

Consent Documents for Oncology Trials: Does Anybody Read These Things?

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Abstract: This study was conducted to assess the readability and length of informed consent documents used in clinical trials in oncology. One hundred seven consent documents from clinical protocols open to accrual at the Emory University Winship Cancer Institute were quantitatively analyzed. These included trials sponsored or organized internally, by commercial interests, and by various cooperative groups. Each form was analyzed using the electronic text version of the consent document approved by the Emory University IRB. Readability software was used to determine the length of each document and 2 measures of readability: The Flesch Reading Ease Score and a grade-level readability estimate using the Gunning Fog Index. The mean length \pm SD was 2709 \pm 971 words or 10.8 \pm 3.8 pages. The mean \pm SD Flesch Reading Ease Score was 45.48 \pm 5.24. The mean \pm SD grade level using the Gunning Fog Index was 11.9 \pm 1.53. None of the consent documents were written at or below the 8th-grade reading level; 1.8% were at or below the 9th-grade level; 10.5% were below the 10th-grade level. Results were similar regardless of study sponsor. Consent documents for clinical trials in oncology are lengthy and complex to the point that is unlikely that most patients will be willing to read them or be able to understand the concepts they discuss. IRBs and cooperative group review committees are either unwilling or unable to enforce widely accepted readability standards for the consent document. We discuss the implications of this situation and suggest ways to improve it.

Key Words: informed consent, clinical trials, readability

(*Am J Clin Oncol* 2004;27: 570–575)

In most settings, federal regulations require that each subject (or their legally authorized representative) sign a consent document prior to participating as a subject in a research study.¹ The rationale for this requirement is that the consent document should provide the information that the subject needs to make an informed decision about research partici-

pation. For the consent document to be useful, it should be short enough for the subject to be willing to read it completely and it should be written in language that is simple enough for the subject to understand without difficulty. Federal regulations do not mention the length of the document, but the choice of language is addressed in the requirement that “The information that is given to the subject or their representative shall be in language understandable to the subject or representative.”²

Over the past 15 years, numerous studies have evaluated the readability, and in some cases the length of the consent documents used in clinical trials. In general, these studies have found that consent documents are long and complicated to the point that the average person in the United States is likely to find them difficult to read.^{3–8} At the Federal level, concern about the complexity of the consent document has been expressed in determination letters from the Office of Human Research Protection that list complex language in the consent document as a violation of Federal research regulations.⁹

Writing consent documents that are short and easy to read is particularly difficult in oncology studies, where the treatments are often complicated and a wide range of serious toxicities are possible. The last major evaluation of the consent document in oncology trials was published in the *Journal of Clinical Oncology* in 1994 by Grossman and colleagues.¹⁰ They found that consent documents were, in general, likely to be very difficult for the average person to read. As a result of these kinds of studies, improving the readability of the consent document has been a major goal of both oncology researchers and Institutional Review Boards (IRBs). The purpose of this study is to evaluate the current status of these efforts as measured by the length and readability of consent documents that are currently being used in a large group of oncology studies at the author’s institution.

METHOD

One hundred seven informed consent documents that describe clinical protocols that were opened for accrual at the Winship Cancer Institute of Emory University were analyzed to determine their readability and length. Consent documents

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ISSN: 0277-3732/04/2706-0570
DOI: 10.1097/01.coc.0000135925.83221.b3

for protocols involving only the collection of laboratory specimens were excluded. All of the consent documents evaluated in this study had been approved by the Emory University School of Medicine IRB and the Clinical Research Review Committee of the Winship Cancer Institute. The documents studied included both trials sponsored by cooperative groups and pharmaceutical sponsors (including investigator-initiated trials funded by commercial entities). The sponsoring organizations were: Eastern Cooperative Oncology Group (ECOG) 35 trials; commercial sponsors (pharma) 28 trials; Gynecologic Oncology Group (GOG) 17 trials; New Approaches to Brain Tumor Trials (NABTT) 14 trials; Radiation Therapy Oncology Group (RTOG) 8 trials; and National Surgical Adjuvant Breast and Bowel Project (NSABP) 5 trials.

