Consent Form Readability in University-Sponsored Research

Adam O. Goldstein, MD; Pamela Frasier, MA, MSPH; Peter Curtis, MD; Alfred Reid, MA; and Nancy E. Kreher, MEd

Chapel Hill, North Carolina, and Escanaba, Michigan

Background. Consent forms are required in most biomedical research involving human subjects. In recent years, a number of studies from different disciplines have reported problems related to consent form readability.

Methods. We analyzed 284 consent forms submitted to and approved by five institutional review boards (IRBs) (schools of Medicine, Nursing, Academic Affairs, Dentistry, and Public Health) at one university and one IRB at another. We examined consent form readability scores and factors that might relate to readability.

Results. The average reading level of all consent forms was high: 12.2, which corresponds roughly to a 12th-grade reading level. Less than 10% of all consent forms were written at a 10th grade reading level or below. Thirty-two percent of all consent forms had no evidence of revisions, and less than 2% of consent forms were revised more than once. Readability scores were not related to consent form revisions, the type of IRB, the year of study, or the university where the research was conducted.

Conclusions. Poor readability of consent forms probably occurs in all university-related research. We recommend that IRBs require readability checks for research consent forms before researchers submit their proposals to an IRB.

Key words. Informed consent; professional staff committees; institutional review board; research; readability; human subjects; patients.
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The most frequently used method of enrolling subjects for investigational research is written and signed consent, using a document to describe the intervention or study.[1] This document must comprise specific areas of information that have been delineated by the US Department of Health and Human Services regulations for the Protection of Human Subjects.[2] These regulations require that consent forms be written "in language understandable to the subject (or authorized representative)." This means that the subject must read the text and understand the meaning and implications of the study or intervention in order to make an informed decision.

Researchers still debate the best process of obtaining valid consent. Despite three decades of written consent forms, the process of obtaining informed consent is still described by some as "conscription of patients" and "a charade." Some support the establishment of a national commission for the protection of human subjects in research.[3] This may be particularly relevant following recent widespread media publicity over the failure of some medical researchers to provide adequate information in obtaining consent from participants in radiation research projects sponsored by the Department of Energy from 1940 to 1975.[4]

Several studies in recent years have shown that the readability of most consent forms used in biomedical research is at the college level, considerably above the average 6th to 7th grade reading level of the general population.[5-9] These studies, involving adult, geriatric, and

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From the Department of Family Medicine (A.O.G., P.F., P.C., A.R.), and the University of North Carolina Institute for the Generalist Physician (P.C.), University of North Carolina at Chapel Hill, Chapel Hill, North Carolina; and the Department of Family Medicine, Michigan State University, Escanaba, Michigan (N.E.K.). Requests for reprints should be addressed to Adam O. Goldstein, MD, Department of Family Medicine, CB 7595, Manning Drive, University of North Carolina School of Medicine, Chapel Hill, NC 27599-7595.

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pediatric populations, have also noted increasing length and complexity in the informed consent forms.[10] Most of the published literature is specialty-specific, however, and does not report on the types of research for which consent was sought, the numbers of subjects, sources of funding for the studies, or other characteristics that might influence the readability of consent forms. Moreover, the readability of consent forms used in research areas of the university outside medical schools is unknown.

The increasing emphasis and funding of research on low socioeconomic groups and ethnic populations underscores the importance of current efforts to develop practical methods that increase valid informed consent. Having readable consent forms is the first step in this process. To establish the nature of consent form readability from a broad perspective, we undertook a retrospective study of consent forms and projects approved by all the institutional review boards (IRBs) at two universities, the University of North Carolina at Chapel Hill (University A) and Michigan State University in Escanaba (University B), to determine whether poor readability of consent forms is a pervasive problem throughout all university-related research. We also studied both the readability of consent forms over time and factors that might affect readability.

