Promoting Understanding of Informed Consent

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PROMOTING UNDERSTANDING OF INFORMED CONSENT

by

Michael N. Reynolds

A Thesis
Submitted to the
Faculty of The Graduate College
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requirements for the
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Advisor: R. Wayne Fuqua, Ph.D.

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Date 02.02.2012

WE HEREBY APPROVE THE THESIS SUBMITTED BY

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ENTITLED Promoting Understanding of Informed Consent

AS PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE

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Date June 2012
Several studies have shown that research participants who have consented to participate in a study often have limited comprehension of the information presented in the informed consent process. This study compared performance on an end-of-study consent document information retention measure between a read-and-sign consent procedure control group and an enhanced consent procedure experimental group. The enhanced consent procedure consisted of a pre-consent educational module and a question-and-answer style consent document. The control group scored an average of 78.7% correct on the multiple-choice question measure of participant retention of information contained within the consent documents. The experimental group scored an average of 92.3% on that measure, a statistically significant difference. These findings suggest that participants who experienced the enhanced consent procedure retain more information from the consent documents than those who experienced the typical consent procedure. A more highly informed participant pool may fulfill some of aspirational and ethical goals of our field but the side effects of reaching that goal are unknown.
ACKNOWLEDGMENTS

To Kellie.

Michael N. Reynolds
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INTRODUCTION

Informed consent is a foundational component of Federal and ethical guidelines on the protection of human research participants (Belmont Report, 1979). Informed consent has been conceptualized as having three primary considerations (Alkhatib, 2008; Barnett, Wise, Johnson-Greene & Bucky, 2007; Lidz, 2006). Potential participants must be provided with adequate information about the research protocol in a format that promotes understanding. Potential participants must be capable of understanding the information. Finally, they must be making the decision to participate in a coercion-free environment, as advocated by Ethical Principles of Psychologists and Code of Conduct (American Psychological Association [APA], 2002) and required by Federal Law (Protection of Human Subjects, 45 C.F.R. § 46.116, 2009). Empirically evaluating and improving the informed consent process is fundamental to achieving the human subject protections advocated in professional codes of conduct, and in Federal and institutional human subjects regulations. (Agre et al., 2003).

Assessing the Level of Understanding of the Consent Process

HSIRB guidelines typically require the execution of an informed consent process prior to the enrollment of a participant in a study. Although the exact elements may vary across research projects, an informed consent often includes a written or verbal explanation of 1) the purpose of the study, 2) the expectations for participants 3) the risks, benefits and protections for study participants; 4) the obligations of the researchers to the
participants and 5) the rights of the participants. While the goal of the informed consent process is to ensure that all potential participants to make a decision that is truly informed, there is reason to be concerned about the extent to which participants truly comprehend the crucial details that are included in a typical informed consent process.

For example, Agre and Rapkin (2003) found that participants scored an average of 68.3% correct on a test of the content of a typical informed consent document (Agre & Rapkin, 2003). Participants in a hypertension clinical trial scored an average of 71.6% correct on a multiple-choice knowledge test two hours post consent and 61.2% three months post consent (Bergler, Pennington, Metcalfe, & Freis, 1980). Chanaud, Merlani, Luyasu, and Ricou (2006) found that only 32% of ICU patients who had participated in a clinical trial were able to recall the purpose of the clinical trial or the associated risks (Chanaud, Merlani, Luyasu, & Ricou, 2006). A number of other researchers have documented that research participants demonstrate relatively poor comprehension of the details and risks of a study, in spite of completing and signing off on an informed consent process (Everett, Novoseletsky, Cole, Frank, Remillard, & Patal, 2005; Falagas, Korbila, Giannopoulo, Kondilis, & Peppas, 2009; Joffe, Cook, Cleary, Clark, & Weeks, 2001; Rounsaville, Kunkele, Easton, Nich, & Carroll, 2008; Wirshing, Wirshing, Marder, Liberman, & Mintz, 1998). The degree of understanding of consent documents shown by participants of clinical trials may not be satisfactory, although there are few evidence-based benchmarks for determining what a “satisfactory” level of understanding might be (Falagas et. al., 2009). Given the ethical and legal requirements for informed consent, these findings suggest that more effort should be focused on improving participant
understanding of informed consent materials.

Interventions Suggested by the Literature

It has been suggested that assessment of potential participant's understanding of a study should be a standard part of the informed consent procedure (Agre et al., 2002) because it improves participant understanding of research protocols. Surveys about the information contained in the informed consent documents have been used to assess immediate retention of those materials (Agre & Rapkin, 2003). Repeated assessment with corrective feedback has been shown to significantly increase scores on consent document knowledge surveys (Sudoe, Landefeld, Williams, Barnes, Lindquist & Schillinger, 2006). Informing participants of a scheduled post-consent comprehension assessment also produces higher levels of comprehension than a consent process that excluded the a priori announcement of a comprehension assessment, even when the time allocated to study of the informed consent was doubled (Matlin, 2009).

Education about the purposes for the informed consent process prior to exposure to the informed consent document may also improve participant understanding of a research protocol. Schizophrenia patients who received pre-consent education about the goals of the informed consent process showed larger increases in comprehension of consent details than those patients who received the same informed consent process but without pre-consent education. (Wirshing, Sergi & Mintz, 2005). These results are sufficiently robust that some Phase I Clinical Trials have implemented a pre-consent educational module regarding the purpose of informed consent procedures (Kim, Young, Neimeyer, Baker & Barfield, 2008).
Several categories of information regarding a research protocol are typically identified as important areas for inclusion in consent documents. This includes: voluntary participation, purpose of the study, reasons for the study, risk and benefits, treatment alternatives, rights to withdraw, confidentiality of data, and who to contact with questions or problems (Angeles-Llerenas, Wirtz & Lara-Alvarez, 2009; Lansimies-Antikainen, Piertila, Laitinen, Schwab, Rauramaa & Lansimies, 2007; Porteri & Borry, 2007; Simonoff, 2003). The Informed Consent Educational Tool (ICET) covering the purposes of informed consent and organization of the consent document used in this study is based on these findings. These categories were also used to develop the Informed Consent Comprehension Test (ICCT). These instruments are described in detail in the methods section.

How to Study Participant Understanding of Consent Materials

Typically, efforts to study the informed consent process are affixed to an adjunct research protocol on an unrelated topic. In this manner the informed consent process on the separate topic can be the focus of the research efforts to assess or improve the comprehension of the informed consent process. There are two main concerns about research on informed consent processes, the availability of adjunct studies and the use of vulnerable participants. Recruitment of clinical populations for clinical trials is difficult (Agre, Rapkin, Dougherty & Wilson, 2002). It has been assumed that examination of consent procedures would harm recruitment rates for adjunct studies, an important consideration for research protocols with stringent inclusion and exclusion criteria or those studies which focus on low-base rate disorders. A review of informed consent
studies in the literature did not reveal any change in recruitment rates in adjunct studies (Agre et al., 2003). However, in order to alleviate some of the recruitment difficulties that clinical trials have with low numbers of participants, some attached informed consent studies make use of surrogate participants (Agre & Rapkin, 2003). Surrogate participants are those who would not be eligible for the adjunct studies and, as a nonclinical population, are easier to find and recruit. Surrogate participants have been found to perform less well on assessments of understanding of informed consent materials than clinical populations involved in adjunct studies, or those patients’ families (Agre & Rapkin, 2003). As a non-clinical, easy to find population, with minimal inclusion or exclusion criteria, surrogate participants share many of the qualities that make undergraduate students and Internet recruits attractive as sample populations for research. Despite much of the literature for informed consent being conducted with randomized clinical trial participants, college- and internet-recruited samples share many of the same properties as surrogate participants.

The Adjunct Study: Application of Critical Thinking Guidelines to the Evaluation of Health Claims

Consumers are beset with marketing for products, services, and other claims, for which scientific support is often lacking or contradictory. Many have suggested that consumers need to be armed with “critical thinking skills” to help them evaluate the evidentiary base for such claims and to help them select products and services that are most likely to deliver the advertised benefits and least likely to produce dangerous or unwanted side effects. For example, when a person is diagnosed with hypertension they are faced with a plethora of treatment options. Some of these options have overwhelming
empirical support for their effectiveness, such as diuretics, beta-blockers, or lifestyle changes, while others lack such support, as with toxin cleansing treatments or joint-health bracelets. Persons who choose the latter options are failing to discriminate between treatments with sufficient evidentiary support and those treatments which either lack sufficient evidentiary support or contain misleading and contradictory evidentiary support.

