VERBAL/VISUAL LEARNING STYLE PREFERENCE AND COMPREHENSION OF INFORMED CONSENT MATERIAL IN RESEARCH INVOLVING HUMAN SUBJECTS

A DISSERTATION

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DEDICATION

To Art Arauzo, Maryanne Watson, and Karen Huff--
Who believed in my future

And

To Owen and Michelle Smith--
Who are the future

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In August 1996, during the graduation ceremony for my master's degree, I decided to pursue my Ph.D. At that time, this day seemed very far off. In reality, a great deal has occurred during these four years--a lot relating to my formal education and even more relating to education about life.

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The purpose of this exploratory study was to determine whether visual or verbal learning style preference influenced comprehension of information in an informed consent document for research. Convenience sampling was used to obtain a study sample (n = 84) of female college students enrolled in undergraduate health-related courses. Verbal and visual learning preference was determined for each participant using the Verbal and Visual Learning Style questionnaire (Kirby, et al., 1988). Participants were asked to read a sample consent form, which was adapted from an IRB-approved longitudinal research study on the status of women's health across the lifespan. In addition, demographic data were collected and responses were solicited for suggestions to make the consent form easier to understand. Finally, the participants completed a multiple-choice test to assess their comprehension of the informed consent material. Overall comprehension of the consent form was 72%. There were no significant correlations between comprehension scores and age, ethnicity, education level, or academic major. In addition, there was no significant difference between comprehension scores for those reporting they had previously signed a research consent form versus those who had never signed a consent form. Comprehension scores for verbal learners (n = 20) and visual learners (n = 54) were not significantly different. Pearson r was

significant (p = .05) for visual score and comprehension score, though accounting for less than 5% of the total variance. Using a standard multiple regression analysis, a small though significant predictive relationship was found between visual learning style score and comprehension score (r = .214, p = .05). A taxonomic analysis of responses to the research question revealed two major themes: (1) elements of the consent form perceived as barriers to understanding and (2) suggestions for additions or changes that would aid understanding. Examples of barriers to understanding included the length of the document, complexity of wording, and sentence structure. Participants suggested the inclusion of visual aids, definitions, and explanations along with changes in formatting as ways to improve understanding. In conclusion, learning style preference may affect comprehension of written informed consent material and this area of research deserves further exploration.

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INTRODUCTION TO THE STUDY

Obtaining informed consent from research participants prior to conducting experimental medical procedures has been a tenet of ethical research conduct with humans since the 1948 court opinion in the Nuremberg Trials (as cited in Katz, 1972). As outlined in the Nuremberg Code, truly informed consent requires information, voluntariness, and comprehension: not just a signature on the document. In the past three decades, ethicists, researchers, and regulatory bodies have questioned the validity of signed consent documents (Byrne, Napier, & Cuschieri, 1988; Cassileth, Zupkis, Sutton-Smith, & March, 1980; Meisel & Roth, 1981; Rorabeck, 1997; Schultz, Pardee, & Ensinck, 1975). The overwhelming majority of studies have shown that subjects' comprehension of the information in the forms is alarmingly low.

Informed consent is ideally a process of information sharing and decision making that spans the course of the investigator-subject relationship (Faden & Beauchamp, 1986). In today's litigious society, the informed consent document itself has become the focus of the process. In many cases, the disclosure in the form is often the major--or only--source of information for the potential subject. As Power (1998) wrote, "there will always be some people prepared to obtain such consent technically without any real commitment to it spirit, because all they see it as is a signature at the bottom of a form and not a partnership" (p. 1003). Informed consent requires "not only that full

information be given to the subject but also that the subject be able to comprehend this information well enough to base a reasonable decision on it" (Annas, Glantz, & Katz, 1977, p. 37). Therefore, methods and techniques for improving comprehension of consent forms have been a major focus of recent research.

Readability of the printed information was one of the first focus areas for research regarding comprehension of informed consent in research and clinical settings (Grudner, 1980; Handelsman & Martin, 1992). The findings of these studies conducted with competent adults most often showed that more readable forms yielded higher levels of comprehension. Alternate and supplemental methods of presenting the necessary information were also studied. Such methods included the use of oral presentations, videotapes, and visual aids (Agre, Kurtz, & Krauss, 1994; Askew, Pearson, & Cryer, 1990; Baskerville, Heddle, & Jarrett, 1985). Though the findings have been mixed, the results tend to show an increase in comprehension when the written informed consent document is supplemented or replaced.

To date, little research has focused on possible reasons for differences in levels of comprehension when alternate forms of information giving are used. Based on the relevant literature, exploring the role of learning style preference on comprehension of written informed consent documents appears justified. According to Cross and Tilson (1997), learning styles and the role they play in learning have been the focus of researchers since the 1970s. The research shows that learners use different ways of collecting and organizing information into useful knowledge. Research in education and psychology has shown that individuals differ in their preferred method for processing

information and that the preferred style may have an impact on learning (Das, Kirby, & Jarman, 1979; Van Wynen, 1997). As Van Wynen (1997) noted, whether a learner is auditory, tactile, kinesthetic, and/or visual plays an important role in how he or she learns. The instructional methods used and the learning style of the learner are known to interact (Stawar, Stemm, & Truett, 1992), while one's preferred sensory modality has been shown to interact with teaching method and academic achievement (Dunn, Beaudry, & Klava, 1989). Based on these findings, it is reasonable to hypothesize a link between learning style preference and comprehension of written information.

