

"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.

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 PROPOSED RESEARCH METHODS

3.1 Participants

This research study will include 20 Clemson University undergraduate and graduate students. Participation in the study is voluntary, and no compensation will be given.

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3.2 Experimental Design

A one-way, between-subjects multivariate analysis of variance (MANOVA) will be used 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 will verbally instruct the participant to carefully read the informed consent document and will notify the participant of a short comprehension quiz at the end of the experiment. In the ‘no instructions’ condition, the experimenter will verbally instruct the participant to carefully read the informed consent document, but will not notify the participant about the quiz.

Reading accuracy. A hidden message related to the true purpose of the study has been included within the body of the consent form text, and instructions are provided as to how a participant can signal to the experimenter that they have found the hidden message. Reading behavior will be coded as a binary variable (found/not found). This measurement is 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 cannot 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 will use a first-pass fixation time as our *initial processing time* measurement. This measurement will be calculated for each area of interest (AOI) on the consent form image, and compared between the instructions and no-instructions conditions.

We will also calculate 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 will be 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 will measure the number of regressions that are outside the normal range (more than 10 letter spaces long or to another line) for each participant. This measurement will be 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 will be measured using Coefficient K, where positive values indicate focal viewing and negative values indicate ambient viewing [9]. This measurement will be 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.

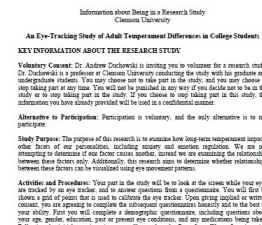


Figure 1: Example consent form stimulus

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

3.4 Apparatus

Participant eye movement and fixation data will be 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 will be used on a 22 inch Dell P2213 monitor screen, running at a resolution of 1680x1050 pixels. The viewing distance for all participants will be approximately 57cm.

3.5 Procedures and Stimulus

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

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

If the participant agrees to continue the study, the participant will then be asked to look at images of the Penn State Worry Questionnaire. This part of the experiment is designed to resemble a typical psychology or eye tracking experiment, and its only purpose is to continue to conceal the true purpose of the study. The participant will be instructed to read each question and look at their chosen response for 2 seconds before moving to the next question.

When the questionnaire has been completed, the participant will press the spacebar to exit. This signals to the experimenter that the participant has completed the questionnaire. The experimenter will terminate the eye tracking software recording, and this portion of the study ends.

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

To be determined.

ACKNOWLEDGMENTS

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