Deficits in the critical thinking skill set are not uncommon. Eisenberg (1993, 1998) surveyed Americans in order to assess alternative medical treatment use, defined as treatments not included in medical school curricula or generally offered in hospitals. They found that 42% of their 1997 sample used at least one type of alternative therapy in the previous year, an increase over the 33.8% of those in a 1990 sample who used alternative therapies. MacLennan found similar numbers of alternative therapy consumers (52%) in a 2006 survey of Australians. The rates of usage are dramatically higher amongst vulnerable populations. Patterson (2002) found that 70% of participants in a sample of American cancer patients had used at least one type of alternative therapy in the past year. Rates of usage were highest for women, younger individuals, those with more years of education, and those participants of higher socioeconomic status (Patterson, 2002). The annual expenditure on alternative medical treatments in the United States is over 34 billion dollars (Herman, 2005). This is a substantial monetary investment in treatments that have little or no empirical support (Barnes et al., 2002).

Several people have offered guidelines to help consumers evaluate the believability of claims based on standards of evidence. For example, in his book The
Demon Haunted World, Sagen described the Baloney Detection Kit (Sagen, 1996, p. 210), a set of guidelines for discriminating between evidentiary claims and faulty claims. In a similar manner, Shermer describes 25 fallacies that lead to faulty decision making (Shermer, 1997, p. 44) and supplies a series of questions to guide the evaluation of various claims such as: have the claims been verified by another source; how does the claim fit in with how we know the world works. While these guidelines are helpful in evaluating the scientific credibility of various claims, they have not been subject to experimental evaluation with regard to their impact on the “believability” of various claims and a person’s willingness to take action based on the claims (e.g., to purchase or use a product based on such claims).

The goal of the adjunct study was to evaluate the effects of a critical thinking checklist on the believability of unsupported medical treatments. The adjunct study, while interesting in and of itself, provides a vehicle to the primary study, an analysis of participant comprehension of the informed consent protocol for the adjunct study. The results of the adjunct study will be reported elsewhere.

METHODS

Participant Recruitment

In order to be eligible for this study, the potential participants had to be over the age of 18. Minors were excluded because their participation would require the consent of a guardian as well as the minor’s assent thus diverting focus from the consent process that is typically used with competent adults. There were no exclusionary criteria for potential
participants; there was an implicit requirement that participants have access to the Internet for the purpose of completing online surveys.

Participants were recruited using four methods, the first three of which were implemented on the Western Michigan University campus. The first method involved posters (Appendix L) displayed in academic buildings on campus. The second method involved presentations using PowerPoint slides in undergraduate classes (see Appendix K for the presentation script). The third method used Sona Systems, a commercial participant recruitment software package, to contact participants who registered on the Western Michigan University Sona Systems database (see Appendix M for the Sona Systems application form). The first three methods were intended to recruit students attending Western Michigan University (WMU). The fourth method was Facebook advertisement (see Appendix N for a screen shot of the Facebook advertisement).

Participant Descriptions

While 74 individuals consented to participate in this study, there were 37 women, 19 men and one transgendered individual who completed the study. A total of 17 individuals dropped at various stages of the study, eight participants from the experimental group, two participants from the control group and 7 individuals who withdrew before being sorted. One woman was recruited via Facebook, while the rest were recruited from WMU. Participants who were university students reported an average GPA of 3.21. Participants were between 18 and 51 years old with a mean age of 21.86 years.
Instrumentation

The Research Protocol Map (Appendix A) is included as a visual counterpart to the prose explanations of this study's design. It shows the path that participants take through the study, diverging down different paths for control and experimental groups.

The Informed Consent Educational Tool (ICET; Appendix B) is a brief set of informational slides that contain information on the purposes and conceptual foundations of the informed consent process for human participant research. The information contained on these slides is similar in nature to the information contained within the question-format consent template provided by the WMU Human Subjects Institutional Review Board. Participants were shown the slides in sequence on the survey, being required to click a button labeled 'Read this slide” to advance to the next slide.

Participants were shown a total of 12 slides, three of which are represented below.

<table>
<thead>
<tr>
<th>Slide 1</th>
<th>Slide 4</th>
<th>Slide 7</th>
</tr>
</thead>
<tbody>
<tr>
<td>▲ Foundations in Informed Consent</td>
<td>▲ Non-Coercive Environment</td>
<td>▲ Procedures</td>
</tr>
<tr>
<td>▲ Informed Consent has three requirements</td>
<td>▲ Participation in a research study must be completely voluntary</td>
<td>▲ Should contain information about</td>
</tr>
<tr>
<td>○ Information Disclosure</td>
<td>○ An individual must not be coerced into participation by removal of privileges or with excessive rewards</td>
<td>○ What participants will be asked to do</td>
</tr>
<tr>
<td>○ Capacity to Consent</td>
<td></td>
<td>○ Descriptions of those activities</td>
</tr>
<tr>
<td>○ Non-Coercive Environment</td>
<td></td>
<td>○ The Time Requirement of the Study</td>
</tr>
</tbody>
</table>
Following completion of the ICET, participants in the experimental group began the first section of the consent form. In order to address the risk of having participants exposed to research manipulations before consenting, each slide of the ICET had the following disclaimer about a participant's right to withdraw from the study, “You have the right to withdraw from this study at any time, you can accomplish this by closing your browser window. Your information will not be saved.”

The Informed Consent Comprehension Test (ICCT) is a pair of 15 multiple-choice question surveys. Form 1 of the ICCT (Appendix C) is used piecemeal during the modified consent procedure, its' questions positioned sequentially with sections from the consent form for this study. Only the Experimental Consent Group participants were exposed to Form 1 of the ICCT. Form 2 of the ICCT (Appendix D) was given to all participants following completion of the medical claim vignettes and believability index iterations. Form 2 of the ICCT contains questions about similar content as was covered in Form 1 but the questions are phrased differently and as a result, the correct answers differ from Form 1 to Form 2. Form 2 of the ICCT was administered at the end of the adjunct study and allows for about one hour between presentation of the consent document information and retention assessment.

The Demographic Survey includes questions concern gender, education level, GPA during last education, age, and WMU enrollment status (Appendix E). These data were used for describing the participant sample and as mediating variables.

Revised Paranormal Belief Scale (RPBS; Tobacyk, 2004; Appendix F.) is a 26-item measure of paranormal beliefs. The RPBS is designed to measure an individual’s
degree of belief on seven dimensions: Traditional Religious Beliefs, Psi, Witchcraft, Superstition, Spiritualism, Extraordinary Life Forms, and Precognition. Participants were asked to rate their belief in statements (e.g. The number '13' is unlucky, Some psychics can accurately predict the future.) on a seven point Likert-scale, ranging from “strongly disagree” to “strongly agree” with a central score meaning uncertain or neutral. The RPBS includes questions about an individual’s religious beliefs alongside questions about paranormal beliefs; this may have caused discomfort for some participants. In order to assuage some of this possible discomfort, the following phrase has been added to the top of the measure: “There are no right or wrong answers, this is a sample of your own beliefs and attitudes. This study does not presuppose that some beliefs are correct or incorrect, rather that individuals differ in what beliefs they have.”

A Personal Belief Scale (Appendix G) was developed for this study and included 15 original items designed to assess the participant's belief in different alternative and complementary medical treatments. Participants were shown statements (e.g. Dietary changes can affect a person's cholesterol levels, or Hypnotic suggestion is an effective way to bring about weight loss.) and were then asked to rate their belief in that statement on the same Likert scale described above.

The Medical Claims Vignettes (Appendix H) are a set of five hypothetical direct-to-consumer medical advertisements adapted from existing advertisements. The original advertisements were modified, to obscure the identity of the product or treatment. The intent was to present each vignette as a novel advertisement for which each participant was to judge based solely on the information contained within the claim, not on their long
history of exposure to information about alternative medical treatments such as hypnosis or massage therapy. An example a de-identified advertisement for herb-based toxin cleansing footpads appears as Vignette 4.