Purpose of the Study

The purpose of this study was to determine whether visual or verbal learning style preference influenced comprehension of information in an informed consent document for research involving human subjects.

The participants for the study were female student volunteers enrolled in health-related undergraduate classes at the Denton campus of Texas Woman's University (TWU).

Hypotheses

The following hypotheses were examined at the .05 level of significance.

1. Learning style preference (verbal learner, visual learner) has no statistically significant effect on comprehension scores.
2. There are no significant relationships between verbal learning preference, visual learning preference, and comprehension scores.
3. Learning preference scores are not predictive of comprehension score.

Research Question

1. What comments did participants have about improving the comprehension of informed consent information?

Definition of Terms

The following definitions of terms were utilized to help clarify the study.

1. Comprehension. For the purposes of this study, comprehension is defined as "a measure of individuals' understanding tested within twenty-four hours of the initial disclosure of information" (Sugarman et al., 1999, p. 2). In this study, comprehension was measured by a recall test. In an earlier study, Cassileth et al. (1980) found a positive and significant relationship between participants' perceived comprehension of information in an informed consent document and their scores on a recall test ($p < .001$).
2. Informed Consent. Knowing consent of an individual "so situated as to be able to exercise free power of choice without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter as to enable him to make an understanding and enlightened decision" about participating in a research study (United States v. Karl Brandt as cited in Katz, 1972, p. 305). The basic elements required for such consent include (a) an explanation of the procedures involved and which procedures are experimental, (b) a description of potential discomforts and risks, (c) possible benefits, (d) alternatives to participation, (e) the opportunity to have any questions answered, and (f) a statement that the

subject can freely withdraw the consent without prejudice. (Protection of Human Subjects, 1991).

3. Learning Style Preference. The type of learning a person prefers. Those with a verbal learning preference prefer to learn verbally (in words, by reading or listening). Others prefer information that is more visual in nature (graphs, diagrams, or pictures) (Kirby, Moore, & Schofield, 1988).
4. Verbal Learner. For the purposes of this study, a subject whose score on the verbal portion of the Verbal and Visual Styles questionnaire was higher than the score on the visual portion.
5. Visual Learner. For the purposes of this study, a subject whose score on the visual portion of the Verbal and Visual Styles questionnaire was higher than the score on the verbal portion.

Limitations

Non-probability convenience samples were used due to time limitations and lack of monetary resources. Therefore, results of this study may not be generalizable to the larger population of women.

Delimitations

This study was limited to voluntary participants at TWU who were at least 18 years of age. Participation was not limited to females, however, only data from female respondents were used in data analysis. All subjects were English speaking. Participants who were enrolled in The Pioneer Project were not eligible for this study. Readability of

the consent form was not considered as a factor in this study. The method of data collection did not allow for follow-up questions.

Assumptions

For the purpose of this study, the researcher assumed that participants in the sample provided honest answers on the self-report instruments. The researcher also assumed that subjects in the sample did not experience significant anxiety, which has been shown in other studies to affect comprehension. She also assumed that subjects in the sample had at least a ninth grade reading level.

Significance

> "The informed consent *process* is to provide people with sufficient information so they can make informed choices about whether to begin or continue participation in clinical research...The informed consent *document* provides a summary of the clinical study and the individual's rights as a research participant. The document acts as a starting point for the necessary exchange of information between the investigator and potential research participant" (National Cancer Institute [NCI], 1998, p. 1).

With these definitions in mind, the authors of the Recommendations for the Development of Informed Consent Documents for Cancer Clinical Trials (1998) reported that "many informed consent documents have become too long and complex, and do not provide a sound basis for informed decision-making" (p. 1).

Federal regulations, among others, require that informed consent information be given to a potential participant in a language that is understandable to her or him (Protection of Human Subjects, 1991). This edict has been interpreted in various ways, including having the consent form written in the participant's native language or lowering the readability level to that of the average American. With the average US adult reading

at the eighth grade level (Kirsch, et al., 1993), most Institutional Review Boards (IRBs), including TWU's, have policies stating that the consent form should be readable at below eighth grade level (Texas Woman's University [TWU], 2000). And, as Faden and Beauchamp (1986) pointed out, "the *readability* of a consent form...taken by itself, says nothing about *understanding*, even if it stands to reason that readability facilitates understanding" (p. 327). Raich (1998) suggested that additional research should focus on the "impact of how information is presented on subject comprehension..." (p. 115). In addition, the National Cancer Institute (National Institutes of Health [NIH], 1996) has called for research aimed at simplifying the consent process, increasing the comprehension of consent information, and identifying methods to provide information to diverse populations in cancer prevention and research.

