Uninformed Consent? The Impact of Reading Level, Format, and Interactivity of Consent Forms on Participant Comprehension

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ABSTRACT

The present study examined participants' comprehension of consent form information based on the consent forms' reading level, format, and level of interactivity. Our sample consisted of 228 adult English speakers who were randomly assigned to one of eight groups. Each group saw consent forms with a different combination of reading level, format, and interactivity of questions. All participants were asked to answer 12 multiple-choice questions about two consent forms (framed as two studies). Participants read and self-reported whether they read the form or not. Asking participants questions immediately after exposure to the information in the consent form improved comprehension compared to asking all comprehension questions after reading the entire form. Reading level and bulleted format did not improve comprehension significantly. Furthermore, participants were more likely to report that they read the consent form if they were given interactive questions about the form. Results suggest that interactive questions can be an effective method for improving participant comprehension of the purpose, risks, and benefits of the study or procedure in which they plan to participate.

KEYWORDS

Comprehension; Informed Consent; Format; Reading Level; Interactivity; Participants; Ethics in Research; Consent Form

INTRODUCTION

Research with human participants often requires informed consent. However, when a participant is presented with a consent form prior to participating in a study, they make the personal decision to read it or ignore it, leaving them uninformed. Even when participants read the consent form, it may not be fully understood by research participants. This study examined several factors that may assist in participants' reading and understanding of consent forms: reading levels, bulleted vs paragraph formats, and the interactivity of questions. If we can identify which factors promote reading comprehension, researchers may be able to save participants' time and promote more ethical treatment of participants.

Past research showed that even when participants felt satisfied with the informed consent process, many were unable to identify the risks, benefits, or purpose of the study in which they participated.¹⁻³ On the other hand, some participants do not read or skim the information in consent forms. Participants may do this when they believe that the forms are too long or because the key points do not stand out in some way.⁴ Furthermore, consent forms are becoming increasingly more difficult to understand, as even pediatric forms are typically written at a 10th-grade reading level.⁵ This makes both choosing to read the consent form and understanding the information provided difficult, especially for low-literacy populations, the elderly, the cognitively impaired, and patients with certain psychiatric conditions, who are often the focus of clinical research.⁶⁻⁹

The difference in attention given to consent forms with different formatting and timing of when comprehension questions are asked could be attributed to habituation. The theory of habituation suggests that people pay less attention to a stimulus that is often presented to them because they identify it as information they have already mentally processed.¹⁰ Participants may become habituated to the material presented in most consent forms due to frequent exposure to "terms and conditions" forms in today's digital age. These "terms and conditions" forms may function similarly to consent forms, as both are required to continue with a desired task. Therefore, participants may comprehend more information when it is given in bullet point form because it draws attention to changes made in consent forms or to what makes this consent form different from others. The same theory could be applied to interactive questions in the way that the questions break the habituation process by directing the participants' attention back to the information that is necessary for them to know and understand.^{10–13} A study done by Geier and colleagues also

indicated that participants could pay more attention to the content presented in interactive consent forms, as participants spent more time on average with this version.¹²

The current literature on consent forms has tested the reading level of consent forms and their impact on participant comprehension.^{1,9} Results suggest that consent forms written at a lower reading level are easier for participants to read.¹⁴ However, while one study indicated that forms with lower reading levels also improved participant comprehension,⁹ another suggested that reading level showed no difference in participant comprehension.¹ Furthermore, a study done by Joffe³ and colleagues showed no difference in participants also reported using outside resources to aid in their comprehension, indicating that many participants are unable to comprehend material in consent forms on their own.³ This suggests that the reading level of consent forms and their impact on participant comprehension should be studied more in-depth.

Furthermore, several studies have tested the effects of consent form format on participant comprehension and found that shorter, more precise forms that highlighted key points were more likely to be read and understood.^{9, 15–19} The use of bullet points was particularly helpful to some groups that were tested on their consent form comprehension.^{15, 18–19} However, there is evidence to contrast this finding, in which formatting had no impact on participant comprehension.^{12, 20–21} Therefore, concise bullet point formatting of consent forms may make significant differences in participants' comprehension of the information, compared to more lengthy paragraphs.