Methods

The Department of Health and Human Services of the National Institutes of Health requires that all research projects undergo review by an IRB to ensure the protection of subjects.[2] Federal law requires IRBs to maintain fields of every proposed research project from an institution, including correspondence between researchers and the IRB. The IRB file also contains copies of any approved consent forms if the project involves research in which a consent form is required. Consent forms are required in all research proposals unless: (1) the research involves only minimal risk to subjects, (2) the consent form itself is the only link between the research and subject, and such a link impedes subject confidentiality, or (3) the research involves the use of public data or is for educational purposes. The IRB decides whether a study is exempt from obtaining informed consent.

Sample Population

At University A, research projects are monitored by five IRBs in the schools of Medicine, Academic Affairs, Dentistry, Nursing, and Public Health. At University B, one IRB monitors all projects. The source of analysis for our research was the IRB files of research projects submitted to the IRBs. At both universities, we submitted our own research protocol to each IRB, seeking permission to abstract data from their respective IRB research fields. As part of the protocol to examine the full contents of the IRB research files, we requested consent from the principal investigators of their respective IRB projects.

Because each IRB had slightly different mechanisms for storing and retrieving data from their IRB files, our sampling strategy varied by necessity to ensure the cooperation and participation of each IRB. To assess changes in readability over time, we selected for review a sample of all proposals submitted to each IRB in 1988 and in 1991. Eligible proposals included those that underwent actual review by the IRB with an attached consent form. Research projects were excluded if they had been submitted to an IRB but were never fully approved, or if they were exempt from IRB review and therefore did not require a consent form. We obtained a random sample of files and consent forms from the IRB at University B and from the schools of Medicine and Academic Affairs at University A. From the schools of Dentistry, Nursing, and Public Health at University A, we selected a convenience sample of files and consent forms. Samples included approximately 20% of all research reviewed by the IRBs of the two universities in 1988 and 1991.

Data Collection

The data collection form had three sections. In the first section, we recorded information relating to the IRB itself in each of the 2 years studied, including the type of IRB (eg, medicine or nursing), the number of IRB members, the male/female ratio, and the presence or absence of a lay person on the board, as required by the National Institutes of Health. In the second section, we abstracted data concerning the proposed research project, including the type of study (survey, drug, or clinical trial), primary source of funding (federal, institutional, private foundation, or pharmaceutical), number and age of proposed subjects, evidence of consent form revisions prior to approval, and the number of revisions. In the third section, we examined the actual consent form for readability. All data were coded numerically to protect the confidentiality of individual researchers as well as any specific material, such as use of experimental medications, that might be contained in the IRB file.

All information pertaining to the IRB files was abstracted by a trained research assistant working within the IRB offices. Copies of final approved consent forms were obtained and then entered into an optical scanner at the Department of Family Medicine at University A. Each copied and scanned consent form was then visually checked to ensure that it was reproduced in the computer

Table 1. Consent Forms Analyzed and Composition of the Institutional Review Boards of the Two Study Institutions in 1988 and 1991

	University A						
	Academic Affairs	Dentistry	Medicine	Nursing	Public Health	University B All Schools	Total
1988							
Consent forms analyzed (n)	5	10	23	7	14	48	107
IRB members (n)	11	12	21	9	12	17	
IRB composition (M/F)	8/3	10/2	16/5	1/8	9/3	13/4	
1991							
Consent forms analyzed (n)	8	11	38	7	16	97	177
IRB members (n)	13	12	20	10	14	17	
IRB composition (M/F)	9/4	10/2	18/5	2/8	6/8	13/4	

IRB denotes institutional review board.

exactly as it appeared in its original form. Complete data forms were collected from the IRBs at University A, while at University B, we were able to obtain only the consent forms and information about the composition of the IRB.

