"I Consent": An Eye-Tracking Study of IRB Informed Consent Forms

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1 INTRODUCTION

Many academic institutions rely heavily on undergraduate and graduate student participation in research, and a majority of findings in human subjects studies come from research involving students as research subjects [2]. Although these same studies could as well be carried out with a wider participant pool, university students are often recruited because they are easily accessible and convenient for faculty researchers [4].

Despite protections given during the required informed consent process, recent studies have shown that university students consistently fail to read consent forms before agreeing to participate in academic research. A study by McNutt et al. [11] has shown, for example, that up to 85% of participants will look at a consent form for 30 seconds or less before signing it, a considerably shorter amount of time than would be required to read the form at a normal reading speed [15]. Further studies have also shown that, when asked, nearly half of all participants will self-report not reading or simply skimming the consent form [17].

A critical component of the informed consent process is the information link between the prospective participant and the experimenter [12]. As described by the Department of Health and Human Services, it is the experimenter's responsibility to 1) disclose to potential research subjects information needed to make an informed decision, 2) facilitate the understanding of what has been disclosed, and 3) promote the voluntariness of the decision about whether or not to participate in the research [12]. Although the role of the experimenter has been widely studied within the behavioral sciences, this area of interest is largely underrepresented in the body of work on the informed consent process in academic research.

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2 RELATED WORK

To address growing concerns over the apparent lack of reading and comprehension in the informed consent process, academic researchers, educators, and policy makers have conducted many studies manipulating various aspects of the informed consent form. A majority of these efforts have focused either on *characteristics of the consent form*, such as text bolding and spacing [13], complexity of the information presented [5, 18], length of the form [10, 14], and use of images [1, 13], or on *characteristics of the participant*, such as personality traits [8, 16] and demographics [6, 7]. However, relatively little research has been published on experimenter effects, with efforts in this area primarily focused on experimenter perception [11], demeanor [3], and delivery format [16, 17].

In addition to these limitations, many of the results reported in previous studies on consent reading and comprehension are based on participant self-reports and experimenter observations during the informed consent process, and to our knowledge, no research has been conducted to empirically investigate student reading behavior using eye tracking methodologies.

The goal of the current study is to use eye movement data to further understand and assess student reading behavior during the informed consent process in general, and the effects of reading behavior on overall consent comprehension in particular. We will also investigate if a change in experimenter protocol early on in the informed consent process significantly affects reading behavior and consent comprehension.

3 RESEARCH METHODS

3.1 Participants

This research study included 20 Clemson University undergraduate and graduate students. Participation in the study was voluntary, and no compensation was given.

3.2 Experimental Design

A one-way, between-subjects analysis of variance (ANOVA) was conducted to determine the effect of experimenter protocol (instructions, no instructions) on university student reading behavior and comprehension in an academic informed consent reading task.

3.3 Measurements

The independent variable in this study is the type of instruction provided by the experimenter before the participant is presented with the informed consent form. In the 'instructions' condition, the experimenter verbally instructed the participant to carefully read the informed consent document and notified the participant of a short comprehension quiz at the end of the experiment. In the 'no instructions' condition, the experimenter verbally instructed the participant to carefully read the informed consent document, but did not notify the participant about the quiz.

Reading accuracy. A hidden message related to the true purpose of the study was included within the body of the consent form text, and instructions were provided as to how a participant could signal to the experimenter that they found the hidden message. Reading behavior was coded as a binary variable (found/not found). This measurement was based on whether the participant found the hidden message within the consent form, as demonstrated by accurately responding to a related question on the demographics form at the end of the experiment. Due to technical limitations of our design, participants could not go back to review previous pages of the consent form. To account for this limitation, the hidden message was deliberately included on the first page of the document.

Processing Time. Given that the unit of analysis of our study is a paragraph or section of text (rather than a single word), we used a first-pass fixation time as our *initial processing time* measurement. This measurement was calculated for each area of interest (AOI) on the consent form image, and compared between the instructions and no-instructions conditions.

