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To read or not to read: the usefulness of informed consent

Natasha E. Webb
University of Tennessee at Chattanooga

Elizabeth D. Taylor
University of Tennessee at Chattanooga

To Read or Not To Read: The Usefulness of Informed Consent

Natasha E. Webb and
Elizabeth D. Taylor
University of Tennessee
at Chattanooga

Informed consent is an important ethical factor for medicine, psychology, and other needed disciplines. It is necessary for participants to understand an intended research project or procedure in which they plan to take part. This study examined the usefulness of informed consent by administering such a form prior to an irrelevant questionnaire. A simple task was inserted into the reading, which allowed assessment of whether participants actually read the form. Results obtained through the experiment supported the hypothesis that the majority of the participants would not read the consent form. While less than half of each sex actually read the form, more women tended to read it than their male counterparts. Theoretical implications for these findings are discussed.

Research has been a major focus of universities and institutions throughout history. However, the practice of informing and protecting participants in such research is a relatively new development. Informed consent is the notion that "a subject makes his or her own decision to participate in the research project, free from overt pressures, based upon sufficient information to make an intelligent, 'informed' decision" (Stuart 1978). In short, informed consent lets a participant know everything about a particular research so that he or she can decide whether or not to take part in or to continue in an experiment. Incidences such as the Nuremberg Trials after World War II, the Public Health Services' Tuskegee syphilis study in the 1930s—lifesaving treatment was withheld from the participants (poor, Black males)—the Jewish Chronic Disease Hospital study—patients were unknowingly injected with live cancer cells—and Stanley Milligram's study of obedience—participants were led to believe that they were giving dangerous and even lethal electrical shocks to others—have made the concept of informing and protecting participants in research studies essential (Brody, et. al. 1997). From the errors made in the past, researchers in all sciences must ensure that participants have autonomy and choice in the study and that no harm comes to the individuals. The Nuremberg Code (1946) implemented guidelines for voluntary consent that later researchers found to be too complex and so altered them to fit their needs. Today, researchers are required to administer informed consent forms to participants before they complete an experiment. However, some researchers argue that for natural observations, no consent is needed.

Previous experiments have shown that simply signing a consent form or having the experimental procedure explained to a potential participant does not mean that the participant understands the experiment, and so new researchers are looking for new ways to improve consent comprehension. However, even when tremendous steps are taken to help improve this, participants can still fail at consent comprehension, or even at reading the form at all. Stuart (1978) showed that even with a three-part consent form—the first explains the experiment, the second asks questions about the experiment to judge comprehension, and the third asks participants to describe the experiment in their own words—many participants fail to comprehend what was written. Furthermore, it was found from this study that the more participants knew about the experiment from the three parts, the less willing they were to take part.

The lack of consent form comprehension is present not only in institutional projects but with medical procedures as well. Physicians and all healthcare providers are under legal obligations to inform their patients on their medical procedures and to give them the choice to participate. Lack of consent comprehension arises here because patients feel that they are obligated to listen to whatever their doctor has to say, and, therefore, must go along with whatever course of treatment he or she prescribes (Widdershoven and Verheggen 1999). Even with attempts to combat this comprehension failure with two readability formulas, which were developed to make consent forms easy to understand (Grundner 1978), the problem still remains.

While so much attentions has been paid to examining consent form comprehension, little attention has been paid to whether research participants actually read the forms at all. Once this obstacle is examined, then word complexity and comprehension can enter the scenario. The goal of this experiment was to see whether, given a simple paragraph consent form, participants read to form to completion and if these results would support the hypothesis that the majority of the participants would not read the form.

METHOD

Participants

Four separate classes—three psychology and one sociology—were used for obtaining participants. Seventy-five students—consisting of 69 undergraduate and 6 graduate students—from the University of Tennessee at Chattanooga participated in this study. Fifty-four of the participants were female and twenty-one were male. The undergraduate majors of the participants varied and while most were psychology majors, several were criminal justice, sociology, and communication majors, and a few were anthropology, biology, theater, and political science majors. The age range was 19-48 with a median age of 24. Participants volunteered for this study with no guarantee of receiving extra credit.

Procedure

Students in 300-400 level classes were asked to participate in a quick psychology study involving a small, five-question survey on study habits and research papers. Participants were first handed their consent forms about the supposed questionnaire project—which was in fact the real experiment—and asked to complete them. Also, participants were informed that their participation was strictly voluntary and could be terminated at any time. The consent form completion involved printing his or her name at the start of the form and signing and dating it once finished reading.

