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Informed Consent Forms: Are They Readable?

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Abstract

This study examined the readability of 13 randomly selected informed consent forms used by researchers at Southern Illinois University at Carbondale in various disciplines such as Education, Social Work, Journalism, Administration of Justice, Psychology, and Linguistics. In accordance with previous studies, researchers hypothesized that the informed consent forms were written at a higher reading level than the intended population can understand. To test this hypothesis, programs found in Microsoft Word version 6.0 were utilized to assess the readability of the consent forms. Specifically, forms were analyzed according to traditional measures such as the Flesch Reading Ease, Flesch-Kincaid Grade Level, Coleman-Liau Grade Level, and Bormuth Grade Level. Researchers for this study revealed that their findings not only supported their original hypothesis, but also research previously published in this field. The effects are discussed further in the following pages.

Informed Consent Forms: Are They Readable?

The vast majority of human service disciplines have established ethical criteria for the administration of research with human participants. These regulations attempt to guarantee the application of methods that are designed to preserve the dignity and welfare of all participants (Lynch, 1994). Unfortunately, informed consent for participation in social science research has seldom been studied experimentally (Mann, 1994). However, throughout recent decades, clinicians and other researchers have observed federal regulations, judicial rulings, and professional standards concerning the proper way to treat participants during a research study (Grunder, 1978). A recurrent theme among these guidelines is the use of an informed consent form, which is the primary document utilized to inform participants about the research study. Included in this consent form should be all of the necessary details concerning participation in the study. Depending on the research, these forms may be difficult to comprehend as a result of its technical terminology and, occasionally, pharmaceutical names. At times, the wording of the consent forms is complex because it is poorly written, a problem that is complicated further when the reader has substandard reading ability (Peterson et al., 1992).

The field of psychology has a great deal of influence on health related professions, especially on ethical issues concerning informed consent (Kent, 1994). Moreover, Kent (1994) states that as a result of their training, psychologists can determine if information has been communicated effectively and comprehended by the reader in addition to evaluating the competence of a potential participant. Therefore, psychology enables clinicians and future clinicians alike to identify situations in which consent is questionable and to take the first step in resolving problems (Kent, 1994). As cited in the research of Mann (1994), the American Psychological Association (1992) declares that psychologists must "inform participants of the nature of the research; they [must] inform participants that they are free to participate or to decline to participate or to withdraw from the

research; they [must] explain foreseeable consequences of declining or withdrawing; they [must] inform participants of significant factors that may be expected to influence their willingness to participate" (p. 1608).

In addition to the disclosure of information, understanding is a key element of informed consent. Handelsman et al. (1986) believe that utilizing written consent forms can be disadvantageous because the clinician never knows whether or not participants understand what the form entails. Therefore, the clinician will not spend time discussing the form with clients. Handelsman and his colleagues (1986) propose assessing the understanding of participants by evaluating the readability of the informed consent form. Those forms that are readable do not guarantee that the participants will understand them, but these forms will facilitate understanding and make it feasible. Reading ability cannot be determined by neither the appearance nor the socioeconomic status of the participant. Hence, researchers should write the informed consent forms in a language that is understandable to as many people as possible (Peterson et al., 1992). In fact, the majority of participants do not know how to register complaints regarding the experiment or what responsibility the researcher has if they are injured during an experiment. Also, the act of signing a consent form provokes participants to assume that they have waived their rights to sue the researcher. Those, who read an identical form, but do not sign it, are not under the impression that their rights are waived. As indicated by Mann (1994), these findings imply that an oral consent procedure be utilized because signing a consent form misleads participants into believing that they have waived the rights that the informed consent is intended to protect. Further, Mann (1994) suggests that participants either give oral consent and not sign a form or sign a form and be reassured that they have not relinquished any of their rights.

In contrast to the small amount of psychological research done on informed consent forms, medical research abounds with such experiments. However, the findings from the

medical field should not be readily applied to those in the field of psychology because participants hold different expectations regarding psychological and medical research. Consequently, serious risks play a part in both fields. In medical research, participants are frequently seeking treatment, possibly surgery, for an illness. Whereas, psychological research predominantly deals with manipulating variables such as participants' self-esteem, mood, and/or ability. Currently, a number of psychologists are adding medical techniques to their repertoire. Therefore, participants in both psychological and medical research must understand not only the concept, but also the content of the informed consent form (Grunder, 1978).