Another component that should be considered in participants' abilities to read and understand information in consent forms is the level of interactivity they have with the material.^{11, 12} Flory and Emanuel's¹¹ research found that participants had higher levels of comprehension when consent forms offered a comprehension test or feedback from a healthcare professional.¹¹ Moreover, the level of interactivity and engagement with material on the consent form was positively correlated with the level of comprehension questions and was more likely to get participants to read the form.¹² Therefore, it is also possible that asking comprehension questions immediately after exposure to important information in consent forms may improve participants' likelihood of reading the forms and their comprehension of them. Although this could be a result of short-term memorization, given that long-term memory for the information in consent forms is unneeded, comprehension immediately after presentation would still be useful for informed consent.

Ultimately, the current literature on consent forms has tested the readability of forms based on reading level, formatting (bullet points, spacing, bolding, etc.), and the level of interactivity with the material, and each of these components' impact on participant comprehension. The findings of past studies in these areas are variable, and therefore not conclusive.¹⁻²¹ Moreover, there is yet to be a study that has tested interactions among all these conditions on participant comprehension. Developing a new consent form template or criteria may aid in the advancement of ethical research practices and lead to more informed participants. Therefore, the current study examined whether different combinations of reading level, format, and level of interactivity affect consent form comprehension. In other words, which modifications to consent forms make participants more informed? In the current study, participants were placed into one of eight different groups. Each group had a different combination of these three variables. Consistent with previous research,^{3,9} it was hypothesized that participants who read the lower reading level consent forms would have better comprehension scores than participants who read the higher reading level consent forms. Based on past literature, it was predicted that participants in groups that read the bullet point format consent forms would have higher comprehension scores and would be more likely to self-report actually reading the form than those who received the paragraph format consent forms.9, 15-19 Previous findings also led us to predict a main effect for the level of interactivity, in which participants in the interactive questions group would have higher comprehension scores and would be more likely to self-report actually reading the form than the group without interactive questions.¹⁰⁻¹³ We also expected an interaction between format and reading level, in which lower reading level consent forms in bullet point format would show higher scores of comprehension. Lastly, we hypothesized an interaction between the interaction group and format. Specifically, we expected the groups that read the bullet point consent forms with interactive questions to have the highest comprehension scores out of all the groups.

METHODS AND PROCEDURE

Institutional Review Board approval from the university where the study was conducted was obtained for the project title [2174108-1], and all hypotheses and methods were pre-registered in the OSF database prior to collecting data. We recruited 324 English speakers over the age of 18 through social media and the snowball method of convenience sampling. Although we pre-registered a larger sample size, we had to stop collecting data before the planned number of participants was met due to a deadline at the university where the study was conducted. After removing all test trials and participants who were underage or who completed less than half of the survey, the final sample consisted of 228 participants, including 36 men (15.79%), 191 women

(83.77%), and one (0.44%) participant that was either non-binary or another gender. The mean age for the final sample was 43.54 years. In terms of racial and ethnic demographics, 190 (83.33%) participants identified as white, 25 (10.96%) identified as Black or African American, six (2.63%) identified as Hispanic or part of the Latinx community, four (1.75%) identified as Asian or Asian American, and three (1.32%) identified as some other racial or ethnic identity. In terms of education, 59 (25.88%) had a high school diploma or GED equivalent, 22 (9.65%) had an associate's degree, 79 (34.65%) had a bachelor's degree, 48 (21.05%) had a master's degree, and 19 (8.33%) had a doctorate or professional degree. There was also one participant (0.44%) with a cosmetology license.

To hide the true purpose of our study and analyze what participants do naturally when confronted with consent forms, the participants were told that this study would measure their understanding and comprehension of different texts, but not that the texts they needed to comprehend were the consent forms. Instead, they were told that they would complete several shorter studies so that they would believe that each consent form was for a new study. After participants gave consent to take the survey, they were randomly assigned by Qualtrics to one of eight groups. Each group contained a different interaction of our independent variables using a factorial, between groups design 2 (reading level; high or low) x 2 (format; paragraphs or bullet points) x 2 (level of interactivity; questions during or after reading consent form), which resulted in eight conditions. Each condition had two trials with two different consent forms. The content of the two consent forms given to each participant differed, but both consent forms contained the same key qualities (i.e., in terms of designated reading level, format, and interactivity).