To see whether the form was actually read, a sentence in the second-to-last line of the paragraph asked the student to once again print his or her name under the signature line. This rather discrete method was used to protect against other students glancing at a neighbor and seeing something out of place on the form, and thus, going back and reading the form. This key sentence was specifically placed so that students would have to read the entire paragraph to notice it and not just the first and/or last line of the form.

The consent form was collected individually from each student when he or she signed the form, and then the questionnaire was given. The faulty questionnaire on study and research habits was used so that participants would not become suspicious of the consent form if it was collected and nothing else was given in return. Also, since most psychology experiments performed at this university collect the consent forms immediately, it would also evoke suspicion to have participants turn the forms face down and collected as a whole—as some students could turn the form over and read it was collected.

Once both the consent forms and the questionnaires had been collected, the participants were debriefed—by verbal communication and written statement—as to the real purpose of the experiment.

RESULTS

Out of the seventy-five students that participated in this experiment, twenty-two read the consent forms to completion—printed his or her name under the signature line. The 29.3% result supports the hypothesis that the majority of participants would not read the informed consent forms. Females read the form more than males—33.3% versus 19.0%. Also, when comparing percentages of psychology to non-psychology majors, more non-psychology majors read the form. Table 1 shows the results of the study.

TABLE 1

Consent form Reading Between Psychology and Non-Psychology Students

MAJOR	TOTAL	READ FORM	PERCENT READ	MALES READ	FEMALES READ
Psychology	51	13	25.5	2	11
Non-psychology	24	9	37.5	2	7

Note: Total number of males: 21, total number of females: 54. Also, six psychology graduate students are figured into the first category.

DISCUSSION

The hypothesis was supported by the data collected and gave further support to previous studies and their the notion that simply signing a consent form does not mean that the person comprehends the purpose of the experiment or what was read in the consent form.

Even though there were about half as many non-psychology participants, this group had a higher reading percentage than their psychology counterparts. It could be presumed that because they participate in a greater number of studies throughout each semester, they may have come to expect a certain amount of deceit in an experiment and, thus, ignore the consent form. Because of the small sample size, no generalizations can be made about each non-psychology major, and the same applies for the six psychology graduate students.

It is also interesting to note that none of the psychology graduate students read the consent form, which could further support the idea that psychology majors have become "immune" to the consent forms and expect some degree of misleading information. Females also read the consent form more than males, which could imply that females are more attentive to details and to what they read, a notion that has been circling amongst women throughout history.

As with most studies, the results obtained here cannot be taken as absolute proof that people, for the most part, disregard consent forms, but they do lead to speculation. A larger and more diverse sample may be needed to either confirm or disprove these results. Also, in this experiment, the line, which told participants to print their name under the signature line, was placed intentionally in the second-to-last line to avoid obtaining skewed results from students who only read the first line or two and the last line before they signed their name. Perhaps a further study needs to be performed in which such a statement is moved to the first or second line of the form and/or the last line to see whether the placing of vital information alters results. Furthermore, the consent form used in this experiment consisted of a single paragraph, about half a page in length. Future research may need to vary the length of the formto see if results differ from the ones obtained here.

Informed consent is a major issue concerning ethics in all experiments and procedures.

While there has been much attention on informed consent validity when dealing with medical emergencies, children, and the mentally disabled, no attention has been given to the mundane situations people face on a daily basis—signing a contract for a car or house or reading disclaimers for purchases on the internet or on a

job application. This studied attempted to shed light into this area and provided rather ominous results on how little attention people pay to what they sign, no matter how insignificant. Attempts to improve consent among patients and doctors by using interactive computer software—interactive shared decisionmaking programs (SDPs)—and giving the patient more information and options about a particular treatment (Widdershoven and Verheggen 1999) are showing promise, but with informed consent, progress has been minimal.

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APPENDIX

INFORMED CONSENT

I,_____,
voluntarily give my consent to participate in this psychology project from the University of Tennessee at Chattanooga. I have been informed about, and feel that I understand, the basic nature of the project.
I understand that I may leave at any time and that my presence here today as a participant of this project is strictly voluntary and that my responses are truthful. I also understand that all personal information obtained during this experiment—name, year in school, and any other information that may be needed to fulfill the project requirements, will be kept confidential and only used for overall findings and for statistical purposes. Upon recognizing such provisions, if you are actually reading this form, please print your name again under your signature. Your participation is this project is greatly appreciated and will enable the researchers to obtain the most accurate data possible.

_____

Signature of Research Participant & Date