Unfortunately, previous experimental research regarding the readability of consent forms is disturbing. In fact, research has indicated that forms utilized to acquire informed consent may be too hard for the typical patient to comprehend (Grunder, 1978, 1980; Handelsman et al., 1986). Specifically, Grunder (1980) utilized two of the most popular readability formulas to assess five representative surgical consent forms. He found that one form was written at the level of a specialized academic journal and the other four were as difficult to read as a scientific journal (Grunder, 1980; Ogloff & Otto, 1991). Waggoner and Mayo (1995) describe a recent study which consisted of 71 consent forms from a midwestern university which were analyzed using a computer analysis of the Flesh-Fry scoring. Results of this study reveal that 70% of the language comprising informed consent forms is written at a level for juniors in college to understand. This finding implies that roughly 37% of the United States adult population could read and comprehend them (Waggoner & Mayo, 1995). Furthermore, Young, Hooker, and Freeberg (1990) mention the research conducted by Gray, Cooke, and Tannenbaum which reports that 77% of the 1526 consent forms assessed had readability levels consistent with a scholarly/academic or scientific/professional journal.

Young et al. (1990) firmly believe that many research participants are not reading at

a collegiate level; therefore, these participants cannot fully comprehend the consent forms for the research which they are volunteering to participate. Moreover, several studies conclude that the higher the participants' education and vocabulary level, the more of the consent form that they understand. Also, poor memory and comprehension of the main ideas in the consent form contribute further to the problem (Young et al., 1990).

Obviously, over the years, science has become specialized to the extent that unprecedented levels of knowledge have emerged. Consequently, the side effects of this new wealth of information require that more expertise be needed in order to comprehend newly published research and theory not only in one's own field but also in other fields of discipline (Hayes, 1992).

As cited in Handelsman et al. (1986), Morrow, Gootnick, and Schmale (1978) discovered that by permitting cancer patients to take consent forms home, their recollection of pertinent information is markedly enhanced. Both the written consent form and personal recall enriches the clients' ability to determine whether or not to undergo the procedure. Kent (1994) reports that several situations exist that diminish the ability for clients to understand information. In fact, experiencing a particular emotional state, such as anxiety or distress, can disrupt the participants' concentration. The emotional state enhances the clients' preoccupation with their personal thoughts and feelings instead of focusing on the advice and explanation of the clinician, especially if the clinician is the bearer of bad news. Kent (1994) emphasizes that the average patient can only remember roughly half of their consultation with the doctor, and frequently, this results from emotional reactions. Morrow (1980) applied a similar procedure to 60 cancer treatment consent forms and revealed that the average reading level is similar to that of a medical journal. Even though these analyses predominantly focus on medical procedures, data exists which advocates that the same predicament applies to psychological research (Handelsman et al., 1986).

The research of Mann (1994) evaluates psychology participants' understanding of two consent forms – a long, detailed form and a shorter, less detailed form. In order to analyze the participants' comprehension of the data included in the consent forms, Mann (1994) designed a questionnaire. The results of Mann's (1994) study support the following relevant conclusions. First, shorter forms, withholding some detail, facilitate participants' comprehension more than longer forms explicating a procedure in its entirety. Ironically, the federal regulations contribute to the confusion of the participants by supplementing the previously long forms with still more imperative information. Mann (1994) insists that further research on the readability of informed consent forms is necessary. Although no extensive research is currently available to determine whether research participants comprehend consent forms, researchers proceed to add more information to the forms such as the rights, liability, and confidentiality of participants so stated by federal guidelines. Furthermore, Mann (1994) suggests that short, concise consent forms be used to optimize participants' understanding.