Though information-giving methods are already being explored, another aspect of understanding has been virtually ignored; that of learning style preference. Since instructional method and learning style have been shown to interact (Stawar, Stemm, & Truett, 1992), this study is a first step in focusing on the role of learning preferences on participant comprehension. With an estimated 16,000 to 20,000 medical experiments being conducted per year in the United States with an unknown number of actual participants (General Accounting Office [GAO], 1996), identifying learning factors that influence the comprehension of informed consent information could have broad practical application.

CHAPTER II

REVIEW OF THE LITERATURE

Informed consent requires "not only that full information be given to the subject but also that the subject be able to comprehend this information well enough to base a reasonable decision on it" (Annas, Glantz, & Katz, 1977, p. 37). Therefore, methods and techniques for improving comprehension of consent forms have been a major focus of recent research. Though information-giving methods are already being explored, another aspect of understanding has been virtually ignored; that of learning style preference. Since instructional method and learning style have been shown to interact (Stawar, Stemm, & Truett, 1992), this study is a first step in focusing on the role of learning preferences on participant comprehension.

The historical and theoretical bases of the doctrine of informed consent in clinical practice and research has been discussed extensively by several authors and will not be repeated here (Annas, et al., 1977; Faden & Beauchamp, 1986; Katz, 1972). Though much of the research has been conducted in clinical settings, the findings are applicable to informed consent in research and will be included in this review. In addition to an explanation of the role of informed consent in research, this chapter will review the professional literature of research on the informed consent document, including those examining readability, content, supplemental materials and alternate methods, and those

that attempted to measure or improve comprehension. In addition, the relevant learning styles research will be outlined, particularly in the areas of how various researchers have defined and measured learning style, and it's relationship to comprehension.

Informed Consent

The Purpose of Informed Consent in Research

Alexander Capron (1974) summarized the objectives of informed consent in research settings, enumerating six goals of the process. According to Capron, the aims of informed consent are to: (1) promote individual autonomy; (2) protect the status of research participants as human beings worthy of respect; (3) avoid duress and fraud; (4) encourage self-scrutiny by the researcher; (5) promote rational decision-making; and (6) involve the public in important questions about research and health care policy. As stated in the Office of Health Services Research (1997), "Guidelines for Writing Informed Consent Documents", "valid informed consent requires: (1) disclosure of relevant information to prospective subjects about the research; (2) their comprehension of the information, and (3) their voluntary agreement, free of coercion and undue influence, to research participation." Similarly, in their comprehensive work, A History and Theory of Informed Consent (1986), Faden and Beauchamp argued that the primary justification for informed consent in research was to enable autonomous choice by participants. Their findings were based on the historic and ethical evolution of informed consent in medical and research settings.

As Daugherty (1999) eloquently stated, "undoubtedly, a meaningful informed consent process will remain an enormously important and undeniable ethical obligation to patients...and others who are asked to become the subjects of research" (p. 1610). Obviously, without comprehension on the part of the potential research volunteer, truly informed consent can not be achieved. As the director of the Office for the Protection from Research Risks (OPRR) stated, "When there are any problems in human research, they often center on poorly informed consent, which is not consent at all" (Monmaney, 1999, p. A24).

The Consent Document

The research literature on informed consent has been cataloged by several authors in recent years (Raich, 1998; Silva & Sorrell, 1984; Sugarman, McCrory, & Hubal, 1998; Sugarman et al., 1999). Researchers have focused on such issues as the consent form, the consent process, special and vulnerable populations, the IRB review process, research investigators, recruitment, participant preferences, and decision-making. As Byrne and colleagues noted in 1988, "studies in the United States have found poor understanding and recall of consent form information" (p. 839). Research on the consent document itself has focused on issues such as readability, content, and use of supplementary materials and alternative methods of obtaining consent to improve comprehension. The research in these three areas will be discussed below.

Readability

To date, many researchers have focused on measuring and improving the readability of consent forms in research and clinical practice. Less readable forms tend to

be recalled less (Handelsman & Martin, 1992). Several researchers have hypothesized that low literacy is one of the key obstacles to truly informed consent (Grossman, Piantadosi, & Covahey, 1994; Jubelirer, 1991; Williams, et al., 1995). In his review of relevant research, Raich (1998) found that while most of the reported research on the topic of informed consent focused on the readability of a variety of consent forms, "the almost uniform conclusion from these studies is that consent statements are written at a reading level too high for the majority of the US population" (p. 107). For example, Hopper and colleagues (1998) studied 616 hospital consent forms for routine surgical procedures. Over 25% of the forms required college-level reading skills and 9% required a postgraduate education in order to read, and hopefully understand, the form. Based on their results and the findings of the 1992 National Adult Literacy Survey, the authors concluded that only 3% to 20% of adults could understand most informed consent forms.