Vignette 4

The genius’ breakthrough is one in which he or she escapes the rigidities of the normal and tired patterns of thought — unconventionality is one great measure of brilliance. One such example of an all-natural product of unconventional (but no doubt effective) thought is the concept of Treatment 4 by Brand Zero.

Treatment 4 is a very effective treatment, which uses only natural herbs, allowing for the body’s complete response to Condition 4. Spoke S. Person, who is almost a century old, is the eager spokesperson of the product, and thus becomes the perfect testament for Treatment 4 claim to healthy living.

Each portion of Treatment 4 contains vegetable fiber, vitamin C, dextrin, loquat leaves, chitosan, tourmalines, houttuynia cordata, and bamboo and wood vinegars. Treatment 4 is manufactured in Asia where most of its natural ingredients are harvested. Treatment 4 is applied to the area affected by Condition 4 at least 8 hours every night, although sometimes longer applications might be necessary depending on an individual’s body chemistry. The aforementioned ingredients then all work together, to help the body alleviate the cause of Condition 4. Quite simply, Treatment 4 works.

The Believability Index is a 3-item survey designed to measure the degree to which the treatment described in each vignette seems like a “good choice.” The specific
questions are: I believe that Treatment X is effective in the treatment of Condition A. I would choose Treatment X if I had Condition A. If a friend or family member had Condition A, I would not recommend Treatment X. Participants are asked to rate how much they agree with the statement on a 7 point Likert-scale spanning completely disagree to completely agree, with a central ranking being uncertain. This measure is attached in Appendix I.

The Critical Information Checklist (CIC; Appendix J), is a 16-item checklist that was intended to assist participants in identifying pseudoscientific medical claims. There are four domains on this checklist, each containing four questions. The first domain is Authority, which includes questions on the source of evidence for claims made (e.g. Does the claim suggest their product or treatment is well known elsewhere but is actively hidden by stronger competitors here?). The second domain is Logic, which includes questions about the logical consistency of claims made, including; Does this claim suggest that findings that are currently unexplained or will be never be explainable?. The third domain is Non-Evidence, which includes questions about the legitimacy of evidence presented in support of claims made (e.g. Does this claim use personal anecdotes as a substitute for scientific research?). The fourth domain is Language Use. This domain includes questions such as; “Does the person or organization making this claim hide behind complex words or language to mask the lack of evidence behind their claim? For example, "When asked about the source of her powers, a local psychic explained that quantum mechanics provide the power behind her clairvoyant abilities.” Many items include examples of the error such as the psychic mechanics example. Participants were
asked to answer the 16 checklist items with Yes, No, or Not Relevant, for each of the five medical claims vignettes.

The consumer satisfaction survey (Appendix K) is a 4-item questionnaire that was intended to measure the participant's experience with the consent procedure they experienced at the beginning of the study. The questions are:

- How difficult do you think this consent procedure was?
- How informed about this study do you feel as a result of this informed consent process?
- How useful do you feel this informed consent procedure was?
- What is your overall impression of the informed consent process?

Participants answered each question using a 7-point Likert scale that ranged from the opposing extremes at one and seven, with the neutral response at four.

Participant Protections

There were several slight risks for participating in this study. The first was the purposefully vague explanation of the manipulations to the informed consent process for the experimental group. This was done to hide the measurement of participant's retention of material from the consent document. It was our concern that if participants were fully informed as to the nature of those measurements, they may have had paid special attention or used remembering tactics they might otherwise not have used when they were reading the consent document. Instead potential participants were informed that “A secondary purpose of this study is to explore the effects of a modified consent procedure.” and that part of the requirements of participation is “...be exposed to one of
two different consent procedures.” In this manner, participants were not explicitly told the details of the experimental manipulation. Participants were informed about this deception and the rationale for it, following completion of the study. The debriefing script is attached in Appendix L.

The second minor risk is based on some of the questions from the Personal Beliefs Scale, which posed questions about beliefs in magic and monsters adjacent to questions about belief in a God or a Devil. Participants may have felt anxiety or insulted if they felt we were putting commonly held religious beliefs in the same category as beliefs about supernatural phenomena. We attempted to address this risk by placing the following disclaimer at the top of the Personal Beliefs Survey: “There are no right or wrong answers, this is a sample of your own beliefs and attitudes. This study does not presuppose that some beliefs are correct or incorrect, rather that individuals differ in what beliefs they have.”

The third portion of this study that posed potential risks to participants is the use of the Informed Consent Educational Tool, which was presented before participants had formally consented to participate in the study. In order to address this issue without breaking the deception regarding the informed consent manipulation, each slide of the ICET had a disclaimer attached that informed potential participants of their right to withdraw from the study at any time. This disclaimer read “You have the right to withdraw from this study at any time, you can accomplish this by closing your browser window. Your information will not be saved.”
Experimental Procedures and Design

The participant flow chart in Appendix A provides a graphical representation of the experimental procedures and participant flow for this study. All potential participants from WMU were referred to the Sona Systems participant recruitment software. The Sona Systems advertisement provides some basic information about the study and funneled interested individuals to the study's web-based survey site. Potential participants recruited through Facebook were also directed to the same web-based.

Once potential participants reach the study's Survememonkey site, they were randomly assigned to two groups, the standard consent control group and the enhanced consent experimental group. The control group was exposed to the consent form for this study (Appendix M) asked to read the consent form, and then click consent to continue or clicking refuse/close the browser to refuse consent. The experimental group was first asked to read the 12 slides comprising the ICET, this requires that participants click continue after reading the each slide. Following the ICET the participant was shown the consent form with each section separated by ICCT questions such as:

What are we trying to find out in this study?
In our information intensive, media saturated world, we are bombarded every day with lots of health related information and claims. Some of these health claims are accurate but, unfortunately other claims are unproven or, in some cases, misleading. The primary purpose of this study is to assess the effect on believability of medical claims as result of exposure to an evidence checklist. A secondary purpose of this study is to explore the effects of a modified consent procedure.

2. Which of the following is a purpose of this study?

a. Test a new PTSD survey

b. Assess differences in Medical Claims
c. Test a Therapy Technique

d. Assess effects of Text Coloring

After reading each section, experimental group participants were asked to answer related questions from the ICCT. Once participants had read all seven sections of the consent form and answered the last set of ICCT questions each participant was given the opportunity to click consent to continue or refuse to consent. Participants were told that refusing to consent is accomplished by closing the browser window or by clicking the refuse button.

Critical Thinking Methods

Following the control and experimental consent procedures, all participants were asked to fill out a demographics survey, and the personal beliefs scale. The medical claims control group was asked to read five medical claims vignettes and then complete a believability index for each. The medical claims experimental group was asked to complete a CIC for each of the medical claim vignettes in addition to the believability indices. Following completion of the medical claim vignette iterations, all participants were asked to complete Form 2 of the ICCT, and a consumer satisfaction survey concerning the consent procedure they experienced. Following completion of all study measures participants were debriefed, and fully informed of the deception related to the consent procedure manipulations. Participants were encouraged to contact the research if they have any questions or concerns. After completion of the debriefing sequence participants' browsers were rerouted to the web address of the "kitty hugging a bear" gif file (Appendix N), the reward for completion of the study.
Location of Data Collection

This study took place on the Internet, specifically the Surveymonkey website (Surveymonkey.com, 2009). This website utilizes SSL encryption in order to ensure secure transmission of responses from participants and of data to researchers. Surveymonkey does not use the information gathered through use of their website and all materials used are considered confidential and are handled as such. Data collected were backed up daily on Surveymonkey servers, and all these data were stored in a password-protected, SSL encrypted, electronic format. This website is Section 508 (29 U.S.C. ' 794d) compliant, meaning that it is accessible to those with limited mobility and visual sensory deficits. Participants were free to complete the study from any computer, and were not restricted to certain labs, operating systems, or Internet browsers.