Handelsman et al. (1986) adds that sentence length appears to influence readability scores more than syllables per word. Therefore, short sentences can increase readability considerably (Handelsman et al., 1986; Kent, 1994). According to Chase, (1983) several conditions exist which influence and reduce the readability of a document in general. These variables include the content, grammar, spelling errors, expectations of the reader, reading difficulty, and the length of the form (Chase, 1983; Mann, 1994). By simply organizing the material in a manner that is easier to read, researchers can design their informed consent forms to be more effective. Specifically, Lynch (1994) declares that those forms which include a great deal of undefined technical language are geared toward an audience which excludes many readers. To communicate technical information more efficiently, jargon should either be eliminated or simplified into everyday English. Translation of this jargon can be facilitated by consulting a thesaurus or unabridged dictionary (Lynch, 1994).

The act of distributing consent forms among research participants does not assure that they will grasp the meaning of the experiment. According to Waggoner and Mayo (1995), medical experts and psychologists alike believe that their informed consent forms are brilliantly written. On the contrary, more often than not these forms utilize jargon frequently used in clinical research by professionals, but completely unknown by participants (Waggoner & Mayo, 1995). In fact, when consent forms are written in such an astute manner, they do not serve their intended purpose of facilitating the participants' choices concerning research involvement (Handelsman et al., 1986). As cited in Handelsman et al. (1986), the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1978), with regards to the institutional review boards, evaluated the consent forms utilized by 61 institutions. The commission found that relatively few consent forms define technical or medical terms, and the majority of the forms are written at a level more difficult than Time magazine. In fact, Waggoner and Mayo (1995) state that informed consent forms are infested with technical terminology and seem to baffle the average reader.

Applying a different technique, Handelsman et al. (1986) surveyed 196 psychologists in private practice regarding how they acquire their clients' informed consent. Similar to the studies on medical consent forms, the findings of Handelsman et al. (1986) indicate that the readability of the received consent forms is typical of an academically oriented journal. In addition, those clinicians who participated in this study claimed that the primary use of consent forms is to simplify the process of fee collection. Secondary functions of consent forms are to raise the clients' awareness on ethical issues, potential danger, client protection, and confidentiality. In fact, the nature, purpose, benefits, and risks of alternative treatments are rarely acknowledged. Moreover, Gray et al. (1978) discovered that merely half of the informed consent forms utilized at various institutions notify potential research participants that they can inquire about the research study or

procedures. None of the forms analyzed by Handelsman and his colleagues (1986) contain all of the essential ethical requirements. By using written consent forms, clinicians seem to be preoccupied with eluding malpractice suits and, in the process, are failing to meet the ethical criteria guaranteed by the informed consent (Ogloff & Otto, 1991; Handelsman & Martin, 1992).

The study conducted by Ogloff and Otto (1991) produced results similar to those of previous research. Consent forms, including those endorsed by the institutional review boards, have an unsuitably high level of readability across many disciplines and all age groups. Specifically, Ogloff and Otto (1991) assert that the consent forms used in medical research for adult participants have readability levels typical of the sixteenth-grade. Likewise, Ogloff and Otto (1991) report that consent forms across many disciplines have an average readability level of 14.7 years of education as indicated by the Fry Readability Graph. Similarly, the Flesch Readability Formula revealed the level of reading as that typically found in a reputable magazine (Ogloff & Otto, 1991; Handelsman et al., 1986; Riecken & Ravich, 1982). These high levels of readability are not suitable for the proposed population.

In order to increase the readability and understanding of informed consent forms, Grunder (1978), Riecken and Ravich (1982), Young et al. (1990), and Morrow (1980) believe that consent forms for adult participants should be written at or below the seventh- or eighth-grade reading level. Kent (1994) claims that 12 years is the prevailing reading age of the general public. Thus, it is imperative that consent forms be comprised of short sentences and few multi-syllabic words. As described in the research of Peterson and his colleagues (1992), Davis and his co-workers, using the Peabody Individual Achievement Test, revealed that 120 university or clinic patients, who reportedly completed up through at least the tenth grade, read only at the fifth or sixth grade level.

Since information is frequently conveyed orally, participants may not understand

that mode of communication as easily as some other type, such as the written word.