Each of the consent documents evaluated was available as electronic text and each had been formatted to meet the requirements of the approving IRB. Each was scanned electronically into a word processing program (Microsoft Word), and the number of words was counted using the automatic word-counting feature of the program. Similarly, the program's readability statistic feature was used to determine the Flesch Reading Ease Score. The Gunning Fog Index was determined by using a second word processing program (RightWriter 4.0).¹¹ The final version of the consent document, as approved by the Emory University IRB, was used so that any effect of IRB review would be reflected in the results.

Readability is linked to the difficulty of the material being presented, usually measured by word length, and the complexity of the material being presented, usually measured by sentence length. The Flesch Reading Ease ("FRE")¹² score is a measure of a document's overall readability based on word difficulty and sentence length. The FRE is reported on a 100-point scale; the higher the score, the easier it is to understand the document. The FRE provides a measure of readability that is not tied to the concept of educational level. However, a score of 60 or more is generally associated with a 9th-grade or lower educational level, while a score in the 30 to 50 range would be associated with college level reading materials. The FRE is determined using the following formula: $206.835 - (1.015 \times ASL) - (84.6 \times ASW)$ where: ASL is the average sentence length and ASW is the average number of syllables per word. While the FRE score can be determined from a sample of at least 100 words from a given document, the scores reported in this study were based on an analysis of the entire document.

The Gunning Fog Index ("GFI")¹³ is also based on an analysis of sentence length and word complexity. The formula for calculating GFI is: $0.4 (\text{average sentence length} + \text{percent words of more than 2 syllables})$. Contractions, hyphenated words, and compound words were counted as single words, and to determine the number of polysyllabic words,

the base words for all hyphenated words were used. As with the FRE, the GFI can be determined from a small (100-word) sample of the text, but in this study the full text of each document was used in the analysis. The GFI provides a measure of readability that is linked to the average number of years of education required to read the material with comprehension.

Both of these indices of readability are widely used, and neither is a perfect measure of readability, but both have been evaluated for reliability and validity using measures of reading speed, expert judgment, readership, and comprehension, with correlation ranging from 0.62 to 0.90.¹⁴⁻¹⁶ Some variance in the calculation of readability scores using different computer programs has been noted, but the reliability and consistency of individual programs is high.¹⁷ To provide a basis for comparison, the same measures of readability have been determined for 2 nonmedical samples. The Flesh Reading Ease and Gunning Fog Index scores were determined for 20 sequential Ann Landers newspaper columns and 10 consecutive lead editorials in the *Wall Street Journal*.

These comparative readability scores have been previously reported.⁸

Data obtained were subjected to descriptive statistics, including determination of the mean, standard deviation (using N-1 weighting), and determination of the 95% confidence interval around the mean.

RESULTS

The consent documents examined were from studies sponsored by several National Cancer Institute recognized cooperative research groups (79 documents) and by commercial/pharmaceutical sponsors (28 documents).

Table 1 presents the results of the analysis of the length of the consent documents, both for the total and for each of the cooperative groups or for those receiving commercial sponsorship. The documents in this sample ranged from 955 to 6453 words, with the mean being 2709 words. This is the equivalent of an average length of 10.8 pages (assuming 250 words per page), with a range of from 3.8 to 25.8 pages of text. The only statistically significant ($P \leq 0.05$) difference between groups was between the GOG and each of the other groups as well as the entire sample. Although the NSABP trials were generally longer (ie, included more words) than the others, the difference was not statistically significant. The average length of the comparison documents was 248.4 words for the Ann Landers columns and 321.8 words for the *Wall Street Journal* editorials. Recommendations for adult learning materials suggest that readers are more likely to read articles of less than 1000 words than longer articles.¹⁸ Longer documents may be perceived as threatening by subjects, particularly those with less formal education. Also, the amount of time available to read the consent document is often limited, and the length of the documents may make it