RESULTS

This study focused on the impact of strategies to enhance comprehension of informed consent protocols. Even though data on the believability of various medical claims were collected, they are not reported herein as that is not the focus of this experiment. The primary dependent variable in this study was percentage of correct responses regarding the content of the consent documents as measured by the ICCT administered approximately one hour after the presentation of the informed consent materials, as assessed by the ICCT. This was calculated as percentage correct, which was compared between the experimental group and the control group, as depicted in (Table 1.) The control group (n = 26) earned an average score of 78.71 percent correct on the ICCT,
with a standard deviation of 15.66 and a range of 26.67 to 100 percent correct. The experimental group (n = 31) earned an average score of 92.9 percent correct, with a standard deviation of 6.42 and a range of 80 to 100 percent correct. There was a difference of 14.19 percent correct between the group's mean scores on the ICCT and that difference was significant at the .001 level (F = 21.223, p < .001).

Participants were split into gender specific groups to allow for within experimental group comparisons. Only one individual self-identified as transgendered, they were not included in this analysis due to the lack of a comparison group. For those participants in the control group, women (n = 17) earned an average score of 80.39 percent correct on the ICCT. Men (n = 8) earned an average score of 74.16 percent correct on the ICCT. There was a difference of 6.23 percent correct between the two subgroup's scores on the ICCT, but this result was not significant at the .05 level (F = .543, p = .588).

For those participants in the experimental group, women (n = 20) earned an average score of 92.33 percent correct on the ICCT. Men (n = 11) earned an average score of 93.93 percent correct on the ICCT. There was a difference of 1.6 percent correct between the two subgroup's scores on the ICCT, but this result was not significant at the .05 level (F = .435, p = .515).

Participants were split into high and low GPA subgroups for within experimental group comparisons. The groups were split at 3.21, which was the average GPA for all participants. One participant did not provide GPA data and was not included in this analysis. For those participants of the experimental group, the high GPA subgroup (n =
20) earned an average score of 92 percent correct on the ICCT. The low GPA subgroup (n = 10) earned an average score of 94 percent correct. There was a difference of 2 percent correct between the two subgroup’s scores on the ICCT, but this result was not significant at the .05 level (F = .95, p = .39).

For those participants of the control group, the high GPA subgroup (n = 10) earned an average score of 83.33 percent correct on the ICCT. The low GPA group (n = 16) earned an average score of 75.83 percent correct. There was a difference of 7.5 percent correct between the two subgroup’s scores on the ICCT, but this result was not significant at the .05 level (F = 1.435, p = .243).

Participants were also split into subgroups based upon their scores on the paranormal beliefs portion of the personal beliefs scale. The groups were split at a score of 81.51, the mean score for this participant sample. For control group participants, the high belief subgroup (n = 17) earned an average score of 77.64 percent correct on the ICCT. The low belief subgroup (n = 9) earned an average score of 80.74 percent correct. There was a difference of 3.1 percent correct between the subgroup’s scores on the ICCT, but this was not significant at the .05 level (F = .222, p = .642).

For experimental group participants, the high belief subgroup (n = 11) earned an average score of 91.51 percent correct on the ICCT. The low belief subgroup (n = 20) earned an average score of 93.66 percent correct. There was a difference of 2.15 percent correct between the group’s scores on the ICCT, but this was not significant at the .05 level (F = .790, p = .381).

Finally, participants were split into subgroups based upon their scores on the
medical beliefs portion of the personal beliefs scale. There was only one participant who reported higher belief in unsupported medical claims than empirically supported medical claims. Participants were split into groups based on the discrepancy between their rankings of belief on the empirically supported subscale of the PBS and their rankings on the unsupported subscale. Groups were split at the mean discrepancy of 1.83 points. For control group participants, the high discrepancy group (n = 9) earned an average score of 82.96 percent correct on the ICCT. The low discrepancy group (n = 17) earned an average score of 76.47 percent correct. There was a difference of 6.49 percent correct between the group's scores on the ICCT, but this finding was not significant at the .05 level (F = 1.01, p = .325).

For experimental group participants, the high discrepancy group (n = 20) earned an average score of 93 percent correct on the ICCT. The low discrepancy group (n = 11) earned an average score of 92.72 percent correct. There was a difference of .28 percent correct between the group's scores on the ICCT, which was not significant at the .05 level (F = .012, p = .912).

The consumer satisfaction survey was used to measure participant's experiences with the experimental and standard consent procedures (Table 2). All of the control group participants reported that the standard consent procedure was easy, while all but 3.2% of the experimental group thought the modified consent procedure was easy. In the control group 61.6% of participants reporting feeling informed about almost all or all aspects of the research protocol as a result of the consent procedure, compared with 74.2% of the experimental group. For control group participants, 84.6% felt that the consent procedure
was at least somewhat useful, compared with 90.3% of the experimental group. When asked of their overall impression of the consent procedure they experienced, 69.2% of control group participants had a positive experience, compared with 74.2% of the control group.

**DISCUSSION AND FUTURE DIRECTIONS**

The significant difference in performance on the ICCT between control and experimental groups suggests that exposure to the modified consent procedure increases retention of related information. These findings also suggested that there was no significant performance differences between subgroups based on gender, GPA, paranormal beliefs, or medical beliefs. The lack of significant difference for confounding variable subgroups suggests that the primary factor driving performance differences between the control and experimental groups was the modified consent procedure.

The modified consent procedure was rated as slightly difficult by 3.2% of the experimental group. The experimental consent procedure was also rated by participants as more informing, more useful, and an overall more positive experience, when compared with control group ratings of the standard consent procedure. This suggests that the modified consent procedure is no more aversive to participants than standard consent procedures, and may even be preferable.

There are several questions prompted by the results of this study. The enhanced consent procedure involved a combination of two potentially active variables, a component analysis may reveal whether the pre-consent educational tool or the during-consent assessment was the primary driver of performance differences. It will also be
important to look for additional variables that may contribute to performance on the ICCT, such as past research experience or knowledge of research design. The mechanism for advancing through the comprehension test could also be open for exploration, such as requiring correct answers before participants can continue through the consent procedure.

While this enhanced consent procedure was successful at increasing participant comprehension of consent materials, there is no empirical benchmark against which to judge the value of this improvement. Additional research is needed to determine what level of consent understanding, under what circumstances, is best. The level of participant risk involved in a research protocol may be an important variable for determining satisfactory levels of participant understanding. Perhaps 90% understanding would be satisfactory understanding for high-risk research protocols, while 80% would be enough for low-risk protocols. There may also be differential levels of understanding required for different elements of the consent materials. Participant understanding of the risks and benefits of a research protocol could be held to a higher standard than understanding of the theoretical background of a protocol.

The enhanced consent procedure requires significantly more input from potential participants than does the standard consent procedure. The relatively high response cost of the enhanced consent procedure may have contributed to the higher rate of drop out in the experimental group (25%) compared to the control group (7%). Future researchers may want to focus on increasing the aesthetic and functional aspects of an enhanced consent procedure to minimize any variables aside from high response cost that may increase participant attrition.
This study used gender, self-reported GPA, a measure of paranormal beliefs, and a measure of medical beliefs as possible variables that could confound performance on the ICCT. The latter two variables were convenient to use, as the data were collected for the adjunct study. Future studies should focus on other more likely influential variables such as reading level, past experience as a research participant, or education about research methods.

The differential effects of participant understanding are not well understood. Participants with a high degree of understanding about the research protocol may respond differently than those with a low degree of understanding. Additional research is needed to document and explore the corollary effects of increasing participants’ understanding of research protocols.

There are several improvements that could be made to the enhanced consent procedure for future users. The response cost of coming up with a comprehension test based on consent materials is quite high for researchers, and the development of a comprehension questionnaire template could help. There is also a higher response cost in terms of delivering the modified consent procedure, when compared with the low cost of administering and collecting a signed form. In multi-language settings, translation of consent materials could prove an additional barrier to adoption of the enhanced consent procedure. A software delivery system for the modified consent procedure may be able to address the magnitude of the response cost problems and ease translation issues.