Budwig (1991) admits that physicians should become increasingly aware of the language and terms that are included in the informed consent. However, even if information is exchanged and understood, clients might feel forced into participating in research. Kent (1994) adds that clients may anticipate aversive consequences if they do not participate in a research study or undergo prescribed treatment. Handelsman et al. (1986) insist that free choice results only when adequate information is provided within the consent form. These decisions enable clients to be more responsible and less likely to be exploited (Handelsman et al., 1986). Further, Kent (1994) implies that clinicians are exerting effort toward increasing the understanding of their clients by giving clients a tape recording of the consultation. As a result, clients state that they reviewed the tape 3 to 5 times before they captured the full meaning of what was discussed with the clinician (Kent, 1994). Furthermore, Morrow (1980) suggests that more benefits will result from patients critiquing the consent forms instead of colleagues. Riecken and Ravich (1982) discovered that approximately one-fourth of the participants in their experiment had any kind of college education. Hence, consent forms with a readability level exceeding that of a high school graduate will be challenging for the majority of people to understand. In general, the findings of Young et al. (1990) suggest that the reading level conveyed by the informed consent form has an effect on the ability of the participants to understand them. Further, those participants with lower education levels have a more limited understanding of the information contained within the document even when the information is simplified (Young et al., 1990).

Throughout the research of Young et al. (1990), participants given consent forms written at the sixth-grade level obtained a greater understanding of informed consent than those given consent forms written at the college graduate level. As a result, participants in Young et al.'s (1990) study who endorsed the informed consent forms might not have

been completely enlightened regarding the research that they agreed to undergo. Therefore, their informed consent is not only useless, but their research participation is also unethical and infringes upon federal stipulations (Ogloff & Otto, 1991). Grunder (1978) believes that consent is of no value to either participant or researcher except when it is an informed consent. The term *informed consent* implies that participants must understand the information contained in the form. The regulations of the institutional review board stipulate that the informed consent forms must include: the purpose of the research, the risks and benefits involved, other available treatments, confidentiality, who to contact in case of questions or complications, consequences of withdrawing from the study, and the voluntary nature of their participation. Furthermore, Young et al. (1990) assert that these guidelines are helpful, but the information contained in the form must be written in such a way that it can be clearly understood. Unfortunately, even though the required components for informed consent have received a tremendous amount of attention, very few clinicians, psychologists, and researchers seem to be concerned about whether or not the readers of these forms can understand their content (Grunder, 1978). Researchers and clinicians are directed to allow only those individuals who give informed consent in their research (Ogloff & Otto, 1991).

Obviously, children have different needs than adults, but both children and adults require appropriate information if they are to utilize their rights (Kent, 1994). When children participate in research, clinicians must notify the institutional review boards as to how informed consent is obtained. Creating suitable tactics to explain a research study or the research process or to obtain informed consent from children serves as a test for parents, clinicians, and researchers. While designing these strategies, researchers should consider whether children can make decisions regarding research and comprehend the purpose, procedures, and meaning of research (Helling & Buchanan, 1994). According to Piaget's theory on cognitive development, children can understand the informed consent

form just as well as adults as long as the form is worded at a level appropriate for children (Kent, 1994).

In contrast, Helling and Buchanan (1994) point out that during the course of acquiring informed consent, clinicians believe that children who are younger than 12 years old do not possess the ability to determine whether to take part in research or understand the meaning of the informed consent form. As a result, clinicians often resort exclusively to the parents to obtain the informed consent of the children. Specifically, Helling and Buchanan (1994) evaluated 5- to 12-year old children on their capacity to consent to psychological research. According to their findings, the majority of children seem to possess the capability to determine if they want to take part in a study, but lack considerable understanding of the key principles of informed consent, such as confidentiality and voluntariness. In fact, children, who are subjected to information and experiences concerning the process of research, hold a more accurate conception of the reasons for partaking in research, increase their satisfaction and awareness of research, as well as appear more cooperative with research staff. Helling and Buchanan (1994) conclude that the reliability and validity of research will increase if children find satisfaction in engaging in research studies, feel comfortable and relaxed during the studies, and have a general understanding of what is happening in the study. Furthermore, children who have a positive experience with research will be more inclined to participate in future research (Helling & Buchanan, 1994). These findings also hold true for adult participants.