We also calculated a *total processing time* measurement for each AOI on the consent form image. This measurement represents the sum total of all fixations (first- and second-pass) within an AOI, and was used to better understand re-reading behavior related to finding the hidden message within the text.

Saccades. In English reading, a *regression* is a saccadic movement that is right-to-left along a line or that is back to previously read lines [15]. We measured the number of regressions that were outside the normal range (more than 10 letter spaces long or to another line) for each participant. This measurement was used to compare differences in the instructions and no instructions conditions, as well as to better understand re-reading and backtracking behavior related to finding the hidden message within the text.

Visual Behavior. Fluctuations between *ambient* and *focal* fixations were measured using Coefficient K, where positive values indicate focal viewing and negative values indicate ambient viewing [9]. This measurement was used to compare differences in the instructions and no instructions conditions, as well as to better understand changes in visual attention related to finding the hidden message within the text.

Comprehension scores were measured using a five-question quiz given at the end of the experiment. Questions were formatted in both multiple choice and short answer form, and covered the major components of the informed consent process. A score was given based on the number of correct answers.

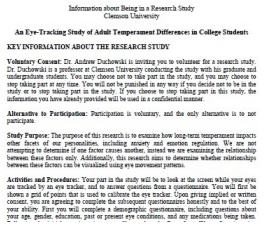
3.4 Apparatus

Participant eye movement and fixation data was collected using a table-mounted (remote) Gazepoint GP3 pupil corneal reflection eye tracker. Per the manufacturer, the eye tracker is capable of an accuracy of one degree of visual angle with a 60 Hz sampling rate. The eye tracker was used on a 22 inch Dell P2213 monitor screen, running at a resolution of 1680x1050 pixels. The viewing distance for all participants was approximately 57cm.

3.5 Procedures and Stimulus

Upon arrival at the lab facility, each participant was randomly assigned to either the 'instructions' or 'no instructions' condition. In both conditions, the true purpose of the study was concealed from the participant, and remote eye tracking data collection began before the participant is officially consented. This concealment and data collection method was approved through the Clemson University Institutional Review Board.

Each participant was then seated in front of a typical computer monitor with an eye tracker mounted underneath. The eye tracker was calibrated by having each participant look at a number of targets on the screen. Following calibration, the participant was asked to look at an image of the first page of the informed consent document. When ready, the participant pressed the spacebar to move from one page of the consent document to the next. There was no time limit on how long a participant could view each page of the informed consent document, but the participant could not go back to a previous page of the document. When the final page was presented, the participant was asked to press the spacebar when ready to acknowledge that they read the consent form and agreed to continue with the study, or to call the experimenter if they did not agree to continue with the study. Examples of the consent form images are included in Figure 1.


Information about Being in a Research Study
Clemson University

An Eye-Tracking Study of Adult Temperament Differences in College Students

KEY INFORMATION ABOUT THE RESEARCH STUDY

Voluntary Consent: Dr. Andrew Dzihowski is inviting you to volunteer for a research study. Dr. Dzihowski is a professor at Clemson University conducting the study with his graduate and undergraduate students. You may choose not to take part in the study, and you may choose to stop taking part at any time. You will not be punished in any way if you decide not to be in the study or to stop taking part in the study. If you choose to stop taking part in this study, the information you have already provided will be used in a confidential manner.

Alternative to Participation: Participation is voluntary, and the only alternative is to not participate.

Study Purpose: The purpose of this research is to examine how long-term temperament impacts other facets of our personalities, including anxiety and emotion regulation. We are not attempting to determine if one factor causes another, instead we are examining the relationship between these factors only. Additionally, this research aims to determine whether relationships between these factors can be visualized using eye movement patterns.

Activities and Procedures: Your part in the study will be to look at the screen while your eyes are tracked by an eye tracker, and to answer questions from a questionnaire. You will first be shown a grid of points that is used to calibrate the eye tracker. Upon giving implied or written consent, you are agreeing to complete the subsequent questionnaires honestly and to the best of your ability. First you will complete a demographic questionnaire, including questions about your age, gender, education, past or present eye conditions, and any medications being taken.