TABLE 1. Analysis of Document Length (Number of Words) by Sponsor Type

Sponsor Type	Range	Mean (95% CI)	Mean Pages*	Standard Deviation
ECOG (n = 5)	1224–6046	2915.30 (± 356.49)	11.7	1037.77
GOG (n = 17)	1451–2675	2176.8 (± 195.96)	8.7	381.13
NABTT (n = 14)	955–5196	2805.79 (± 614.32)	11.2	1063.97
NSABP (n = 5)	1108–6463	3651.2 (± 2505.0)	14.6	2018.2
RTOG (n = 8)	2205–2799	2478.63 (± 172.87)	9.9	206.77
Pharma (n = 28)	902–4513	2623.6 (± 318.77)	10.5	822.07
Total (N = 107)	902–6453	2709.15 (186.13)	10.8	971.28

ECOG, Eastern Cooperative Oncology Group; GOG, Gynecologic Oncology Group; NABTT, New Approaches to Brain Tumor Trials; NSABP, National Surgical Adjuvant Breast and Bowel Project; Pharma, commercial sponsors; RTOG, Radiation Therapy Oncology Group.

*1 page + 250 words.

difficult for subjects to carefully and completely read it during the informed consent encounter.

Table 2 presents results of the analysis of the Flesch Reading Ease score. The mean score for the entire sample was 45.68 (95% confidence interval 44.68–46.68), which roughly equates to a college level of reading difficulty. There were no statistically significant differences between the documents from any of the sponsoring groups. The most difficult document to read was a consent document for a pharmaceutical trial, while the easiest to read was for a trial sponsored by the ECOG.

Table 3 presents results from the analysis of the Gunning Fog Index. This index is expressed in the number of years of education required to read the material comfortably. Many authorities have proposed that consent documents and similar documents should be written at approximately an 8th-grade level, consistent with the findings of the National Adult Literacy Survey that found that 21% of US adults are functionally illiterate and 27% have marginal literacy skills.¹⁹ An 8th-grade reading level is also recommended by the

National Cancer Institute.²⁰ The reading level of the consent documents in this sample ranged from 8.3 to 17.5 years. Thus, some of the documents would be accessible to an individual who had completed the 8th grade, while the most difficult would require a level of sophistication required of a graduate student. The mean score for the sampled documents was 11.9 (95% confidence level 11.6–12.2), which indicates that most of the consent documents evaluated would require a high school education to read. In the present study, none of the consent documents evaluated was written below the 8th-grade reading level, and only 2 (1.8%) were below the 9th-grade level. Only 11 (10.3%) met the more liberal assumption that consent documents should be targeted at a 10th-grade reading level.

DISCUSSION

The problem of readability of consent is not a new finding. The results of our study are very similar to the results of the study of informed consent documents used in oncology clinical trials conducted a decade ago by Grossman. That study¹⁰ was comparable in many respects to the present study: Both were conducted at academic medical centers; both included only consent documents approved by the institution's IRB; both included consent documents for studies designed and sponsored by a variety of groups, including many of the same cooperative study groups. In the Grossman study, only 1.0% of the consent documents evaluated were written at or below the 8th-grade level, and none in the present trial were written at or below that level.

Consent Document Length

Data are scarce on the impact of length on the readability of consent documents. Both our general experience and formal studies demonstrate that the longer the document, the less likely are people to read it. What little data there are on this factor suggest that, in an educational context, people are unlikely to read entire documents that contain more than

TABLE 2. Flesch Reading Ease Score by Sponsor Type

Sponsor Type	Range	Mean (95% CI)	Standard Deviation
ECOG (n = 35)	38.7–58	47.56 (± 1.9)	5.54
GOG (n = 17)	35.6–52.3	43.78 (± 2.63)	5.11
NABTT (n = 14)	41.3–49.5	46.16 (± 1.23)	2.12
NSABP (n = 5)	43.6–49.5	46.16 (± 4.83)	5.14
RTOG (n = 8)	38–48.7	43.18 (± 2.56)	3.06
Pharma (n = 28)	28.1–52.7	44.05 (± 2.12)	2.12
Total (N = 107)	28.1–58	45.68 (± 1.0)	5.24

ECOG, Eastern Cooperative Oncology Group; GOG, Gynecologic Oncology Group; NABTT, New Approaches to Brain Tumor Trials; NSABP, National Surgical Adjuvant Breast and Bowel Project; Pharma, commercial sponsors; RTOG, Radiation Therapy Oncology Group.