The research studies mentioned previously in this paper indicate that the readability of informed consent forms utilized in medical and psychological procedures is unappropriately high. Unfortunately, all of the studies discussed contain systematic defects. These flaws include utilizing small sample sizes, not randomly selecting consent forms, and not comparing consent forms from various disciplines and age groups. Notwithstanding the limitations of earlier research, the results of these studies suggest that

the informed consent forms utilized in the medical and psychological fields are written at an elevated reading level making it troublesome for most participants to comprehend. The use of informed consent forms is widespread among research settings and frequently is the sole procedure utilized to inform potential participants about the research projects in which they participate (Ogloff & Otto, 1991). Therefore, even though many complicated problems remain in the process of securing the comprehension of informed consent forms, future researchers cannot let the unreadability of the form be one of those problems, especially since this can be resolved easily by using a readability formula (Grunder, 1978).

Even though highly controversial, readability formulas are becoming increasingly prevalent among clinicians because of their ease of application (Koenke, 1987). Since these formulas were developed several years ago, a great deal of research exists about them. Therefore, these formulas can be used more effectively by researchers when attempting to create a readable informed consent form (Fry, 1968; Koenke, 1987). Perhaps, the score indicated by the formula can lead clinicians to keep their intended audience in mind while developing the form (Koenke, 1987). Until more information is known, clinicians should underestimate rather than overestimate the reading ability of clients in order to increase their comprehension of the informed consent forms (Handelsman et al., 1986).

According to Ogloff and Otto (1991), readability formulas utilize certain components of a document such as the number of syllables in words, the number of words per sentence, and compare the text with a word difficulty list to establish the readability level of the form. The most frequently utilized readability formulas are the Fry Readability Graph (FRG, Fry, 1968), Dale-Chall Formula, and the Flesch Readability Formula (FRF, Flesch, 1948). Each of these formulas is characterized as having both strengths and weaknesses (Grunder, 1978). Specifically, the FRG is very easy to use, takes only a few hours to use, and yields an accurate grade equivalence up to the twelfth grade level (Longo, 1982; Grunder, 1978). On the other hand, the Dale-Chall formula requires

several weeks to use, but is the most accurate (Longo, 1982). Finally, the FRF is the most popular formula, has been researched more extensively and is responsive to several levels of readability. Unfortunately, the FRF is more difficult to use and is only accurate up to the seventh grade level (Longo, 1982; Grunder, 1978). All of these formulas have been successful in evaluating informed consent forms. Grunder (1978) suggests that these formulas be utilized by institutional review committees when determining which research studies should be approved. Moreover, Peterson and his colleagues (1992) state that many computer software packages can quickly assess the readability of the text and reveal that several consent forms have readability levels equal to that of someone in college.

In accordance with previous research findings, researchers for this study hypothesize that the informed consent forms are written at a higher level than the general population can understand. Also based on past findings, researchers infer that these conditions are applicable to the targeted population of these consent forms as well. Furthermore, researchers predict that the selected consent forms will not contain all of the necessary elements recommended by the American Psychological Association.

Method

Materials

Researchers contacted the Human Subjects Committee at Southern Illinois University at Carbondale. Next, they requested informed consent forms from various disciplines performing research. The committee randomly selected a total of 13 consent forms and sent them to the interested party. These consisted of 7 forms from the discipline of Education, 1 from Social Work, 1 from Journalism, 1 from Administration of Justice, 1 from Psychology, and 2 from Linguistics.

Procedure

For this study, researchers utilized the readability formulas computed by the programs in the Microsoft Word version 6.0 software package. Specifically, this version

of Microsoft Word counted the number of words, characters, paragraphs, and sentences, assessed the average sentences per paragraph, words per sentence, and characters per word, and calculated the percentage of passive sentences, Flesch Reading Ease, Flesch-Kincaid Grade Level, Flesch Grade Level, Coleman-Liau Grade Level, and Bormuth Grade Level.