In a follow-up to an earlier study, LoVerde, Prochazka, and Byyny (1989) found that 88 consecutive consent forms from a Veteran's Administration hospital required a mean reading grade level for comprehension of 13.4 years of schooling, as measured by the Fry Readability Scale. These results showed no improvement since the forms were tested six years earlier. Likewise, a 1995 review of consent forms approved by a community hospital over a year ($\underline{n} = 76$) found 96% of the forms had a readability (measured by the Fry score) higher than the targeted eighth grade reading level (Philipson, et al., 1995). The mean readability and processability score, computed using the Readability and Processability Form (RPF), was in the classification of minimally adequate/needs improvement. Descriptive data from the RPF identified aspects of the

written text as unacceptable or poor. Similarly, a study of 82 informed consent documents submitted to IRBs found the mean Flesch grade level required to read all the forms was 13.8 (White, et al., 1996). Not only were these forms written at a high reading level, 22% of the forms lacked several of the federal requirements such as disclosure of alternative procedures and circumstances when participation may be terminated.

Davis et al. (1998) found that most participants (62%) preferred a simplified consent form and found it easier to read (97%). Participants' understanding of the information in the form was not significantly different from the standard form (58% versus 56%). In the hypothetical exercise, the simplified form, written at a 7^{th} grade reading level, was compared to a standard consent form written at a 16^{th} grade reading level. Though comprehension was directly related to the level of literacy, comprehension scores were low for both of the forms, causing the authors to conclude that "lowering the degree of reading difficulty may not necessarily increase overall comprehension" (p. 674). This finding supported that of other studies (Taub, Baker, & Sturr, 1986). However, other researchers (Young, Hooker, & Freeberg, 1990) found statistically ($p < .05$) higher comprehension scores using a simplified form at the 6^{th} grade reading level when compared to a standard form (16^{th} grade level). The statistics are misleading, however, as the mean difference in comprehension was only 0.6 questions answered correctly out of 21 total on the simplified form.

As Hopper et al., (1998) noted, "incomplete or brief did not necessarily mean more readable" (p. 501). Readability and comprehension are also affected by the words or terms used in informed consents. To study this aspect of the informed consent

document, Waggoner & Mayo (1995) and Waggoner, Mayo, & Sherman (1996) conducted two controlled interview surveys of 578 randomly selected lay individuals whose educational backgrounds ranged from seventh grade through doctoral level preparation. The respondents were asked if they understood the meaning of 52 terms commonly used in informed consents. According to the authors, the results showed a substantial problem with understanding basic terms that are commonly used in written consent forms. For example, only 6% of those interviewed could define "pruritis", 12% understood "institutional review board", and 22% understood "randomly". On average, the correct response rate for the 52 terms was 46%. McCormack and colleagues (1997) found a similar lack of comprehension of orthopedic terminology in surgery patients.

Acknowledging that consent forms may stand "virtually alone" in the informed consent process, Hammerschmidt and Keane (1992) reviewed 65 randomly selected consent documents submitted to an IRB. Using Flesch and Fry scores and correcting for confounding features such as jargon, the authors concluded that the forms were readable to only 37.4% (+/- 1%) of the US adult population. After IRB review and approval, the readability did not improve by more than one grade level for any document. In an interesting comparison, the researchers used comparable methods to assess readability of 21 Ann Landers' columns and 15 Reader's Digest articles. The Landers' columns were found to be readable by 75% (+/- 3%) of adults while the magazine articles scored as readable by 59.1% (+/- 3%) of US adults.

According to several researchers, applying readability statistics may not be a meaningful way to measure or improve comprehension (Jubelirer, Linton, & Magnetti,

1994; Hochhauser, 1997). In a study with cancer outpatients, 100 adult patients were tested for reading vocabulary and reading comprehension using the Woodcock-Johnson Psychoeducational Battery (Jubelirer, et al., 1994). The mean grade level completed, reading vocabulary, and reading comprehension of all participants were 12.5, 11.3, and 10.5, respectively. The discrepancy between level of education and reading comprehension scores varied with age. Even after controlling for education level, the mean grade level for comprehension was statistically lower than education level. In essence, the researchers found that comprehension levels averaged three grades below education levels. These findings prompted the authors to warn health professionals not to assume a patient who has completed a certain grade level in school can read and the corresponding level. Their recommendation was that consent forms and other educational materials should be written at least three grade levels below the average educational level of the proposed population.

Jubelirer (1991) had comparable findings in an earlier study. Results with cancer patients ($\underline{n}$ = 127) showed that although the median education level was 10^{th} grade, more than 30% could not be expected to read at that same grade level. The informed consent material tested in the study required college-level reading comprehension. Similarly, in the Davis, et al. (1998) study, the mean education level of the participants was 11.9 while their mean raw score on the Rapid Assessment of Adult Literacy in Medicine (REALM) was 52, indicating that the subjects "were reading, on average, at a 7^{th}-8^{th} grade reading level" (p. 670). Powers' (1988) findings were much the same in a sample of emergency department patients ($\underline{n}$ = 111): years of education did not correspond with literacy levels.