Consent Form Readability

We assessed the readability of each consent document with *RightWriter*, a software package that is no longer commercially available. Using this program, we measured the readability of an entire document, not just samples, thus reducing sampling error. *RightWriter* reports several measures of readability, including the Flesch Reading Ease Formula, the FOG index, and the Flesch-Kincaid index, each of which is well validated and reliable. The Flesch-Kincaid index uses a weighted formula based on mean word length and mean sentence length and yields a number from 1 to 50, corresponding roughly to the reading grade level required to comprehend the document. For example, a readability index of 6 indicates simplistic sentences with few complex words, while an index of 16 is equivalent to graduate level reading. Because of its intuitive interpretation, we report only the Flesch-Kincaid index in this paper; however, as expected, overall results were the same, regardless of which readability index was used.

Data Analysis

Data were coded and entered using the Epi-Info statistical program, with analyses performed using Epi-Info and Systat. Categorical level variables were analyzed by means of chi-square analysis and continuous variables with correlation coefficients. Mean readability scores were compared using analysis of variance or the Kruskal-Wallis test.

Results

A total of 284 consent forms were analyzed from the IRBs at the two universities (Table 1). More consent forms were reviewed from projects in 1991 than 1988, reflecting the general increase in research at these universities over this period. The mean number of persons on each IRB was 16 (range, 9 to 21) and changed little between the years. Table 1 also shows substantial differences in the number of women members in the composition of each IRB.

All IRBs had a lay member on their IRB, as required by federal regulation. At University A, 54% of the sampled consent forms were for research that was part of a clinical trial, 34% were part of a questionnaire survey, and 12% were for research involved with a drug trial. Most of the funding for the research came from institutional resources (44%), followed by federal funds (36%), private foundations (15%), and pharmaceutical companies (5%).

The mean readability index for all consent forms reviewed was high: 12.2 (SD 1.7), corresponding roughly to a 12th-grade reading level. As shown in Figure 1, less than 10% of all consent forms were readable at a 10th-grade level, which is acknowledged as the maximum reading level of the general population. Readability scores varied significantly among the five IRBs of University A ($P<.001$) (Figure 2). Consent forms from the schools of Public Health and Nursing had lower readability scores than those from the schools of Medicine, Dentistry, or Academic Affairs; however, the mean readability index for consent forms from the School of Nursing was still only 10.7 (SD 1.9) and from the School of Public Health only 10.8 (SD 2.1).

Survey studies accounted for 88% of the research conducted in the schools of Nursing and Public Health. As expected, survey studies had more readable consent forms than either clinical or drug trials ($P<.001$). There

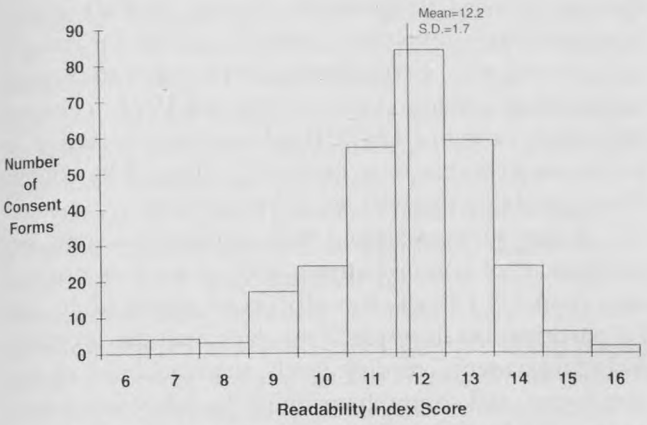

Figure 1. Mean readability of consent forms at the two study institutions, 1988 and 1991. Readability Index Score is roughly equivalent to educational grade level. The average educational level of the general public is known to be no higher than grade 10. SD denotes standard deviation.

was no difference in consent form readability scores between the two universities. Similarly there was no difference in readability scores from 1988 and 1991. Having a higher number of female than male IRB members was related to improved readability scores, even controlling for the type of study.

For the 139 IRB consent forms at University A, we also checked their respective IRB files to determine how often the consent form was revised prior to final approval by the IRB. For 84 (60%) of the consent forms, there was evidence of revision of the initial consent form, while in 44 (32%) of cases, the consent form initially submitted appeared to be the one approved. For 11 (8%) of the consent forms, it was impossible to determine if a revision had been requested. Of the 84 consent forms with revisions, 82 were revised only once before final approval. Consent form revisions were not related to readability scores or the year of consent form approval.