Researchers were sent a total of 13 randomly selected informed consent forms from the Human Subjects Committee at Southern Illinois University at Carbondale. Using the readability formulas found in programs of Microsoft Word version 6.0, researchers scanned the documents into the computer and allowed the programs to analyze the forms. The Flesch Grade Level indicates the Flesch Reading Ease score as a grade level.

<u>Flesch Reading Ease Score</u>	<u>Flesch Grade Level</u>	<u>Reading Difficulty</u>
90-100	5th grade	Very easy
80-89	6th grade	Easy
70-79	7th grade	Fairly easy
60-69	8th-9th grade	Standard
50-59	High School	Fairly difficult
30-49	College	Difficult
0-29	College Graduate	Very difficult

The Flesch Reading Ease Score implies how easy the document is to read based on the number of syllables per word and number of words per sentence. The Flesch Reading Ease Scores represent a number between 0 and 100, The higher the score, the easier the document is to read. The formula for the Flesch Readability Ease is: $1.015 \times (\text{average number of words per sentence}) + 0.846 \times (\text{number of syllables per 100 words}) - 206.835 - \text{TOTAL} = \text{Flesch Reading Ease Score}$.

The Flesch-Kincaid Score suggests the grade level of the document based on the number of syllables per word and number of words per sentence. This score predicts the

difficulty of reading technical documents and is based on Navy training manuals that score in difficulty from 5.5 to 16.3. The formula for the Flesch-Kincaid Grade Level is: $.39 \times (\text{average number of words per sentence}) + 11.8 \times (\text{average number of syllables per word})$. $\text{TOTAL} - 15.59 = \text{Grade Level}$. A readability score of grades 6 to 10 is considered most effective for a general audience.

The Coleman-Liau Grade Level reveals the grade level of the document based on the number of letters per word and number of sentences per 100 words.

The Bormuth Grade Level denotes the grade level of the document based on the average number of letters per word and per sentence. Bormuth scores establish grade levels ranging from 6.3 to 11.6.

Microsoft Word 6.0 also calculates the percentage of passive sentences in a document. A higher percentage of passive voice verb clauses can make the document more difficult to understand. In addition, long sentences with many clauses can be harder for a reader to understand.

Results

For this study, the sample size was too small to conduct significance testing. However, Table 1 includes the necessary building blocks to compute the various readability formulas. From this table, one should notice the range and variability among the number of words, characters, paragraphs, and sentences contained within each consent form. More specifically, the number of words in these consent forms ranged from 232 to 1,411 with the mean being 416.54. Furthermore, the number of sentences varied from 12 to 70 with a mean of 19.92. These extreme high and low figures did not appear to correspond with any particular discipline.

Table 2 consists of the average number of sentences per paragraph, words per sentence, characters per word, and percentage of passive sentences which were all determined by Microsoft Word. From this Table 2 data on percentage of passive

sentences, the numbers varied from 21% to 78%. In fact, 6 of the 13 consent forms are comprised of 50% or more passive sentences. Obviously, a higher percentage of passive voice verb clauses can make the document more difficult to understand. The averages for the number of words per sentence ranged from 16.2 to 24.7. Looking at the means in Table 2 regarding the number of words per sentence, the average was 21.12. Long sentences with many clauses, such as the ones found in these consent forms, can be more challenging and confusing for the reader.

Table 3 reveals the scores for each consent form utilizing the Flesch Reading Ease, Flesch-Kincaid Grade Level, Coleman-Liau Grade Level, and Bormuth Grade Level. Inspection of the means in Table 3 show that the Flesch Reading Ease calculated an average score of 43.98 which translates into a college reading level. The Flesch-Kincaid Grade Level had a mean of 11.41 when a score between 6 and 10 is considered most effective for a general audience. The Bormuth Grade Level revealed a mean of 11.38 when the highest possible score is an 11.6! In fact, 5 of the 13 forms received this score. Utilizing Table 3, it appears as if the informed consent forms with the largest Flesch Reading Ease Scores also have the lowest Flesch-Kincaid Grade Level, Coleman-Liau Grade Level, and Bormuth Grade Level scores. Furthermore, the reverse is also true. The consent forms that scored the lowest on the Flesch Reading Ease Scale also scored the highest on the Flesch-Kincaid Grade Level, Coleman-Liau Grade Level, and Bormuth Grade Level. Moreover, referring to Table 3, one can notice that the forms from the disciplines of Education and Social Work had a tendency to score lower on the Flesch Reading Ease scores and higher on the Flesch-Kincaid Grade Level and Bormuth Grade Level than consent forms from other fields of study.