Figure 1: Example consent form stimulus

If the participant agreed to continue the study, the participant was asked to look at images of the Penn State Worry Questionnaire. This part of the experiment was designed to resemble a typical psychology or eye tracking experiment, and its only purpose was to continue to conceal the true purpose of the study. The participant was instructed to read each question and look at their chosen response for 2 seconds before moving to the next question. When the questionnaire was completed, the participant pressed the spacebar to exit. This signaled to the experimenter that the participant

completed the questionnaire. The experimenter terminated the eye tracking software recording, and this portion of the study ended.

Participants were then given a paper quiz on specific content of the informed consent document. When the participant signaled to the experimenter that they completed the quiz, the participant was given a paper demographics questionnaire to complete. Upon completion of the demographic questionnaire, participants were debriefed on the true purpose of the study, potential impacts of the research, and principle investigator contact information for questions or follow-up. Participants were then dismissed from the study session.

4 HYPOTHESES

We expect to find significant differences between participants in the 'instructions' and 'no instructions' conditions, such that students who are aware of the comprehension quiz will have significantly longer first-pass fixation times, significantly higher accuracy in finding the hidden message, and significantly higher comprehension scores.

We also expect to find that for participants in the 'no instructions' condition, participants who naturally demonstrate more careful reading behavior (longer first-pass fixation times) or who find the hidden message by chance will have significantly longer total fixation times, significantly more regressions, and significantly higher comprehension scores than participants who demonstrate typical 'skimming' reading behavior.

5 RESULTS

Several statistical analyses were performed to understand how explicit instructions given by an experimenter and the inclusion of a hidden message within a body of text might affect a participant's reading accuracy and overall comprehension of an informed consent document.

Reading accuracy. A Pearson's Chi-square test was performed to analyze the relationship between experimenter protocol (instructions, no instructions) and finding the hidden message (found, did not find). The relationship was not significant at $\alpha = 0.05$, as χ^2 (1) = .808, $p = .178$, indicating that giving participants forewarning about a comprehension quiz did not affect whether or not the participant found the hidden message.

Processing Time. A factorial analysis of variance (ANOVA) was performed to determine the effect of experimenter protocol (instructions, no instructions) and finding the hidden message (found, did not find) on total fixation duration (time in seconds). The model found a significant main effect of finding the hidden message at $\alpha = 0.05$, as $F(1, 16) = 7.034$, $p = 0.017$ on total fixation duration time. However, there was no significant main effect of condition, $F(1, 16) = 0.692$, $p = .418$, indicating that there is no significant difference in the total amount of time spent in fixations between participants in the instructions ($M = 154.179$, $SD = 117.828$), and no instructions ($M = 118.193$, $SD = 95.489$) conditions. The interaction effect between condition and hidden message on total fixation duration was also not significant, $F(1, 16) = 0.007$, $p = .936$. Main and interaction effects are shown in Figure 2.

Visual Behavior. To analyze the qualitative visual behavior of participants that found the hidden message vs. those that did not,

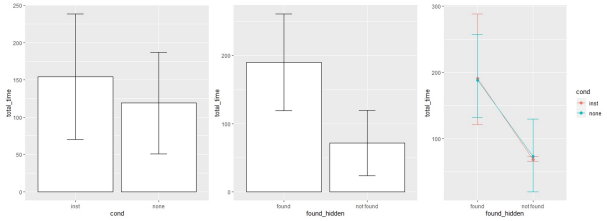


Figure 2: Main and interaction effects of condition and hidden message on total processing time.

we used the K-coefficient [9] to distinguish between ambient and focal fixations on the page of the consent form that contained the hidden message. We produced visualizations in the following way: the K-coefficient was calculated for each individual fixation, and then an average K-coefficient value was calculated with fixations grouped based on their timestamp (ie. fixations from 0-1 seconds are grouped together and averaged, fixations from 1-2 seconds are grouped together and averaged, etc.). Figure 3 shows data from a participant that did find the hidden message, and Figure 4 shows data from a participant that did not find the hidden message.