The reading level of the consent forms was determined by the Flesch Reading Ease Score (FRES), which was calculated using the number of words, sentences, average syllables per word, and average words per sentence. FRES that range from zero to 50 are considered to be college-level or above and FRES that range from 50 to 100 are considered to be below college level. For the current study, reading scores that were at the college level or above were marked as high, and reading scores below the college level were marked as low. Conditions that contained consent forms written at lower reading levels had FRES of 50.1-66.6. Conditions that contained consent forms written at higher reading levels had FRES of 28.1-40.9. FRES scores within reading level groups were made as close together as possible. The exact scores for each trial in each condition and how they were calculated can be found in the **appendix**. In the group with interactive questions, the questions were presented directly after the part of the consent form. All manipulated consent forms from trial one followed the consent form template recommended by the National Academy of Neuropsychology,²² and all manipulated consent forms from trial two followed the consent form template recommended by the Institutional Review Board at the university where the study was being conducted.²³ Both "fake" consent forms were labeled with the trial number and the title "Consent to participate in research," to draw attention to the fact that it was a new consent form.

All participants answered questions about their demographics. Next, depending on which group they were randomly assigned to, they either answered comprehension questions about the consent form during or after reading the first manipulated consent form. They were asked six multiple-choice, comprehension questions per trial, and one question per trial asking if they read the consent form. Comprehension questions included information about the purpose, benefits, risks, withdrawal, expected time to completion, and confidentiality. As a distractor from the consent forms, a textbook paragraph related to neuropsychology was then displayed, followed by a shortened, true-or-false reading comprehension test on that textbook paragraph. Participants were then directed to a second trial and were shown a new manipulated consent form about forensic psychology and asked to answer comprehension questions about the consent form from trial two. They then took another shortened, reading comprehension section on the forensic psychology textbook paragraph as a distraction. By creating a second trial, we were able to gain more data as well as control for the subject of each consent form. For example, participants who strongly dislike neuropsychology may answer more questions incorrectly on the first set of questions because they dislike the subject they are about to answer test questions on. Adding a second trial with different subject matter controlled for this effect. Moreover, the overall performance of each participant was less likely to be due to the specific consent forms used in our study or due to the templates recommended by each institution because the consent forms and templates were diverse in their subject matter and template recommendations but contained the same consent form qualities. Overall, the presence of two trials as opposed to one added validity to the experiment. Before ending the survey, participants were debriefed. All experimental materials can be found in the **appendix**.

The dependent variable, which was the comprehension of information, was operationalized by the number of comprehension questions that each participant answered correctly. One point was given for each correct response chosen. For data analysis, the six comprehension questions from each of the two forms were combined to make a composite score for each participant with a maximum range of zero to 12. Four multiple-choice options were given for each comprehension question, including "I don't know/ I am not sure". Any question that was left blank or questions that participants said they did not know or were not sure

about were recorded as incorrect. For true or false comprehension questions, a "Neither true nor false" option was also given to make the number of options for each question equal. Whether participants self-reported actually reading the form or not was also measured.

All data was analyzed on SPSS. A univariate ANOVA was used to analyze data relating to comprehension scores and a chi-square test of independence was used to analyze the data relating to whether participants reported reading the forms.

RESULTS

The 2 (reading level; high or low) x 2 (format; paragraphs or bullet points) x 2 (level of interactivity; questions during or after reading consent form) ANOVA revealed the hypothesized main effect for interactivity of questions on comprehension score, F (1, 220) = 46.50, p < 0.001, η_p^2 =.174. Thus, those who received interactive questions scored higher (M = 9.71, SD = 2.43) than those who received all comprehension questions after reading the entire form (M = 7.36, SD = 2.71), as we expected. Figure 1 shows the main effect for interactivity of questions. We also hypothesized a main effect for reading level on total comprehension score. However, our results did not support the hypotheses for reading level, F (1, 220) = .04, p = .846, $\eta_p^2 = .000$, and format, F (1, 220) = .04, p = .850, $\eta_p^2 = .000$. Participants who viewed consent forms written at a higher reading level received higher comprehension scores (M = 8.63, SD = 2.90) than the group who viewed consent forms written at a lower reading level (M = 8.45, SD = 2.77), which is the opposite of what we hypothesized, but was not statistically significant. For format, participants who viewed bullet point consent forms received lower comprehension scores (M = 8.50, SD = 2.82), but this finding was also not significant.