Table 4 lists the issues which should be included in all informed consent forms and breaks down the information according to the contents of each individual form. With the exception of 2 consent forms, 11 of the forms did not include the risks or benefits of the

research process. In fact, 2 of the forms did not even incorporate half of these suggested requirements into the text. Aside from that, the majority of these informed consent forms, 9 out of 13, contained all or all but one of these factors. Moreover, all of the forms mentioned the contact person into the text. Referring to Table 4, 9 of the 13 forms required a signature.

Discussion

The findings in this study supported what was originally hypothesized. Clearly, from these results, one can conclude that these consent forms are written at a level that the general population cannot understand. From the findings of previous research studies, one can infer that these conditions are applicable to the targeted population of these consent forms as well. Young and his colleagues (1990) believe that many research participants are not reading at a collegiate level. Hence, these participants cannot fully understand the consent form. Furthermore, Peterson and his colleagues (1992) cite a study which revealed that 120 university or clinical patients, who reportedly completed the tenth grade, read only at the fifth or sixth grade level. Riecken and Ravich (1982) discovered that roughly one-fourth of the participants in their experiment had any kind of college education. The primary purpose of the informed consent procedure is to guarantee that potential research participants are able to choose whether or not they want to volunteer for the research experience. Therefore, both the institutional review boards and researchers need to increase the understandability of their informed consent forms.

Unfortunately, the present study encompassed several limitations. First of all, the sample size of informed consent forms was very small. Also, the subject matter discussed in these consent forms was limited to the disciplines of Linguistics, Education, Social Work, Psychology, Journalism, and Administration of Justice. Even though randomly selected, the sample of consent forms overrepresented the Education field, while it underrepresented the disciplines of Social Work, Journalism, Administration of Justice,

Psychology, and Linguistics. Furthermore, these informed consent documents were written primarily for college students, members of the Carbondale community, parents of public school children, school administrators, female offenders in jails, and employees of a TV station. Not one of the consent forms were analyzed for any other age groups. Moreover, the consent forms used for this study all came from the Human Subjects Committee at Southern Illinois University at Carbondale. Finally, no particular discipline or consent form consistently scored the highest score on all of the readability formulas. This could be explained by the fact that each readability formula takes different aspects of the consent forms into account in order to calculate the score.

For future research, the sample size should be increased to get a more broad variation of these different forms. Documents from various other disciplines should be included. In addition, consent forms intended for other age groups should be analyzed. Also, consent forms from other universities should be assessed to reveal the extent of the readability problem.

Additional suggestions as to how to improve readability and comprehension of informed consent forms are plausible. These include listing the name of the researcher who is conducting the study so that further questions concerning the study can be addressed to him or her (Peterson et al., 1992). In addition, the reading level can be simplified by making use of shorter and simpler sentences, improving organization of the information, using more familiar terminology, and defining technical terms in common language. Handelsman et al. (1986) add that sentence length seems to influence readability more than syllables per word. As a result, the use of short sentences can increase readability considerably (Handelsman et al., 1986; Kent, 1994). Moreover, these consent forms should ideally be constructed with a reading level that does not exceed the 7th or 8th grade audience. Even this level may be too advanced for those participants having lower educational backgrounds or verbal skills.

Other ways to increase the comprehensability of the informed consent forms are to combine oral and written methods of presentation, give participants more time to review the document, and present the information in a clear, brief, and direct manner (Young et al., 1990). Most of the forms analyzed were relatively brief; however, one of the consent forms was three pages long. According to Mann (1994), shorter forms withholding some detail, facilitate participants' comprehension more than longer forms explaining a procedure in its entirety. Hence, consent forms which are short and concise should be utilized by researchers to optimize participants' understanding (Mann, 1994). Furthermore, requiring participants to sign the consent form could be detrimental because according to Mann (1994), the very act of signing a consent form makes a potential participant assume that they have waived the rights that the consent form is designed to protect. Therefore, to make the forms more effective, future researchers should try eliminating the signed consent form and instead implement a verbal consent. Future researchers interested in this particular topic should examine these recently submitted variables and take them into consideration in their own study to establish whether these interpretations were appropriate.