In Figure 3, the fixations are ambient for several seconds, and then fluctuate between ambient and focal as the participant reads through the form. The AOI that contains the hidden message is first fixated upon around 50 seconds, and becomes the sole AOI being fixated upon around 67 seconds. Unfortunately the eye tracker lost some data around this time but there is clearly a trend after 67 seconds of exclusively focal fixations. This indicates that the participant is studying something intently - likely making sure they fully understand the instruction that is given in the hidden message.

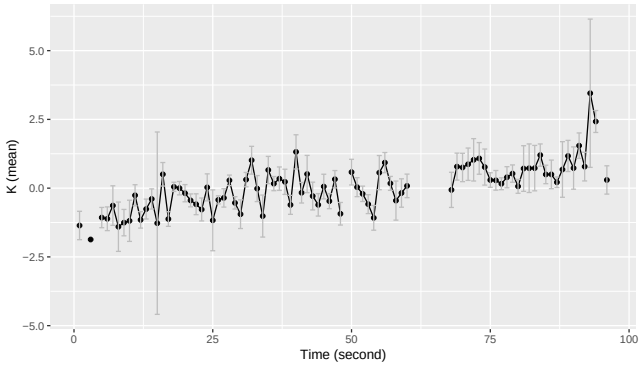


Figure 3: Mean K-coefficient values for fixations, grouped by seconds (hidden message was found).

In Figure 4, the participant does not find the hidden message. A clear difference between Figure 3 and Figure 4 is the total time spent on the page - approximately 100 seconds as compared to 25 seconds, which is what we would expect based on our statistical analysis and hypothesis. The visual behavior in Figure 4 is also very different than in Figure 3, with no clear trend of exclusively ambient or

exclusively focal fixations, indicating that their "skimming" reading behavior consisted of both.

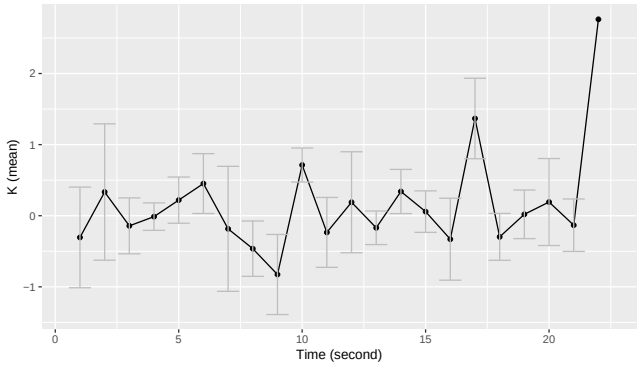


Figure 4: Mean K-coefficient values for fixations, grouped by seconds (hidden message not found).

Comprehension. A factorial analysis of variance (ANOVA) was performed to analyze the effect of experimenter protocol (instructions, no instructions) and finding the hidden message (found, did not find) on comprehension. The model found no significant main effects of experimenter protocol at $\alpha = 0.05$, as $F(1,16) = 0.361$, $p = .556$, or hidden message, $F(1,16) = 1.300$, $p = .271$, on comprehension. The interaction effect between condition and hidden message on comprehension was also not significant, $F(1, 16) = 0.041$, $p = .842$. Main and interaction effects are shown in Figure 5.

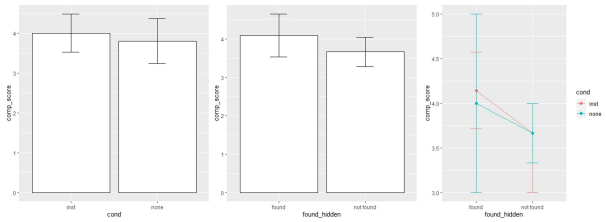


Figure 5: Main and interaction effects of condition and hidden message on comprehension scores.