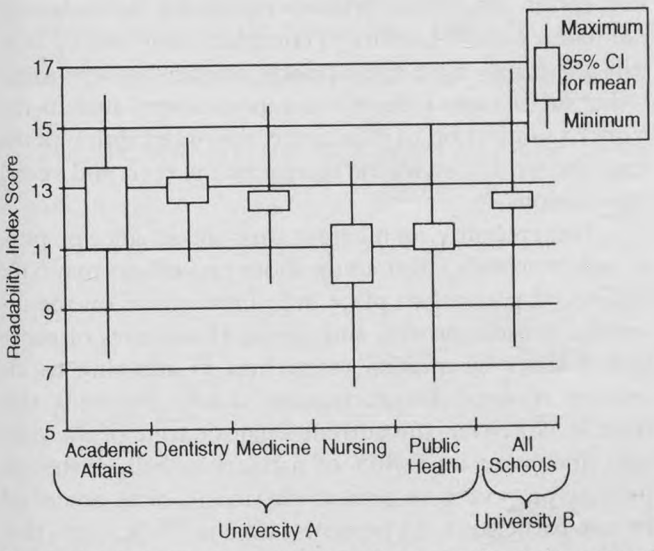

Figure 2. Variation in readability of consent forms by type of institutional review board at the two study institutions. Readability Index Score is roughly equivalent to educational grade level. The average educational level of the general public is known to be no higher than grade 10. CI denotes confidence interval.

Table 2. Minimum Required Elements of Informed Consent Documents for Research

1. Explanation that the study involves research and the purpose of the research study
2. Expected duration of participation
3. Description of the procedures
4. Description of the foreseeable risks
5. Description of benefits
6. Disclosure of any appropriate alternative courses of treatment
7. Methods used to maintain confidentiality
8. Statements concerning compensation or medical treatment should injury occur
9. Name of contact persons
10. Statement that participation is voluntary

Modified from the US Department of Health and Human Services, National Institutes of Health, Office for Protection from Research Risks. Part 46. Protection of Human Subjects, Revised 1995; from the Internet, April 1996.

Discussion

The US Department of Health and Human Services regulations for the protection of human research subjects requires that at least 10 elements be included in informed consent documents and that the information be presented at a level that is easily understandable by the patient[2] (Table 2). Previous research on consent forms indicates that the forms are not readable by a majority of patients who sign them, thus defeating one of the primary purposes of the informed consent process.[5,11–13]

In 1980, Morrow[12] found that consent forms from five national cancer trial groups were "difficult" and at a reading level typical of an academically oriented journal. Also in 1980, Grundner[13] analyzed surgical consent forms used at five major medical facilities in the Los Angeles area. Using several readability formulas, he found that "four of the five forms were written at the level of a scientific journal, and the fifth at the level of a specialized academic magazine."

In studies of Veterans Administration patient consent forms, Baker and Taub[14] found that between 1975 and 1982, consent forms almost doubled in length and required a college-level reading ability. Consent forms used at the Denver Veterans Administration Hospital in 1989 were written at a mean grade level of 13.4 years, and the readability level had not improved since the forms were last tested in 1982. Forms had increased in length by 58%, making them even more difficult for the average

reader to comprehend.[10] There have been similar findings in biomedical pediatric research.[8]

Our data are the first to show that the great majority of informed consent forms used in research projects across all academic disciplines are probably unreadable to most subjects. Consent forms from the two universities in our study remain at college-level readability. As further evidence that the process needs revision, most consent form revisions did not improve readability.

To begin addressing these problems, we suggest that all IRBs consider making readability evaluation an integrated component of their consent form review process. This requirement would be an easy, useful, and inexpensive first step toward providing more comprehensible consent forms. Increasingly, physicians and public health advocates are using patient education materials in their offices that have been pretested for readability. IRBs should insist that researchers do the same for their informed consent documents.