The results of this study suggest that the modified consent procedure produces increased retention of information contained within the procedure than standard consent
procedures, and that the modified procedure is comparable with the standard procedure in terms of participant satisfaction. Despite high researcher response cost and a slight increase in perceived difficulty of the consent procedure, this intervention can assist all researchers in being able to better fulfill their ethical and legal requirements for gathering informed consent. Future research and development may be able to alleviate the response cost issues and promote adoption of this modified consent procedure.
REFERENCES


Appendix A. Research Protocol Map

Control Group:
- Consent Form for Medical Claims Portion of Study (A)
- Demographics Survey (H)
- Personal Beliefs Scale (G)
- Believability Index (F)
- Critical Information Checklist (J)
- Medical Claim Vignettes (1)
- 5 Iterations

Experimental Group:
- Informed Consent Educational Tool (D)
- Consent Form for Medical Claims Portion of Study (A)
- Informed Consent Comprehension Test – Form A (C-A)
- Informative Consent Comprehension Test – Form B (C-B)
- Consumer Satisfaction Survey (E)
- Debriefing Script (P)

Legend:
- Title of Item
- Appendix
- Reference
Appendix B

Informed Consent Educational Tool
Informed Consent Educational Tool

Foundations of Informed Consent

- Informed Consent has three requirements.
- Information Disclosure
- Capacity to Consent
- Non-Coercive Environment

Providing potential participants with enough information to understand their role within a research study.

- What they are expected to do
- What they can expect as a result of participation
- Risks and Benefits of Participation
- Handling of their Confidential information
- Ensuring that this information is understood.

Capacity to Consent

- Potential Participants must be capable of understanding the information presented to them.
- Typically thought of as mental competency.
- Children, Individuals with Mental Deficiencies, and Individuals with Dementia are unable to consent, but instead give assent.
- Which requires the consent of a parent or guardian.

Non-coercive Environment

- Participation in a research study must be completely voluntary.
- An individual must not be coerced into participation by removal of privileges (prison populations) or with inordinate rewards (money to poor individuals).
- The decision to participate should not be influenced by fear of loss.

Sections of an Informed Consent Document

Introduction
- Should Contain Information about:
  - Why you are being invited to participate
  - Who is running the study
  - Any institutional affiliations
  - Why they are running the study

Background Information
- Should Contain Information about:
  - Rationale for running the study
  - Purposes of the study
  - How the data collected will be used
Procedures
- Should Contain Information about:
  - What participants will be asked to do
  - Descriptions of those activities
  - Time requirements

Risks and Benefits
- Should Contain Information about:
  - Amount of Risk posed to participants
  - How to deal with potential risks
  - Description of Withdrawing Rights
  - How to withdrawal from the study
  - Description of Direct Benefits to participation

Compensation
- Should Contain Information about:
  - Description of Direct Benefits
  - This may include financial rewards, organizational rewards, or academic rewards

Confidentiality
- Should Contain Information about:
  - How records of data collected will be treated
  - How identifying information will be stored
  - Who will have access to data collected

Voluntary Nature of Participation
- Should Contain Information about:
  - The Voluntary Nature of the Study
  - How withdrawing from the study will affect you
  - How to withdraw from the study

Contact Section
- Should Contain Information about:
  - How to contact the researchers
  - How to contact the supervisor in charge
  - How to contact the relevant supervisory board
Vignette E
There is nothing mysterious about Treatment 8. It's a natural method of health care that focuses on treating the causes of physical problems and injuries, rather than just the symptom. Treatment 8 is based on a simple but powerful premise: Your body has the ability to heal itself if the important organs are healthy. Your important organs are the main pathways of your important bodily system. Which in turn controls every feeling, movement, and function throughout your body.

When the important bodily system is impaired by injury, stress, or illness it can cause muscles, joints, and organs throughout the body to function poorly. This is why organ 8 is so important in maintaining pain free good health. Your organ 8 is a structure designed for support and protection of the important bodily system. It is much like the frame of your car. When the alignment is off, your car and its' engine do not run as efficiently. The important bodily system is like your car's engine, very much affected by the frame that houses it. Since your organ 8 can affect all parts of the body, problems in your organ 8 can cause other problems, as well.

Because Treatment 8 treats the underlying causes of these problems rather than just relieving symptoms, your body's natural healing process will work for you. The Treatment 8 approach is to locate and correct problems with organ 8 that may cause interferences to the important bodily system. These problems are corrected with adjustments to increase the function of organ 8. Treatment 8 can improve organ 8's strength, balance and mobility, while relieving pain and stiffness. After organ 8 has regained mobility, we teach you ways that you can increase the strength of organ 8 to prevent future damage from occurring.
Appendix I

Believability Index
Use the Following 7-Point Scale to answer the questions.

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Completely Disagree</td>
<td>Some Disagree</td>
<td>Some Agree</td>
<td>Completely Agree</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mostly Disagree</td>
<td>Uncertain</td>
<td>Mostly Agree</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1. I believe that Treatment X is effective in the treatment of Condition A.
   
   
   

2. I would choose Treatment X if I had Condition A.

  1   2   3   4   5   6   7

3. If a friend or family member had Condition A, I would **NOT** recommend Treatment X.

  1   2   3   4   5   6   7
Appendix J

Critical Information Checklist
After you read each medical claim vignettes please answer the following questions.

**Authority:**

Can you identify what person or organization is making the claim?

Yes No Irrelevant

Does the person or organization who is making the claim have anything to gain, such as selling a product or a political ideology?

Yes No Irrelevant

Does the person or organization making the claim focus only on supportive evidence, while ignoring or criticizing the source of contradictory evidence?

Yes No Irrelevant

Does this claim suggest their product or treatment is well known elsewhere but actively hidden by stronger competitors here? For example, The secret cancer treatments that Western Medicine doesn't want you to know about.

Yes No Irrelevant

**Logic**

Does this claim suggest that findings that are currently unexplained will never be explainable?

Yes No Irrelevant

Does the person or organization making the claim suggest that the lack of contradictory evidence is itself evidence that is contradictory? For example, There are no studies demonstrating that the sun is *not* powered by a giant hamster wheel, therefore the sun *is* powered by a giant hamster wheel.

Yes No Irrelevant

Does this claim place agreeing with them or disagreeing with them on two ends of a spectrum even though they are not strictly opposites? For example, When it comes to buying floral arrangements there are two kinds of people, those who love their significant others and people who are cheap.

Yes No Irrelevant

Does the person or organization making the claim suggest that a small step in any given direction, such as not purchasing their product or supporting a competitor, leads down a path of catastrophic consequences?

Yes No Irrelevant
Non-evidence:

Does the claim present two events that happened to occur in sequence as though the first caused the second?
Yes  No  Irrelevant

Does this claim use personal anecdotes as a substitute for scientific research?
Yes  No  Irrelevant

Does this claim use enough personal anecdotes that they can substitute for research?
Yes  No  Irrelevant

Does the person or organization making the claim present the limitations or contraindications for their product or treatment? For example, Antibiotics are great for treating a bacterial infection, but they are below useless for viral infections.
Yes  No  Irrelevant

Language Use:

Does the person or organization making this claim hide behind complex words or language to mask the lack of evidence behind their claim? For example, When asked about the source of her powers, a local psychic explained that quantum mechanics provide the power behind her clairvoyant abilities.
Yes  No  Irrelevant

Does this claim appeal to you emotionally when it should be appealing to your rational side? For example, Only a hateful parent would refuse their children cod liver oil.
Yes  No  Irrelevant

Does this claim attempt to bolster their claims by tearing down a poorly built version of their opponents evidence? For example, It is clear to us that pigs may be made to fly as our opponents have only used glue to attach the porcine wings. And never staples, the lynchpin of the Dominic's Flying Pig construction process.
Yes  No  Irrelevant

Does the person or individual making the claim present their opponents as negative caricatures or their arguments in a simplistic way? For example, Dr. Jergins only has a PhD in behavior analysis. Even if he could manage to see past his facial hair and operant chambers, he is not qualified to assess whether soap stone pendants can cure cancer.
Yes  No  Irrelevant
Appendix K

Consumer Satisfaction Survey
At the beginning of this study you went through an informed consent process.

1. How difficult do you think this consent procedure was?

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very Easy</td>
<td>Not Hard or Easy</td>
<td>Very Hard</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2. How informed about this study do you feel as a result of this informed consent process?

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Informed at All</td>
<td>Somewhat Informed</td>
<td>Informed about All Aspects</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3. How useful to you feel this informed consent procedure was?