Hochhauser (1997) concluded, "there is no one-to-one correspondence between reading ability and educational attainment" (p. 5) and that readability formulas are not good predictors of how understandable a document would be for adults.

Content

As early as 1969, researchers were recognizing that simpler informed consent documents were better informed consent documents (Epstein & Lasagna, 1969; Tymchuk, Ouslander, & Rader, 1986). Professionals in the fields of patient and health education have found that the comprehension of health education material can be increased by improving the presentation of information through graphics, headers, bold text, and colors (Meade & Howser, 1992; Doak, Doak, & Root, 1996; Michielutte et al., 1992). Doak, Doak, and Meade (1996) studied materials used in cancer education, including informed consent documents. In order to improve materials so that they could be read and understood, the authors recommended "a systematic process" which assesses the target audience, focuses the content, and presents the context of the message first. They also stressed the importance of verification of comprehension and suitability of the material for the target audience. A National Cancer Institute working group (1998) recommended that informed consent documents use active voice, short sentences, large fonts, wide borders, outlines, diagrams, and other graphics to make them easier to read and understand.

Rogers et al. (1998) suggested other factors that might hinder comprehension for parents considering enrolling their children in a research protocol. Among these factors were the inclusion of unnecessary information, the format of the consent form required

by the IRB, and the fact that the parent was required to sign the consent form granting permission for their child to participate. The researchers created a revised consent form that required only a signature for those refusing to participate and deleted information related to patient rights that appeared before the description of the study. The results showed that no significant differences were found between the standard and revised consent procedures except that mothers in the modified consent group scored higher in recall and understanding.

Supplemental Materials and Alternate Methods

Supplemental materials and alternate methods of conducting the informed consent process have been studied as means to improve informed consent. Research with supplemental materials included use of videotape or disc to disclose additional information (Agre, et al., 1997; Jimison, et al, 1998), supplementary written information (Davis, et al., 1998; Berner, Partridge, & Baum, 1997; Dodd, 1982; Doak, Doak, & Meade, 1996; Michielutte, et al., 1992), and computer-assisted aids (Llewellyn-Thomas, et al., 1995). Different methods studied include the use of audio- or videotaping of the consent encounter to be viewed again at a later time (Deutsch, 1992; Dunn, et al., 1993; Johnson & Adelstein, 1991; Hogbin & Fallowfield, 1989; Tattersall, et al., 1994), sending follow-up or consultation letters to the participant (Davis, et al., 1998; Tattersall, et al., 1994), and formal follow-up nursing interventions (Aaronson, et al., 1996).

Overall, the majority of the results of the studies listed above have shown increases in comprehension, though many are modest at best. As summarized by Daugherty (1999), studies involving audiotapes have shown evidence for and against

improvement, while follow-up or consultation letters showed no significant evidence for improvement. The use of videos appeared to increase comprehension for procedure-related care, though computer-assisted aids showed no improvement when compared with audiotape. Follow-up phone contact and additional written material also showed evidence of improvement.

Weiss and Coyne (1997) advised clinicians to "consider using nonwritten materials to communicate information to patients, especially patients with limited literacy" (p. 273). They recommended simple materials such as picture books, slide or tape presentations, videotapes, audiotapes, and models along with more elaborate, computer-based multimedia techniques. In several studies using these techniques to inform patients about surgical and clinical procedures, researchers have reported an increase in knowledge among patients, regardless of literacy level (Adler, et al., 1993; Kumar, et al., 1993; Llewellyn-Thomas, et al., 1995; Randall, 1993).

Patients undergoing endoscopy who were shown an instructional video and an explanation of the procedure by a physician preferred this method of obtaining information to a written consent document alone (Agre, et al., 1997). Onel and colleagues (1998) did report an increase in understanding by patients after they viewed an instructional video that presented different treatment options for prostate cancer. Without a control group, however, the meaning of these results is unclear.

Wadey and Frank (1997) conducted a study into the mechanism of obtaining informed consent with patient's undergoing anterior cruciate ligament reconstruction. Both the experimental ($\underline{n}$ = 8) and control ($\underline{n}$ = 12) groups "received a

standard surgical consultation consisting of knee models, diagrams, open dialogue and informed consent to surgery" (p. 124). Patients randomized to the experimental group were required to accurately verbalize the information on risks and benefits before the operation. One month after the surgery, patients were given a three-question questionnaire about the risks and benefits of the procedure. The experimental group showed a greater understanding and retention of the information than control group (p = .03). The small sample size and short assessment obviously limit the generalizability of these results. Using another alternate method, Morrow and colleagues (1978) found that radiation patients who were allowed to take an informed consent document home for 2-3 days for consideration possessed greater knowledge than a control group when assessed by a structured interview within 24 hours of signing the consent form.