Institutional review boards could incorporate readability checks into their review process by means of two methods. First, an IRB could require that any consent form submitted have a readability check and printout attached. The actual standards for consent form reading levels would be left to the IRB, but a target goal of no higher than a 9th-grade reading level should be set for most consent forms. Appropriately, the responsibility for ensuring the readability of consent forms should rest on individual researchers. Computer software for readability analysis is inexpensive (less than $75), accessible to most researchers, and quite easy to learn.[15] Noncomputer formulas for readability are also readily available, but they are less reliable and less consistent than computerized programs.

Alternatively, the IRB itself could incorporate computerized consent form readability programs into its reviews. Such work, however, inappropriately places increased responsibility, time constraints, and potentially higher personnel costs onto the IRB.

Our study has several limitations. We examined research files from only two universities, and as such, the work may not be representative of other institutions. Moreover, because of sampling strategies employed, we were not able to take a random selection of all IRB consent forms, but adjusted the selection process based on criteria demanded by the different IRBs. Nonetheless, there was little actual variation among IRBs with respect to readability scores or the revision process, regardless of the year the forms were examined. Furthermore, our data are the largest and only representative sample reporting on readability issues across a wide range of academic research. Based on the number of subjects who were recruited by investigators for the sample of research projects that we reviewed at University A alone, 36,950 subjects were potentially involved in and affected by our research on consent forms. Extrapolating this number to the population of all research done in 1988 and 1991 in just one university, a total of 184,750 subjects participated in research projects that were potentially affected by consent form readability that was less than desirable.

It may also be argued that readability is only one component of comprehension and, as such, is not very important.[5,16] Clearly, the process of informed consent for participation in research involves multiple processes, including patients' reading levels, the readability of consent forms, and comprehension in the informed consent process.[7,17–19] Patient comprehension is far more complex than the reading process alone. For example, some patients, relying on verbal transmission of information, may fully understand a research protocol and its concomitant risks or benefits without being able to read the consent form. Other patients may be able to read the form but may not fully understand the project.[18] While some researchers may read the consent form to subjects, in addition to relying on the readability of the form, the written consent form remains the most expedient and widely used vehicle for obtaining informed consent from most patients.

To measure comprehension, one would need to test patients' understanding or recall of the consent form, preferably at the time of signing the consent form. Some researchers have developed and advocated the administration of reading tests that measure patients' actual reading levels.[9] This has not been well studied in relation to consent forms. Moreover, while a readability formula may estimate a patient's ability to comprehend written text, it will not compensate for a poorly written consent form. Other factors also influence comprehension, such as the reader's motivation to participate, the organization of the text, the writing style, the format of the text, and verbal explanations.[19]

Until recently, an inherent trust and reliance on physicians to provide information about procedures may have influenced patients to place little importance on the informed consent process and forms. Disclosures of widespread laxity by medical researchers in adhering to informed consent documentation clearly threatens this trust.[20] Moreover, the current legalistic tone of the consent document leads 80% of patients to believe that its primary purpose is to protect physicians, or as described by one participant, "it prevents lawsuits."[21] It seems that consent forms that are too complex, adversarial, legalistic, or unreadable are alienating patients from a process that is intended to protect them. Other patients unknowingly risk serious harm and even death by a process that fails to get proper informed consent.[22] A former associate chief

counsel for enforcement of the Food and Drug Administration recently said, "One important point to keep in mind about the FDA's enforcement . . . is that . . . from a regulatory standpoint, it is better that an uncomprehending subject sign a well-designed form than it is for a fully informed individual to sign a deficient form."[23]

Despite 12 years of published research, readability of consent forms remains poor. In addition, patient illiteracy remains a serious problem that prevents many patients from participating optimally in health care settings.[24] Therefore, as a small but necessary first step in improving informed consent documents and ultimately the process itself, we recommend that IRBs set consent form readability standards and guide their implementation.

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