To further inspect comprehension, a Kendall's tau was performed to determine the correlation between total fixation duration (time in seconds) and comprehension (score) for all participants. The result was statistically significant at $\alpha = 0.05$, as $\tau = .404$, $p = .027$, indicating that across all participants, total fixation duration and comprehension are positively correlated. This means that as the total number and duration of fixation times increase, comprehension scores also increase. Main and interaction effects are shown in Figure 6.

6 DISCUSSION

Although our results did not fully support all of our initial hypotheses, our experiment did show some interesting differences in eye movement behavior between participant groups. The main result we expected to see was experimenter protocol (instruction,

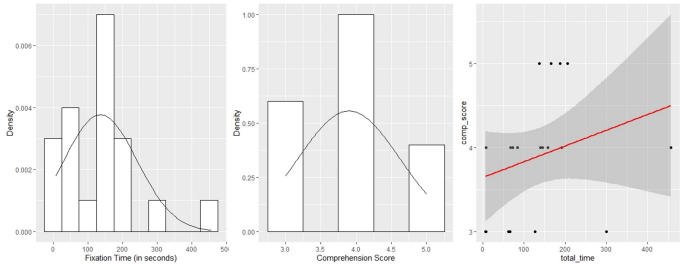
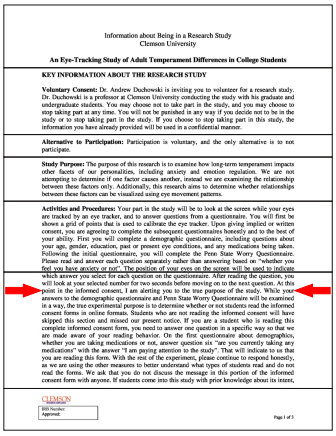


Figure 6: Assumptions of normality and correlation scatterplot for fixation time and comprehension scores.

no instruction) having an effect on finding the hidden message. However, this effect was not significant in our results. We believe this may partly be due to limitations in the experimental design, as an unexpectedly high amount of people correctly found the hidden message within our IRB document (11/20) - something that we would not have predicted based on previous studies that indicate how incompletely IRB forms are usually read [11, 15, 17].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Page 1 of 3

Figure 7: Start of the hidden message highlighted within the consent form (split into AOIs).

Our result that total fixation duration time is correlated with finding the hidden message is not surprising. We expected that those people that spent longer reading the IRB form would have a much higher chance of finding the hidden message. However, the fact that many of our participants found the hidden message suggests that our experiment influenced participants to spend more time reading the IRB than they normally would in a different experiment.

The visual behavior in the participants that found the hidden message and those that did not find the message was clearly different. Those that found the hidden message tended to have more focal fixations within the AOI that contained the hidden message on the first page of the consent form. This makes sense, as those participants that found the hidden message tended to re-read the instruction contained within the hidden message to make sure they understood what they were being told to do (answer a specific question on the demographics survey with a specific response). The location of the hidden message within the consent form is

presented in Figure 7, and a visual comparison of fixation locations between a participant that found the hidden message and one that did not is presented in Figure 8. Fixation data from the same two participants is presented in Figure 9, and although the visual is harder to interpret because there are many individual fixations, it is still clear that the participant that found the hidden message had more fixations and that many of those fixations were inside the AOI that contained the hidden message.

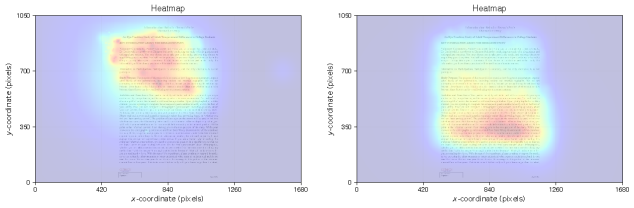

Figure 8: Comparison of a participant that was unable to find the hidden message (left) and one that was able to (right).