Freda and colleagues (1998) designed a prospective qualitative study of women considering screening for maternal serum alpha-fetoprotein. The women (n = 53) received information from a provider and viewed a videotape about the test. In subsequent interviews, the women were asked questions about the test. According to the authors, the women met a few but not all of the criteria for informed consent, though all had signed the informed consent document. While they understood that the test was voluntary, the women's comprehension of the meaning and implication of the test result was deficient. For instance, only 45% could describe the follow-up for a positive test and 59% thought a negative result meant their infant would be healthy in all respects.

Computer-generated videos have also been used to help patients understand the clinical procedures and concepts involved in a research protocol (Guide to Good Clinical

Practice, August 1996). Though this specific process has not been the subject of empirical inquiry, anecdotal evidence has shown the videos to be effective as adjuncts to consultations.

Comprehension of Consent Information

As stated earlier, most research studies into the comprehension of informed consent information have shown a consistent theme. "Overall, patients who served as research subjects did not adequately comprehend (understand, know, recall) the information presented to them" (Silva, 1985, p. 118). The sections below will review the literature regarding factors affecting comprehension, studies that measured comprehension, and the difficulty defining and measuring comprehension.

Factors Affecting Comprehension

Several factors have been found to be associated with decreased comprehension of consent forms. These include limited education, increasing age of the subject, and the readability of the consent form (Taub, 1986; Taub, Baker, & Sturr, 1986; Taub & Baker, 1983; Stanley, et al., 1984; Young, Hooker, & Freeberg, 1990; Meade & Howser, 1992). In addition, empirical research has shown that comprehension is influenced by the nature of the information, method of presentation of information, demographic factors, and personal factors (Silva & Sorrell, 1984).

The level of comprehension has been related to severity of illness and care with which informed consent information is read (Cassileth, et al., 1980), complexity of the information (Davis, et al., 1998; Muss, et al., 1979), length of the consent form (Epstein & Lasagna, 1969; LoVerde, Prochazka, & Byyny, 1989), and whether recall is measured

immediately or delayed (Bergler, et al., 1980). Surgery patients with an internal locus of health control (those who believed their health to be in their own control) were better informed about their surgical procedure compared to those with an external locus of health control when questioned six months after discharge (Lavelle-Jones, et al., 1993).

A review of the informed consent literature in older populations identified factors such as lower vocabulary and educational level, and chronic and acute medical illness, that have been found to amplify the detrimental effects of aging in impairing comprehension (Christensen, et al., 1995). Surprisingly, the findings of Taub, et al. (1987) suggested that the age-related differencess in comprehension they observed (young-old through old-old volunteers, $\underline{n} = 235$) may have been due to visual and not cognitive deficits. Comprehension varied directly with education and inversely with age and typeface was found to interact with age-related differences with smaller but not the largest typefaces.

Studies Measuring Comprehension

The inadequacy of comprehension of consent information has been demonstrated in studies involving routine medical procedures (i.e., surgical procedures, consent to medical treatment). For example, Byrne and colleagues (1988) interviewed 100 consecutive surgical patients treated in one surgical unit to determine their level of knowledge about the nature of their operation. The patients were interviewed prior to discharge by an independent medical observer. The procedure for consent was not changed for the study. In a consultation the day before surgery, the patients were told about the nature of the intended operation. Later the same day, the patient met with

another staff member who repeated the details of the proposed treatment and obtained signed consent. The independent observer interviewed the patients 2-5 days after surgery and requested information about their awareness of having had an operation, knowledge of the organ removed, and basic details of their operation. While all of the patients knew they had undergone surgery, 27 of the patients did not remember what organ was operated on and 44 were unaware of the basic facts regarding their surgery. The authors did find a significant relationship ($p < .001$) between age of the patient and knowledge of the operation, with those patients over 50 remembering less than those aged 50 and under. These findings led the authors to conclude that, "although the signed consent form before surgical treatment fulfills a legal requirement, it in no way guarantees that the patient is fully aware of the exact nature of the treatment" (p. 840).

Cassileth et al., (1980) asked cancer patients ($n = 200$) to recall information they received relative to giving informed consent on the previous day for chemotherapy, radiation, or surgery. The respondents had a mean score of 8.26 out of 12 for correct answers. In addition, only 59% correctly understood their treatment and only 55% could name one possible major complication. Similarly, Muss et al., (1979) interviewed 100 breast cancer patients 0-24 months after the start of chemotherapy to determine their understanding of informed consent information. The results showed that up to 74% of patients had inadequate or erroneous comprehension of information in identification of their drugs, possible side effects, and the purpose of chemotherapy. Though the previous two studies did not standardize the informed consent procedure, a study by Kennedy and Lillehaugen (1979) did, and resulted in similar findings. More than 50% of the

participants (n = 38) were confused about whether they had given permission to have either research drugs or tests done on them.

Silva (1985) created an eight item multiple choice test based on the information needed to give informed consent such as study purpose, nature of subject involvement, risks, benefits, etc. for use with the spouses of surgical patients. Her results showed adequate comprehension (n = 75, mean = 7.6, range = 3 – 8) which was low though significantly related to years of schooling (r = .22, p < .03) but not related to age or gender. The author admits limitations to the study resulting from sample size, nonprobability sampling, and the newly developed comprehension instrument. In addition, recall was immediate and the consent form was simple and short (one page).