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Useful</td>
<td>Somewhat Useful</td>
<td>Very Useful</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4. What is your overall impression of the informed consent process?

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very Negative</td>
<td>Neutral</td>
<td>Very Positive</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Do you have any additional comments or suggestions about the informed consent procedure?
Appendix L

Debriefing Script
Thank you very much for your participation in this study!

The second goal of this study was presented in a purposefully vague way. Research has documented deficiencies in the informed consent process of human subjects research protocols. This study aims to compare two variations of informed consent procedures in order to see which promotes better participant understanding. You have been exposed to one of two situations as part of this study. Half of participants will go through a standard consent procedure, where they were asked to read a consent form and click a check box to indicate their consent to participate in this research study. The second half of participants were shown a series of slides that contain information on the rationale for gathering informed consent from research participants. The second half were then asked to read sections of the consent document and then to answer multiple choice questions about what they had read. All participants were then asked to complete a short quiz about the information in the consent document.

I apologize for the deception. If participants had been informed on the intent to measure the amount of information they remembered from the consent form, they may have paid closer attention than if they had not been informed of this measurement. Much the same way a student will focus their studying on material a teacher says will be on a test.

The researcher would also like to reward you for your participation with the following popular internet reward (Appendix R. Internet Based Compensation)

If you have any additional questions or concerns about this study please Contact the researcher at: Michael.Reynolds@wmich.edu
Appendix M

Consent Form
Western Michigan University  
Department of Psychology

Principal Investigator: Wayne Fuqua, PhD.  
Student Investigator: Michael Reynolds, MA.  
Title of Study: Effects of a checklist on the believability of medical claims, and an analysis of consent procedures.

You have been invited to participate in a research project titled "Effects of a checklist on the believability of medical claims, and an analysis of consent procedures." This study is being conducted as part of the thesis requirement of the behavior analysis program at Western Michigan University. This consent document will explain the purpose of this research project and will go over all of the time commitments, the procedures used in the study, and the risks and benefits of participating in this research project. Please read this consent form carefully and completely and please contact the researcher at michael.reynolds@wmich.edu if you have any questions.

What are we trying to find out in this study?
In our information intensive, media saturated world, we are bombarded every day with lots of health related information and claims. Some of these health claims are accurate but, unfortunately other claims are unproven or, in some cases, misleading. The primary purpose of this study is to assess the effect on believability of medical claims as result of exposure to an evidence checklist. A secondary purpose of this study is to explore the effects of a modified consent procedure.

Who can participate in this study?
You are being invited to participate because you are either a student attending Western Michigan University or clicked on the study's advertisement on Facebook©. You must be over the age of 18 and have access to the internet to participate in this study.

Where will this study take place?
This study is conducted over the internet at surveymonkey.com.

What is the time commitment for participating in this study?
This study will take about 60 minutes of your time, in a single session. It is not possible to stop taking the survey halfway through and then come back to finish later.

What will you be asked to do if you choose to participate in this study?
If you agree to participate, we will ask you to: Read and respond to a series of nine medical claim vignettes, complete an anonymous demographics survey, complete a survey about your personal beliefs on a variety of topics, and be exposed to one of two different consent procedures.
What information is being measured during the study?
A variety of information is being collected in this study; Believability of medical claims, demographic information, a profile of your personal beliefs, and the effects of a modified consent procedure. All data collected will be used only for these purposes, and will not be shared with any other persons or organizations.

What are the risks of participating in this study and how will these risks be minimized?
There is slight risk to you for participation in this study. Some of the questions on the personal beliefs survey may produce anxiety. For example several of the questions will ask about beliefs of a spiritual or religious nature, while others ask about supernatural creatures. This survey asks about a wide variety of beliefs and is not intended to insult or judge any specific beliefs. You have the right to withdraw from the study at anytime. If you choose to withdraw, please close the browser window in which this form is displayed.

What are the benefits of participating in this study?
There is little to no direct benefit to you for participating in this study.

Are there any costs associated with participating in this study?
There is no cost to this study except for the time it takes to participate.

Is there any compensation for participating in this study?
There is minor compensation for completing this study, in the form of an animated gif. file of a cat hugging a teddy bear. This image is presented after one has completed this study, which may be around one hour after one has begun.

Who will have access to the information collected during this study?
The information collected from you is completely anonymous. There is no way to link the information collected with you. The information will be stored on surveymonkey.com's servers until the end of data collection (See www.surveymonkey.com for information on their security procedures). Following data collection, information will be stored on a password protected computer in the behavior medicine lab for seven years. If you choose to withdraw from the study, your data will not be included for analysis.

What if you want to stop participating in this study?
You can choose to stop participating in the study at anytime for any reason. You will not suffer any prejudice or penalty by your decision to stop your participation. You will experience NO consequences either academically or personally if you choose to withdraw from this study. To accomplish this, simply close the browser that contains the survey.
Who should I contact if I have Questions?
If you have any questions now, during, or after completion of the study, you are encouraged to contact the researcher at Western Michigan University, Wood Hall Suite 3700, 269.387.4500 (Psychology Department Office) or by email at Michael.Reynolds@wmich.edu. To contact Wayne Fuqua, the supervisor of this study, call 269.387.4474 or email him at wayne.fuqua@wmich.edu. You may also contact the Human Subjects Institutional Review Board at 269-387-8293 or the Vice President for Research at Western Michigan University, Dr. Dan Litynski, at 269-387-8298 if questions arise during the course of the study.
Appendix N

Study Compensation
A five second animated .gif file of a cat hugging a tiny stuffed teddy bear.

Source of Image: http://i.imgur.com/5CJbI.gif
Appendix O

Human Subjects Review Board Approval Notification
Date: April 12, 2011

To: Wayne Fuqua, Principal Investigator
   Michael Reynolds, Student Investigator for thesis

From: Amy Naugle, Ph.D., Chair

Re: HSIRB Project Number 11-04-08

This letter will serve as confirmation that your research project titled “Testing a Procedure to Promote Participant Understanding of Informed Consent Documents with a Linked Research Project on the Believability of Medical Claims” has been approved under the exempt category of review by the Human Subjects Institutional Review Board. The conditions and duration of this approval are specified in the Policies of Western Michigan University. You may now begin to implement the research as described in the application.

Please note that you may only conduct this research exactly in the form it was approved. You must seek specific board approval for any changes in this project. You must also seek reapproval if the project extends beyond the termination date noted below. In addition if there are any unanticipated adverse reactions or unanticipated events associated with the conduct of this research, you should immediately suspend the project and contact the Chair of the HSIRB for consultation.

The Board wishes you success in the pursuit of your research goals.

Approval Termination: April 12, 2012
Appendix P
Tables and Figures
Table 1. Group Performance on End-of-Study Informed Consent Comprehension Test

<table>
<thead>
<tr>
<th>Comparison</th>
<th>Group 1 Label</th>
<th>Group 2 Label</th>
<th>n</th>
<th>Mean</th>
<th>n</th>
<th>Mean</th>
<th>F</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control vs. Experimental</td>
<td>Control</td>
<td>Experimental</td>
<td>26</td>
<td>78.71</td>
<td>31</td>
<td>92.9</td>
<td>21.22</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Gender within Control</td>
<td>Women</td>
<td>Men</td>
<td>17</td>
<td>80.39</td>
<td>8</td>
<td>74.16</td>
<td>0.54</td>
<td>0.58</td>
</tr>
<tr>
<td>Gender within Experimental</td>
<td>20</td>
<td>92.33</td>
<td>11</td>
<td>93.93</td>
<td>0.44</td>
<td>0.515</td>
<td></td>
<td></td>
</tr>
<tr>
<td>GPA within Control</td>
<td>High GPA</td>
<td>Low GPA</td>
<td>10</td>
<td>83.33</td>
<td>16</td>
<td>75.83</td>
<td>1.44</td>
<td>0.243</td>
</tr>
<tr>
<td>GPA within Experimental</td>
<td>20</td>
<td>94</td>
<td>10</td>
<td>9.5</td>
<td>0.39</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Paranormal Beliefs within Control</td>
<td>17</td>
<td>97.64</td>
<td>9</td>
<td>80.74</td>
<td>0.222</td>
<td>0.642</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Paranormal Beliefs within</td>
<td>11</td>
<td>91.51</td>
<td>20</td>
<td>93.66</td>
<td>0.79</td>
<td>0.381</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical Beliefs within Control</td>
<td>9</td>
<td>82.96</td>
<td>17</td>
<td>76.47</td>
<td>1.01</td>
<td>0.325</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical Beliefs within Experimental</td>
<td>20</td>
<td>93</td>
<td>11</td>
<td>92.72</td>
<td>0.01</td>
<td>0.912</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 2. Participant Satisfaction with Consent Procedures