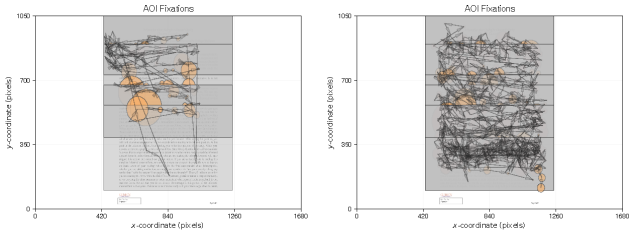

Figure 9: Fixations and corresponding AOIs for the same participants as in Figure 8.

7 LIMITATIONS

The main limitation of this experiment was using a digital version of our consent form. We were forced to present the consent form in this way because the eye tracker we used required the participant to be looking at a computer screen, which is very different than a typical paper copy of an IRB form. Since we also chose to use the Gazepoint Analysis software for capturing our data, this also meant we were limited in our ability to customize the experiment. This led to two major potential issues:

(1) Suspicion of true purpose of study
(2) Influenced reading behavior

As participants entered the room and began the experiment, we had no choice but to calibrate the eye tracker before they were presented with the consent form, otherwise we would not have been able to gather accurate data. To the intelligent participant, this may have seemed bizarre - why would we need to set up the eye tracker before we present them with the IRB consent form? We attempted to minimize this concern by designing the experimenter script to not draw attention to this fact.

Our use of the Gazepoint software also meant that participants could not backtrack to view a previous page of the consent form. This was communicated to the participants during their instructions and may have influenced their reading behavior. If a user is aware they cannot backtrack to a previous page to re-read something they did not understand on the first read through, they may be more likely to read it more intently. A screenshot of the Gazepoint software and the relevant written instructions about the inability to go backwards is presented in Figure 10.

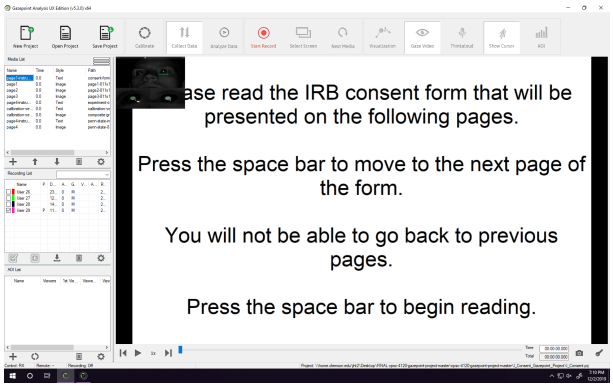

Figure 10: Gazepoint Analysis software.

We also identified potential issues with two of our participants - and with a relatively small sample size of 20 students these problems may have affected our results. One of our participants had previously designed and ran their own study at Clemson University, which meant they were familiar with the IRB process and the importance of informed consent. Because of this, we anticipated that the participant would read through the consent form carefully. However, that was not true: the participant disregarded the consent form entirely by clicking through it without reading. This could be because of their previous experience with IRB forms and the assumption that they all generally contain the same kinds of information. We also had one participant who was a Japanese exchange student studying English, and who required significant assistance and translations throughout the process. Because of this, their reading behavior during the experiment was likely significantly different than a native English speaker.

8 CONCLUSION

In this experiment, we asked participants to read an informed consent document and make a decision about whether or not to participate in an academic research study based on their understanding of the purpose, risks, and activities involved. With IRB approval, we disguised the true nature of our study, which was to collect eye-movement behavior data from our participants while they read the informed consent document. This deception was necessary to ensure that our participants would read the document as they would under normal circumstances. We collected data on reading accuracy and comprehension, user fixations per area of interest, and ambient versus focal fixations. Although the results of our study did not support our initial hypothesis that explicit instructions from an experimenter would lead to more careful reading behavior, we were able to demonstrate that more careful reading behavior has

a strong positive relationship with reading accuracy and overall comprehension. Given the special nature of the informed consent process, particularly as it relates to student participant populations, we believe that future studies into this topic are warranted. As discussed in previous sections, a future study with a larger sample size may more clearly demonstrate diferences in student engagement with the informed consent process, and provide the information necessary to change current practices and policies in academic research programs.

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