Furthermore, we hypothesized an interaction between reading level and format, F (1, 220) = .12, p = .734, $\eta_p^2 = .001$, and between format and interactivity of questions, F (1, 220) = 2.08, p = .151, $\eta_p^2 = .009$. However, neither of these interactions were significant. Group means and standard deviations can be found in **Table 1** and **Figure 2**.

Reading Level	Format	Interactivity	Comprehension Score
Low	Paragraph	Yes	9.93(2.65)
	Paragraph	No	7.40(2.57)
	Bullet Point	Yes	9.54(2.56)
	Bullet Point	No	7.62(2.72)
High	Paragraph	Yes	10.42(1.78)
	Paragraph	No	6.74(2.65)
	Bullet Point	Yes	9.41(2.67)
	Bullet Point	No	7.64(2.93)

*M(SD) = Comprehension Scores

Table 1. Mean comprehension scores based on reading level, format, and interactivity of questions.



Figure 2. Mean comprehension score by version of consent form.

In terms of the self-reported reading of the consent forms, we hypothesized main effects for interactivity of questions and format. Although we preregistered the data analysis for this dependent variable as an ANOVA, we used a chi-square test of independence, which is more appropriate than an ANOVA, as the dependent variable consisted of a binary "yes" or "no" response. Therefore, we used a chi-square test of independence to examine the relation between the level of interactivity and whether participants self-reported reading the consent forms. The relation between these variables was significant, χ^2 (2) = 11.44, p = .003, ES = .116. Those who answered interactive questions were more likely than those who answered all questions after reading the consent form to self-report actually reading the form. While 53% of those who answered interactive questions reported that they did read the form, only 47% of those who answered all comprehension questions after reading the entire form reported that they actually read the form.

Contrary to our expectations, there was not a significant main effect for format on self-reported reading of the consent forms, χ^2 (2) = 2.14, p = .343, ES = .061. Those who viewed the paragraph consent form were more likely than those who viewed the bullet point consent form to self-report actually reading the form. Out of those who viewed the paragraph form, 50.13% reported that they did read the form, while only 49.87% of those who viewed the bullet point consent form reported that they actually read the form, which is not what we expected, but was also not statistically significant. A graph with all percentages of self-reported reading of the consent forms by group can be seen in **Figure 3**.



Figure 3. Self-reported reading of the consent forms based on group.

DISCUSSION

This study demonstrated that asking participants questions immediately after exposure to the information that answers the given question made participants more likely to self-report reading the form and resulted in better comprehension of that information when compared to answering all comprehension questions after reading the entire form. However, there were no significant differences in self-reported reading and comprehension between those who received paragraph consent forms and those who received bullet point consent forms, nor were there any significant differences in comprehension based on the reading level at which the consent forms were written.

Our finding that asking interactive questions about the consent form resulted in more self-reported reading and better comprehension was consistent with past studies that tested the interactivity of consent forms on participant comprehension.^{11, 12} This is most likely because the interactive questions acted as a reminder to the participant to read the form. If they did not read that section of the form the first time, they may have felt inclined or as though they had more of a responsibility to go back and read it again in order to answer the question correctly. It is also possible that these questions highlighted what was important or different in the consent form, which was also shown to be helpful in a past study.⁴ This finding also corresponds with the theory of habituation in the way that participants become habituated to the material in consent forms and pay less attention to them. The interactive questions broke their habituation by highlighting what was different or what was most important for the participants to know.¹⁰⁻¹³ Moreover, there could have been a forward testing effect in our study, in which interactive questions facilitated the later learning and retention of consent form information.²⁵ Past literature has shown that when tested on smaller quantities of information in the interim, the quality of students' learning and comprehension was better and they were more likely to score higher on cumulative tests later on.²⁵ Therefore, future research should focus on the impact of interactive questions on long-term memory of consent forms as well as how interactive questions on one consent form may aid in the comprehension of consent forms read in one consent form may aid in the comprehension of consent forms read in one consent form may aid in the comprehension of consent forms read in the future that do not contain comprehension questions.