More recently, patients' ability to understand and recall risks and benefits associated with treatment options was assessed when only verbal information was presented (Lloyd, et al., 1999). The patients (n = 56) were considering a prophylactic surgical procedure to reduce the chance of embolic stroke and all were counseled by a medical consultant in a similar manner. Though the patients were informed that their chance of suffering a stroke during the procedure was approximately 2.3%, when questioned 1 month after the consultation, over 10% of patients thought the risk was at least 50%. Additionally, some patients thought there was no risk of stroke associated with the surgery and 11% said they did not know. Only 1 patient was able to accurately report the risks he was told. The authors suggested that "either patients have very little understanding of the risks and benefits associated with a prophylactic procedure or they quickly forget them" (p. 45).

In addition, researchers have found that while patients were able to read informed consent information and report their understanding, objective assessments of their understanding did not confirm the self-reports (Hassar & Weintraub, 1976; Irwin, et al., 1985; Leonard, Chase, & Childs, 1972; Miller, et al., 1996; Robinson & Merav, 1976). For example, one study found that 90% of patients stated they understood all or most of the information provided to them about a research protocol in which they had agreed to participate (Daugherty, et al., 1995). However, only about one third of the patients could correctly state the purpose of the trial when asked. In the Hassar & Weintraub (1976) study, after a four-month clinical trial, participants were given a factual test to determine what they understood and remembered from the consent information they had been given. According to the authors, two thirds of the participants did not remember having been informed about potential risks. Some, who did remember, misunderstood what they had been told, and others developed erroneous ideas about the clinical trial and the study drug.

While much of the research involving informed consent with psychiatric patients has focused on their competency to consent, Wirshing et al. (1998) designed and evaluated a "structured and rigorous" informed consent procedure involving competent patients diagnosed with schizophrenia (p. 1508). When referred patients expressed an interest in participating in a randomized clinical trial, the attending physician described the protocol in detail. Patients who expressed further interest met with the study coordinator who read the consent form to the participant, pausing often to assess the level of understanding and answer any questions. When this procedure was complete, the

coordinator administered a questionnaire assessing the patient's comprehension. When a participant responded incorrectly to a question, the pertinent portion of the consent form was re-explained and the questionnaire was again administered. This procedure was repeated until the participant answered all questions correctly and signed the informed consent document. When the same questionnaire was administered 7 days later, any missed questions were explained to the patient until he or she expressed an understanding and answered the question correctly. Patients who could not answer correctly were excluded from participation in the research protocol, resulting in a study sample of 49. Though a majority of the patients ($n = 44$) required two or more reiterations of the questionnaire in order to demonstrate clear understanding, scores for the entire group improved between the first administration and the day 7 follow-up (McNemar chi sub 2 = 9.8, $df = 1$, $p = .02$). Their findings support those of other studies that have found that psychiatric patients who are exposed to informed consent information on only one occasion retain only a portion of the information (Irwin, et al., 1985; Jaffe, 1986; Munetz & Roth, 1985) and also studies which have demonstrated that patient education components in the informed consent process increase comprehension and retention of information (Brown, Wright, & Christensen, 1987; Kleinman, et al., 1993).

A well-designed study involving women tested for HIV in a South African hospital yielded disturbing results regarding informed consent (Karim, et al., 1998). The participants ($n = 56$) were given counseling and signed an informed consent document prior to testing. Though the women in the study were assured their participation was entirely voluntary and they expressed understanding, 88% of the women said afterward

that they felt compelled to participate. Over a quarter of the women (28%) perceived the research to be part of the hospital services and said they agreed to participate only because they thought their refusal would compromise their care. As the authors concluded, "this medical service setting, and perhaps particularly public care, where the patient has little recourse to alternatives, influenced decisions to participate in a research project" (p. 639). Their results reflect the role of social context and culture in the informed consent process and comprehension of the information presented.

Reading a consent form in order to understand what one is being asked to do can be considered a type of learning. As Lachman (1997) suggested, "the phenomenon of learning as a consequence of a single event--one trial learning--has been demonstrated" (p. 478). And if noted educators and researchers are correct, how people take in information is essential to learning. For example, Reif (1993) wrote that students retain, "10% of what they read, 20% of what they hear, 30% of what they see, 50% of what they see and hear, 70% of what they say, and 90% of what they say and do" (p. 53). These differences could conceivably account for the findings in some of the research on informed consent comprehension outlined earlier in this chapter. For instance, writing a summary of information which is read has been shown to enhance learning (Fox & Siedow, 1985; Sorrell, 1991), and Sorrell identified a trend in her research that suggested that both writing and speaking about written information may have practical significance as strategies to enhance comprehension of informed consent information.