TABLE 3. Gunning Fog Index Reading Level by Sponsor Type

Sponsor Type	Range	Mean (95% CI)	Standard Deviation	Percent <10.0 Grade
ECOG (n = 35)	8.3–15.2	11.6 (± 0.62)	1.79	22.9%
GOG (n = 17)	10.0–15.1	12.67 (± 0.85)	1.65	5.9%
NABTT (n = 14)	11.0–12.6	11.7 (± 0.30)	0.52	0
NSABP (n = 5)	9.5–13.0	11.52 (± 0.86)	1.20	20%
RTOG (n = 8)	11.1–15.1	12.4 (± 1.11)	1.33	0
Pharma (n = 28)	9.8–17.5	12.11 (± 0.57)	1.47	3.6%
Total (N = 107)	8.3–17.5	11.9 (± 0.30)	1.56	10.3%

ECOG, Eastern Cooperative Oncology Group; GOG, Gynecologic Oncology Group; NABTT, New Approaches to Brain Tumor Trials; NSABP, National Surgical Adjuvant Breast and Bowel Project; Pharma, commercial sponsors; RTOG, Radiation Therapy Oncology Group.

1000 words, or about 4 pages.¹⁸ A recent study by Burman and colleagues shows that the length of multicenter trial consent documents has steadily increased since 1975.²¹ Our study does not span this kind of time-frame, but at the very least we can conclude that consent documents are not getting shorter with time.

Another factor is, if one assumes that a subject can read at a rate of 200 to 225 words per minute, the average for a high school graduate in the United States,²² the typical document included in our study would take 12 to 14 minutes to read. In view of the complexity of the issues discussed in the consent document, most people will probably need to read portions of the document several times to understand it. The time required to read the consent document is an important issue because experience suggests that the time spent on the entire consent process in clinical trials is often quite short.²³

The Impact of IRB Review

IRB review is supposed to ensure that the consent document is understandable to the subject: “The information that is given to the subject or their representative shall be in language understandable to the subject or representative.”²²

Our study suggests that the oncology consent documents are often so long that the average patient is unlikely to read the document and/or is written in language that is likely to be too complex for them to understand. In 1992, Hamerschmidt and Keane²⁴ evaluated the impact of IRB review on readability and found that “No document was improved by more than one grade-level by the IRB process and most were unchanged.”

Although investigators and IRBs express a desire to improve consent documents, they are unwilling to set and enforce meaningful standards to accomplish this. The conclusions of Grossman and colleagues¹⁰ unfortunately continue to be accurate: “Consent forms from oncology protocols are written at a level that is difficult for most patients to read, despite national, cooperative group, institutional, and departmental review. The consent process, which is crucial to

clinical research, should be strengthened by improving the readability of the consent forms.”

Why do IRBs continue to approve documents that the average subject is unlikely to read or understand? Although this issue has not been examined in a systematic way, discussions with IRB chairs at several institutions and a general examination of the way consent documents are authored and approved suggest several related problems. First, although the intended purpose of the consent document is to aid the patient in making a meaningfully informed choice regarding participation in the trial, many sponsors and institutions appear to view them primarily as a legal instrument to protect them against civil litigation. Consent documents are frequently drafted by attorneys, and institutions may require review and approval of consent document by legal counsel prior to approval of a trial.