Our study confirmed our hypothesis and the findings of past literature on the interactivity of consent forms and their effect on participant comprehension. However, it is important to note that the average comprehension score for participants who received the interactive questions was not a perfect score, meaning that even when participants had the chance to go back and look at the information, they did not understand it. Therefore, future research should focus on what is confusing and what needs to be made clearer in consent forms.

However, the reading level at which the consent forms were written had no significant impact on comprehension scores, which supports the findings of some other studies,^{1, 14} but conflicts with our hypothesis and with the findings of another study.⁹ This could be due to the fact that most of our participants had at least a high school diploma. Interestingly, the participants given the consent forms written at a higher reading level had slightly higher comprehension scores than those who were given consent forms written at a lower reading level. Given that our results showed very little difference between groups with a slight benefit to those who received the high reading level consent forms indicates that researchers may not need to worry about the reading level at which they write their consent forms. However, the fact that many did not comprehend either consent form regardless of reading level indicates that consent forms may be worded in a confusing way and should be rewritten with even more detail to

relay crucial information to research participants. Future research could focus on identifying which sections of consent forms are most confusing or are most commonly misinterpreted by participants.

Furthermore, no significant differences were found between self-reported reading and comprehension scores of those who read consent forms formatted in paragraphs compared to those who read consent forms formatted with bullet points. This finding did not support our hypothesis and was inconsistent with past literature.^{9, 15–19} However, some other studies found similar results to ours.^{12, 20–21} Although the bullet points were more concrete and drew attention to what was most important to understand, they also made the consent form look longer, which could have deterred participants from wanting to read the whole form. Past literature has shown that expected cognitive load may result in the same feelings that occur when actually completing that task.²⁴ Therefore, longer consent forms may also make participants think that the information will be difficult to understand, and make them more likely to skip the form entirely.

There are several limitations to our study. The first is that our findings are not representative of the entire population. Our sample consisted mostly of white, educated, middle-aged women from the United States. Future research should seek a more diverse sample so that it can be generalized to a wider population. This is especially important when measuring the effect of the reading level of the consent forms on participant comprehension, as a lower literacy population or populations with lower levels of education may have scored lower on comprehension questions if they were given a consent form that was written at a higher reading level. Next, although our participants were randomly assigned, we used the snowball sampling method of collecting data. People known to the researchers or those who volunteer for a study may be different from a completely random sample. Moreover, our sample size was somewhat small, and the results could have been different if we obtained a larger sample size. Therefore, future research should also aim for a random sample that is larger than the sample size of this study. Our fourth limitation involves our methods. We manipulated the reading level by making the low reading level anything below a college level and we wrote the high reading level consent forms at a college level or above. This may not be big enough of a difference in Flesch Reading Ease Scores to properly measure this variable. Future researchers should try to create larger differences in consent form reading levels to check the finding that reading level has no impact on participant comprehension.

In conclusion, including comprehension questions in consent forms may be a good way to gauge a participant's or patient's understanding of the purpose, risks, and benefits of studies or procedures in which they are planning to take part. If participants are unable to answer these questions even when they have the chance to look back at the consent form, they are most likely not giving truly informed consent and should be followed up by a conversation with the researcher or health care provider. This practice may make participants more informed, and ultimately research and clinical procedures more ethical.

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PRESS SUMMARY

This study examines the reading level, format, and interactivity of consent forms, and how these aspects make consent forms more or less easy to read and understand. The results suggested that consent forms that ask comprehension questions at different points in the reading process as opposed to answering a series of comprehension questions after reading an entire form leads participants to better comprehend what they are reading and ultimately agreeing to. These interactive questions also give participants the incentive to actually read the form as opposed to skimming the text or skipping it completely. The authors suggest that interactive questions in consent forms for research studies, clinical trials, and procedures may be a sufficient way to examine participant understanding of what they are consenting to. Additionally, interactive questions and participants' desire to answer the questions correctly may have a similar effect to that of financial compensation for participation in the way that it gives participants an incentive to spend more time and attention on the study and ultimately be more informed in the informed consent process.