<table>
<thead>
<tr>
<th></th>
<th>Control Group</th>
<th>Experimental Group</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ease of Use</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Very easy</td>
<td>53.8</td>
<td>58.1</td>
</tr>
<tr>
<td></td>
<td>19.2</td>
<td>29</td>
</tr>
<tr>
<td></td>
<td>7.7</td>
<td>3.2</td>
</tr>
<tr>
<td>Not hard or easy</td>
<td>11.5</td>
<td>6.5</td>
</tr>
<tr>
<td></td>
<td>0</td>
<td>3.2</td>
</tr>
<tr>
<td></td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Very hard</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Informed as a Result</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not informed at all</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>11.5</td>
<td>9.7</td>
</tr>
<tr>
<td>Somewhat informed</td>
<td>19.2</td>
<td>6.5</td>
</tr>
<tr>
<td></td>
<td>7.7</td>
<td>9.7</td>
</tr>
<tr>
<td></td>
<td>30.8</td>
<td>19.4</td>
</tr>
<tr>
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<td>23</td>
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<tr>
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<tr>
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<td>34.6</td>
<td>35.5</td>
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Appendix C

Informed Consent Comprehension Test Form 1
1. What groups were invited to participate in the current study?
   a. College Students and Facebook users*
   b. Employed Adults and Facebook users
   c. Michigan State Workers and Employed Students
   d. Internet Users and Highschool Students

2. Which of the following is a purpose of this study?
   a. Test a new PTSD survey
   b. Assess differences in Medical Claims *
   c. Test a Therapy Technique
   d. Assess effects of Text Coloring

3. What will the data you provide be used for?
   a. Testing the Effectiveness of Internet Surveys
   b. To develop New Course Curriculum
   c. Solely for the Purposes of this Study *
   d. Track Personal Purchasing Habits

4. Which of the following will you be/were you asked to complete?
   a. A PTSD Survey
   b. A Personality Inventory
   c. A Sexual Health History Survey
   d. A questionnaire about Medical Claims *

5. What is the expected amount of risk to you should you choose to participate?
   a. Monetary Risk
b. Severe Risk

c. Slight Risk *

d. Minimal Risk

6. When are you allowed to withdraw from this study?

a. Only at the Beginning

b. At Any Time*

c. Only at the End

d. At specific times as Prompted

7. What compensation is there for you if you participate?

a. An Animated Gif *

b. Five Dollars

c. A Personality Profile

d. Coupons to a Local Pizzeria

8. Could someone use the data you provide to identify you?

a. Yes, but only if I choose to be identified

b. No, the data could not be used to identify me *

c. No, the data will not be stored

d. Yes, the data will be used to identify me

9. Who will have access to the data you provide?

a. No one as the data will not be stored

b. The Staff of Survey Monkey

c. Only the Researcher and their Principle Investigator *
d. All members of the WMU Psychology Faculty

10. Which relationships will be affected if you decide against participating or withdraw from this study?

a. My Relationship with my Professors, unless I explain why I withdrew.
b. My Relationship with Western Michigan University
c. My Relationship with the Researchers
d. No Relationships will be Affected by Withdrawing from this Study *

11. Who is running this study?

a. Lynn Stage
b. Clifford Galindo
c. Michael Reynolds *
d. Naomi Ellis

12. Who is supervising this study?

a. Lydia Tate MsW
b. Wayne Fuqua PhD*
c. Maria Hornbeck PhD
d. Marco Tovar Eds

13. Where would you go if you wanted to speak with the Researchers?

a. Wood Hall Suite 3700 *
b. Bernhard Center Room 2230
c. Geraldine Tower Suite 12
d. Haenicke Hall Room 1897
14. If you want to express some concern or ask a question of someone other than the researchers, who should you contact?

a. Harry Murphy, President of Researcher Relations
b. Dan Litynski, Vice-President of Research *
c. Rose Mohan, Head of Human Participant Concerns
d. Emma Steele, Assistant Chair of Scientific Conduct

15. With which University are the researchers affiliated?

a. Michigan State University
b. Western Oklahoma State University
c. Western Michigan University *
d. University of Minnesota
Appendix D

Informed Consent Comprehension Test Form 2
1. Are you participating in this study as part of a job requirement?
   a. No, Participation is entirely voluntary *
   b. Yes. Participation is required by my employer.
   c. No. This study is one of several options available to me.
   d. Yes. Participation is required to complete a training seminar.

2. Which of the following is a purpose of this study?
   a. Test a depression survey
   b. Assess differences in Consent Procedures *
   c. Test a New Therapy
   d. Assess effects of Video-Enhanced Presentations

3. What will the data you provide be used for?
   a. As part of a research requirement for an employee training program.
   b. To develop New Course Curriculum
   c. As part of the thesis requirement at Western Michigan University *
   d. Track Personal Internet Habits

4. Which of the following were you asked to complete?
   a. An Anxiety Survey
   b. A Drug History Inventory
   c. A Life History Survey
   d. A questionnaire about Personal Beliefs *

5. Why is there the possibility of a slight amount of risk for this experiment?
   a. Risk of side effects from computer exposure
b. There is no risk to participation in this study

c. Anxiety from A Personal Belief Survey*

d. Exposure to Medical Vignettes

6. How does one withdraw from this study?

a. Contact the Research Supervisor

b. Close the Browser Window*

c. Seek help from Institutional IT support

d. Use the withdraw from study form

7. What compensation is there to participation in this study?

a. An animated Gif*

b. 1 dollar per Survey

c. Treatment for Depression Symptoms

d. A gift card to a local home improvement store

8. Will the Data collected be used to Identify you?

a. Yes, but only if I choose to receive information about the results

b. No, the data could not be used to identify me*

c. No, the data will not be stored

d. Yes, the data will be used to send me coupons to a pizzeria

9. Will just anyone have access to your data?

a. No, the data will not be stored

b. No, Only Institutional IT Support Staff

c. No, just the Researchers conducting the study*


10. Would withdrawing from this study negatively your professional relationships?

a. Yes, My Relationship with my Professors will be negatively affected
b. No, My professional Relationship will be improved by withdrawing
c. Yes, My Relationship with the Researchers will be negatively affected
d. No Relationships will be Affected negatively by Withdrawing from this Study *

11. Who is running this study?

a. Richard Claypool, Graduate Student at WMU
b. Clifford Galindo, Employee Trainer at Comtech
c. Michael Reynolds, Graduate Student at WMU *
d. Jerry Allen, Manager at Allied Healthcare Management

12. Who is supervising this study?

a. Lydia Tate MsW, Trainer at Allied Healthcare Management
b. Wayne Fuqua PhD, Faculty Member at Western Michigan University*
c. Maria Hornbeck PhD, Manager at Comtech
d. Marco Tovar Eds, Faculty Member at Western Michigan University

13. Where can you contact the researchers with questions?

a. 269.387.4500, Psychology Department Office *
b. 269.387.5270, Sociology Department Office
c. 586.630.5009, Allied Healthcare Management
d. 313.915.3125, Comtech Industrial
14. If you want to express some concern or ask a question of someone other than the researchers, who should you contact?

a. Allied Healthcare Management, Research Hotline, 312.276.8579

b. Human Subjects Review Board, 269.387.8293 *

c. Institutional Animal Care and Use Committee, 269.387.5634

d. Comtech Industrial Research Advocacy Line, 267.435.5224

15. With which University are the researchers affiliated?

a. Purdue University

b. Western Oklahoma State University

c. Western Michigan University *

d. University of Michigan
Appendix E

Demographic Survey
Appendix F

Revised Paranormal Belief Scale
Please circle the number next to each item to indicate how much you agree or disagree with that item. Use the numbers as indicated below. There are no right or wrong answers! This is a sample of your own beliefs and attitudes. This study does not presuppose that beliefs are correct or incorrect, rather that individuals differ in what beliefs they have.