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Table 1

Counts performed on documents by Microsoft Word 6.0

Informed Consent	Department	Words	Characters	Paragraphs	Sentences
1	Linguistics	502	2504	19	23
2	Linguistics	344	1796	16	19
3	Education	444	2380	18	18
4	Education	352	1904	17	16
5	Education	294	1627	13	14
6	Education	286	1635	12	12
7	Social Work	321	1682	15	14
8	Education	334	1820	14	15
9	Psychology	232	1318	7	13
10	Education	287	1566	13	14
11	Journalism	259	1395	13	16
12	Administration of Justice	349	1879	12	15
13	Education	1411	7205	28	70
n = 13		EX = 5415	28,711	197	259
		X = 416.54	2208.54	15.15	19.92

Table 2

Averages calculated by Microsoft Word 6.0

Informed Consent	Sentences per paragraph	Words per sentence	Characters per word	Passive Sentences
1	1.2	21.8	4.9	78%
2	1.2	18.1	5.0	31%
3	1.0	24.7	5.2	50%
4	.9	22.0	5.1	43%
5	1.1	21.0	5.3	42%
6	1.0	23.8	5.4	50%
7	.9	22.9	5.0	21%
8	1.1	22.3	5.2	60%
9	1.9	17.8	5.4	38%
10	1.1	20.5	5.2	35%
11	1.2	16.2	4.8	31%
12	1.3	23.3	5.2	73%
13	2.5	20.2	5.0	54%
n = 13	EX = 16.4	274.6	66.7	
	X = 1.26	21.12	5.13	

Table 3

Readability scores calculated by Microsoft Word 6.0 listed with the corresponding consent form and department

Flesch Reading Base		Flesch-Kincaid Grade Level		Coleman-Liau Grade Level		Bormuth Grade Level	
11(J)	54.7	6(B)	13.6	4(B)	24.1	3(B)	11.6
1(L)	51.7	5(B)	13.2	12(AJ)	24.1	6(B)	11.6
2(L)	49.2	7(SW)	12.5	3(B)	23.5	7(SW)	11.6
13(B)	48.9	8(B)	12.0	6(B)	21.7	8(B)	11.6
4(B)	47.8	10(B)	11.8	2(L)	20.8	12(AJ)	11.6
3(B)	46.5	12(AJ)	11.7	8(B)	20.1	1(L)	11.5
9(P)	43.2	3(B)	11.4	5(B)	19.5	4(B)	11.5
8(B)	42.6	9(P)	11.0	9(P)	18.2	5(B)	11.5
10(B)	42.1	13(B)	10.9	1(L)	17.5	10(B)	11.2
12(AJ)	42.0	4(B)	10.7	7(SW)	17.1	13(B)	11.2
7(SW)	41.8	1(L)	10.5	10(B)	15.9	9(P)	11.1
5(B)	32.9	2(L)	9.9	11(J)	15.4	2(AJ)	11.1
6(B)	28.3	11(J)	9.1	13(B)	14.9	11(J)	10.9
n = 13	EX = 571.7		148.3		255.8		148.0
	X = 43.98		11.41		19.68		11.38

Table 4

Content of the informed consent forms

Suggested requirements	Consent form												
	1	2	3	4	5	6	7	8	9	10	11	12	13
Purpose	x	x	x	x	x	x		x	x	x	x	x	x
Volunteer	x	x	x	x	x	x		x	x		x	x	
Risks/Benefits								x					x
Confidentiality	x	x	x	x	x	x		x	x	x	x	x	x
Contact person	x	x	x	x	x	x	x	x	x	x	x	x	x
Consequences of Withdrawing	x	x	x	x	x	x	x	x	x		x	x	x
Signature	x	x	x		x	x		x			x	x	x