Informing patients in an effective, understandable way may be compromised when the document is seen as a legal instrument rather than a communication tool. A contributing factor may be an IRB’s lack of independence from the parent institution, which may lead to reluctance to make unpopular decisions. Both the National Bioethics Advisory Commission²⁵ and the Office of the Inspector General²⁶ have listed a lack of independence as a major weakness in the current IRB system.

Often, as in the case of most studies sponsored by pharmaceutical companies and cooperative groups, the basic consent document is presented to the IRB and the sponsor expects the IRB to approve it with only minor variations and the addition of locally required language. IRBs in such circumstances may feel that if they require simplification, the sponsor will take the project to a more compliant institution. IRBs may come under pressure from the institution they serve to avoid taking actions that reduce revenue from sponsored clinical trials.

Both the regulatory and legal climate may lead IRBs to sacrifice readability and simplification for complexity. Al-

though the FDA mandates “understandable language” for consent documents, the agency also mandates the extensive information that consent documents must include.²⁶ Including a level of detail sufficient to meet all regulatory requirements and to satisfy the concerns of the institution or IRB’s legal counsel can also contribute to the complexity of consent forms. IRBs may be reluctant to impose readability and length standards if they perceive that this may weaken the regulatory compliance or legal protection afforded by the consent document.

IRB members may fail to appreciate the importance of enforcing such standards and may even fail to appreciate how difficult to read and understand most consent documents are. The majority of the members of an IRB will be physicians and scientists to whom the consent document may not seem particularly difficult. IRBs are required to include “lay” members, but these individuals are likely to be well educated and familiar with medical terminology. It would be rare indeed to find an IRB with a member who has only a high school education, to say nothing of a member with only 8th-grade reading ability. IRB members may find it difficult to appreciate the difficulty average patients will have with the consent documents they approve.

For whatever reason, IRBs do not, as a general practice, enforce even those standards they themselves set. Paasche-Orlow and coworkers²⁷ examined 114 Web sites of medical schools in the United States for IRB readability standards and informed consent templates. They then measured actual readability using the Flesch-Kincaid scale. They found that 54% of Web sites specified a reading level standard that ranged from 5th-grade to 10th-grade reading level. The actual average reading level for text supplied by the IRBs was 10.6 (95% confidence level 10.3 to 10.8).

Recommendations

IRBs and other reviewing bodies should adopt standards for the length of consent documents as well as standards for readability, as follows.

- The maximum length of a document should be 1250 words (approximately 5 pages). This recommendation is based on studies that show that the average person is unlikely to read documents longer than 1000 words. Limiting the length of the consent document to 1250 words would mean that the average person could read the document in 5 to 7 minutes.
- IRBs should use commercial software to evaluate the readability of consent documents and set a readability score that will be a requirement for IRB approval of the document. The software used in this trial is widely available commercially, as are other programs that perform the same functions. Software to determine document length and Flesch

Reading Ease level is included with the most popular word processing program, Microsoft Word. If IRBs want investigators to use consent documents that are written at an 8th-grade level (or any level they may choose), then it should be a simple matter to use these readily available software programs to measure readability and insist that the consent documents conform to this standard. If such standards are enforced, investigators will use the same software to check their consent documents prior to submission and the documents will meet the required standards.

- IRBs should recognize the obstacles that have thus far prevented them from establishing and enforcing common-sense standards regarding the readability of consent documents. Understanding and confronting these obstacles are the first steps to making progress on this important aspect of the consent process.

