providing information that is understood by a greater range of candidates. Early adopters will accept a value proposition that includes advantages in subject recruitment, retention and compliance. Ethical considerations should also play a role in adoption.

Increasingly sophisticated and effective multimedia consent systems will be developed that integrate into the consent process and provide wider availability, more effective subject education, and strengthened decision support.

Widespread adoption of multimedia consent forms will require overcoming both attitudinal and technical barriers. Sponsors, investigators, IRB members, as well as potential subjects, must be open to new approaches. Ideally, signatures should be electronic. Signed electronic informed consent forms must be stored in compliance with HIPAA requirements. And, to assure that all candidates receive the same quality of information, uniform access to adequate computers must be provided. For some time, the option of paper consent forms should be provided to subjects based on their preferences.

As these barriers are overcome by organizations participating in clinical trials, the advantages of multimedia-based consent processes are likely to tip the scale toward widespread adoption.

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