1. The soul continues to exist though the body may die.
   1 2 3 4 5 6 7
2. Some individuals are able to levitate (lift) objects through mental forces.
   1 2 3 4 5 6 7
   1 2 3 4 5 6 7
4. Black cats can bring bad luck.
   1 2 3 4 5 6 7
5. Your mind or soul can leave your body and travel (astral projection).
   1 2 3 4 5 6 7
6. The abominable snowman of Tibet exists.
   1 2 3 4 5 6 7
7. Astrology is a way to accurately predict the future.
   1 2 3 4 5 6 7
8. There is a devil.
   1 2 3 4 5 6 7
9. Psychokinesis, the movement of objects through psychic powers, does exist.
   1 2 3 4 5 6 7
10. Witches do exist.
    1 2 3 4 5 6 7
11. If you break a mirror, you will have bad luck.
    1 2 3 4 5 6 7
12. During altered states, such as sleep or trances, the spirit can leave the body.
    1 2 3 4 5 6 7
    1 2 3 4 5 6 7
14. The horoscope accurately tells a person’s future.
    1 2 3 4 5 6 7
15. There is a God.
    1 2 3 4 5 6 7
16. A person’s thoughts can influence the movement of a physical object.
17. Through the use of formulas and incantations, it is possible to cast spells on people.
18. The number “13” is unlucky.
19. Reincarnation does occur.
20. There is life on other planets.
21. Some psychics can accurately predict the future.
22. There is a heaven and a hell.
23. Mind reading is not possible.
24. There are actual cases of witchcraft.
25. It is possible to communicate with the dead.
26. Some people have an unexplained ability to predict the future.
Appendix G

Personal Belief Scale
27. Magnetic Bracelets are effective at providing relief from pain.
28. It is possible to improve one's quality of life by cleansing toxins from one's body.
29. A gluten free diet can alleviate cognitive impairment in children.
30. Childhood Vaccines can cause cognitive impairment.
31. Chiropractic Adjustment is able to prevent bone diseases.
32. Massage is effective at providing stress relief.
33. Acupuncture is an effective strategy for relaxation.
34. Antibiotics can reduce the time to recover from bacterial infections.
35. Therapeutic Touch can balance and promote the flow of human energy.
36. One can reduce the length of a cold by taking more than the daily-recommended dosages of basic vitamins.
37. Dietary changes can affect a person's cholesterol levels.
38. Regular exercise can alleviate feelings of depression.
39. One can recover lost memories from childhood through regression therapy.
40. Hypnotic suggestion is an effective way to bring about weight loss.
41. The analysis of dreams can provide meaningful solutions to life stressors.
Appendix H

Medical Claim Vignettes
Vignette A

Today, there are numerous medical doctors, naturopaths, chiropractors, salons, spas, massage therapists and other health care providers who practice Treatment 2. Treatment 2 is more comfortable and less invasive than conventional treatments. Why pay $25-75 for this service when you can easily do it at home? The benefits have been documented through case histories by qualified practitioners. The benefits include, improved hearing, vision, taste, smell, balance and sharpened mental ability. Treatment 2 helps to detoxify the sinus, lymph congestion, sore throat, earache, swimmers ear, chronic headaches and even allergies. Every body is different, yet Treatment 2 is a therapy that adults, children, and even animals can benefit from. There is absolutely no discomfort during this process. If you experience any pain while during Treatment 2, stop immediately, as this is an indication of a more serious problem than Treatment 2 can address. Treatment 2 is safe and painless; some people become so relaxed they fall asleep during the treatment.

Treatment 2 is not a cure-all, but has proven to be a successful and economic alternative to having other conventional medical treatments. The non-invasive Treatment 2 process has been known to improve hearing, lymph circulation, and balance. Our clients report relief from tinnitus, vertigo, and pressure regulation.

Treatment 2 is especially indicated for people who suffer from allergies, hay fever, asthma, etc. due to the bees interaction with the plant environment. As an added benefit, Treatment 2 has a pleasant aroma and have a very soothing effect. Relaxation is an important part of the Treatment 2 process. All who experience Treatment 2 agree it is safe, soothing, relaxing, painless, and non-invasive.
Vignette B
The genius’ breakthrough is one in which he or she escapes the rigidities of the normal and tired patterns of thought—unconventionality is one great measure of brilliance. One such example of an all-natural product of unconventional (but no doubt effective) thought is the concept of Treatment 4 by Brand Zero.

Treatment 4 is a very effective treatment which uses only natural herbs, allowing for the body’s complete response to Condition 4. Spoke S. Person, who is almost a century old, is the eager spokesperson of the product, and thus becomes the perfect testament for Treatment 4 claim to healthy living.

Each portion of Treatment 4 contains vegetable fiber, vitamin C, dextrin, loquat leaves, chitosan, tourmalines, houttuynia cordata, and bamboo and wood vinegar. Treatment 4 is manufactured in Asia where most of its natural ingredients are harvested. Treatment 4 is applied to the area affected by Condition 4 at least 8 hours every night, although sometimes longer applications might be necessary depending on an individual’s body chemistry. The aforementioned ingredients then all work together, to help the body alleviate the cause of Condition 4. Quite simply, Treatment 4 works.
Vignette C
Naturally occurring treatment with specific properties is called treatment 6, a treatment traditionally worn to guard against condition 6 and to instill a sober mind. The name of treatment 6 comes from the Greek meaning 'without condition 6' and treatment 6 is believed to protect one from poison.

It is used as a dream promotion agent and to help insomnia. Put treatment 6 under your pillow to bring about pleasant dreams, or rub it across your forehead to offer relief from condition 6.

Ancient Civilization 6 used treatment 6 to guard against guilty and fearful feelings. It has been worn as protection from self-deception, as well as a protection against witchcraft. Treatment 6 has long been used to open the spiritual and psychic centers, making it one of the power treatments. It is also used as a meditation aid when worn as a necklace. Treatment 6 is often worn by healers, as it has the power to focus energy. A healer will usually wear several pieces of jewelry with treatment 6 set in silver, especially a treatment 6 necklace. The person to be healed will have treatment 6 to hold while the healing is being done. The healer will place another piece of treatment 6 on the area of the body in need of healing, the important organs usually.

Treatment 6 is used for problems in two important bodily systems. Pieces of treatment 6 are used to keep the air and life force in the home clean and positive. Pieces of treatment 6 placed in a window that receives sun most of the day are very beneficial to use in healing and to heal negativity in the home. Place treatment 6 in moonlight and everyone in the home will be feeling calmer. Using treatment 6 as a meditation focus will increase the positive spiritual feelings. Treatment 6 helps overcome fears and cravings.
Vignette D

Treatment 7 is a contemporary healing modality drawn from ancient practices and developed by Expert A and Expert B. The practice is based on the assumptions that human beings are complex internal systems, and that the ability to enhance healing in another is a natural potential.

Treatment 7 is used to balance and promote the function of internal systems. It is taught in colleges around the world and has a substantial base of formal and clinical research. This research has shown that Treatment 7 is useful in reducing pain, improving wound healing, aiding relaxation, and easing the dying process. It can be learned by anyone with a sincere interest and motivation towards helping others.

Treatment 7 started at Location 7, a gathering site of Organization 7 in the foothills of the mountain range in State 7. It was preceded by the work of Expert A who had a highly developed sensitivity. Through the use of this natural ability she was able to perceive blockages and dysrhythms in a patient’s internal systems, subtle disharmonies not accessible to other medical technologies. Expert A diagnosed numerous perplexing cases referred by physicians and other scientists and often suggested treatments and resources for her patients.

Expert A’s abilities extended beyond the usual awareness of internal systems. For example, she was particularly known for her work with the internal systems in an individual. Since childhood Expert A was aware of such systems, and she made a lifetime study of how they work and how they relate to attitudes and emotions, this awareness later evolved into an understanding of the external system from which both healers and patients can draw improved function of internal systems.