REFERENCES

1. 21 Code of Federal Regulations 50. 25(a)(5)
2. 21 Code of Federal Regulations 50. 20.
3. Morrow GR. How readable are subject consent forms? *JAMA*. 1980; 244:56–80.
4. Tarnowski TJ, Allen DM, Mayhall C, et al. Readability of pediatric bio-medical research informed consent forms. *Pediatrics*. 1990;85: 58–62.
5. Ogloff JR, Otto RK. Are research participants truly informed? Readability of informed consent forms used in research. *Ethics Behav*. 1991;1:239–252.
6. Rivera R, Reed JS, Menisu D. Evaluating the readability of informed consent forms used in contraceptive clinical trials. *J Gynaecol Obstet*. 1992;38:227–230.
7. Goldstein AO, Frasier P, Curtis P, et al. Consent form readability in university-sponsored research. *J Fam Pract*. 1996;42:606–611.
8. Sharp SM. Readability of informed consent documents for medical device trials. *Res Pract*. 2000;1:211–214.
9. Available at www.hhs.gov/ohrp.
10. Grossman SA, Piantoadosi S, Covahey C. Are informed consent forms that describe clinical oncology research protocols readable by most patients and their families? *J Clin Oncol*. 1994;12:2211–2215.
11. RightWriter [computer program] Version 4.0. Carmela, IN: Que Corp.; 1990.
12. Flesh RE. A new readability yardstick. *J Appl Psychol*. 1949;32:221–233.
13. Gunning R. *The Technique of Clear Writing*. New York, NY: McGraw Hill International Book Co.; 1958.
14. Klare GR. *The Measurement of Reliability*. Ames, IA: Iowa State University Press; 1963.
15. Severin WJ, Tankard JW. *Communication Theories: Origins, Methods and Uses in the Mass Media*. 3rd ed. New York, NY: Longman Ltd.; 1992.
16. Stone G. *Examining Newspapers: What Research Reveals About American Newspapers*. Newberry Park, CA: Sage Publications; 1987.
17. Mailloux SI, Johnson ME, Fisher DG, et al. How reliable is computerized assessment of readability? *Computer Nurs*. 1995;13:221–225.
18. Brockett RG. Developing written learning material: A proactive approach. *Lifelong Learning*. 1984;7:16–18.
19. Kirsh I, Jungeblut A, Jenkins L, et al. *Adult literacy in America: A first look at the results of the National Adult Literacy Survey*. Washington, DC: National Center for Educational Statistics, US Dept of Education; 1993.
20. Simplification of informed consent documents: Recommendations. National Cancer Institute, updated August, 2001. Available at: www.nci.

- nih.gov/clinicaltrials/understanding/simplification-of-informed-consent-documents
21. Burman WB, Breese P, Weis S, et al. The effects of local review on informed consent documents from a multi-center clinical trials consortium. *Controlled Clin Trials*. 2003;24:245–255.
 22. Kaslan S. *The Power of Reading: Insight from the Research*. New York, NY: Libraries Unlimited; 1993.
 23. Sharp SM. Improving the process of informed consent. *Appl Clin Res* 2001;10:74–82. (available at: www.oig.hhs.gov/oei/reports/oei9700190)
 24. Hammerschmidt DE, Keane MA. Institutional Review Board (IRB) review lacks impact on the readability of consent forms for research. *Am J Med Sci*. 1992;304:245–255.
 25. National Bioethics Advisory Council. Ethical and Policy Issues in Research Involving Human Participants, Vol. 1. 2001 (available at: www.georgetown.edu/research/nrcb/nbac/reports).
 26. Sharp SM. Assuring informed consent documents are compliant with regulations. *Res Pract*. 2001;2:74–82.
 27. Paasche-Orlow MK, Taylor HA, Bancrate FL. Readability standards for informed-consent forms as compared with actual readability. *N Engl J Med*. 2003;348:721–726.

ERRATUM

An error was made in the author listing for **Thymidine Labeling Index: Prognostic Role in Breast Cancer**, published in *American Journal of Clinical Oncology*, Vol. 27, No. 4, August 2004. The author listing should read: Bilir A, Ozmen V, Kecer M, Eralp Y, Cabioglu N, Ahishali B, Camlica H, Aydinler A. V. Ozmen, M. Kecer, and A. Aydinler are affiliated with Istanbul University Istanbul Medical Faculty, Department of General Surgery, Istanbul, Turkey.

REFERENCE

1. Bilir A, Ozmen V, Kecer M, et al. Thymidine labeling index: prognostic role in breast cancer. *Am J Clin Oncol*. 2004;27:400–406.