Learning Styles

The professional literature on learning styles is vast, conflicting, controversial, and spread across the disciplines (Dunn, et al., 1981; Messick, 1994; Van Wynen, 1997). An extensive review of this literature is beyond the scope of this chapter and only the research that is relevant to this study is discussed below. (For extensive reviews of the research on learning and cognitive styles, see: Claxton & Murrell, 1987; DeBello, 1989; Globerson & Zelnicker, 1989; Rayner & Riding, 1997; Riding, 1997.)

Learning Style Defined

The terms learning style, learning preference, information processing style, and cognitive style are defined differently by some researchers, yet used interchangeably by others (Dunn, et al., 1981). For the purposes of this study, learning style is simply defined as the type of learning a person prefers (Kirby, Moore, & Schofield, 1988). Those with a verbal learning preference prefer to learn verbally (in words, by reading or listening). Others prefer information that is more visual in nature (graphs, diagrams, or pictures). Interestingly, this definition, corresponds to Cranston and McCort's (1985) definition of cognitive style which they define as "one's preferred way of receiving information or of gaining meaning from one's environment" (p. 136), such as listening to a lecture versus reading a textbook. Other researchers apply the same definition to learning mode, (Canfield & Lafferty, 1970) and perceptual strengths or modalities (Dunn & Dunn, 1978).

A national task force defined learning styles as "the composite of characteristic cognitive, affective, and physiological factors that serve as relatively stable indicators of

how a learner perceives, interacts with, and responds to the learning environment" (Keefe, 1979, as cited in Griggs, 1991, p. 1). Included in this comprehensive definition are cognitive styles, defined as "intrinsic information-processing patterns that represent a person's typical mode of perceiving, thinking, remembering, and problem-solving" (p. 1).

Most authors agree with Ramirez and Castaneda (1974) that learning style is not permanently fixed. The Dunns (1978), however, divide learning style characteristics into preferences and factors, where factors are relatively stable over time and preferences may be overcome with interest or motivation. For example, some learners may have preferences in different contexts, but with instruction, are able to switch (Kirby, 1988).

The differences in construct definitions make broad generalization of certain conclusions impossible. Some researchers have concluded that styles vary across context and specific tasks as well as developmental stage, and are socialized by the dominant culture (Sternberg, 1997). Cognitive styles have been linked to different personality and motivational, but their relation to gender is controversial (see Severiens & Ten Dam, 1997).

Perceptual style theories date back to research started in the mid-1970s by French, Gilley, and Cherry (Overview, 2000). Their work defined seven perceptual modes, including print (seeing written words), aural (listening), interactive (verbalization), visual (seeing visual depictions), haptic (refers to sense of touch and grasp), kinesthetic (whole body movement), and olfactory (smell and taste). Other researchers have listed four learning styles based on perceptual learning channels (or modalities): visual, auditory, kinesthetic, and tactile (Reinert, 1976; Dunn, 1983, 1984). In this classification system,

visual learning involves reading or studying charts while auditory learning is associated with listening to lectures or audiotapes. Experiential learning which involves total physical involvement is kinesthetic, while tactile learning uses hands-on learning such as doing laboratory experiments.

Based on her research on learning styles in educational settings, Dunn (1984) estimated that 40 percent of students retained 75% of what they read or saw during a class period. These learners were of two types: those who processed information in word form and those who retained what they saw in diagram or picture form. In addition, she estimated that 30% percent of students remembered 75% of what they heard during a normal class period.

Measuring Learning Style Preference

The conflicting definitions of learning constructs are reflected in the wide array of theoretical models and instruments that purport to explain and measure learning style (Kramer & Conoley, 1993; Dunn, et al., 1981; Kirby, 1979). For example, "among the assessments used to define learning styles, some defined auditory as the ability to hear, whereas others defined it as the ability to remember what was heard, and still others defined it as preferring to learn by listening" (Dunn, et al., 1995, p. 356). Problems with reliability and validity of the various instruments have been well documented elsewhere (Cross & Tilson, 1997; DeBello, 1989; Dunn, et al., 1995; Snyder, 1998; Van Wynen, 1997). Studies by Kirby et al., (1988), however, demonstrated that style scales, such as the Verbal and Visual Learning Styles questionnaire, "show a predictable pattern of correlation with their hypothesized underlying abilities" (p. 181).

The Verbal/Visual Learning Styles questionnaire used in this research was developed from Richardson's Verbalizer-Visualizer Questionnaire (Kirby, et al., 1988). Literature relating to the Verbal/Visual Learning Styles questionnaire itself is sparse. The Verbalizer-Visualizer Questionnaire (VVQ) is a 15-item subset of Paivio's 86-item Ways of Thinking questionnaire and is scored on a single dimension.

In his dual coding theory, Paivio (1971) attempts to give equal weight to verbal and non-verbal processing. The theory assumes that there are two cognitive subsystems, one for processing and representation of nonverbal objects and events and the other for dealing with language. The major principle of the theory is that recall and recognition are enhanced when information is presented in both visual and verbal form. As Paivio (1986) states:

> "Human cognition is unique in that it has become specialized for dealing simultaneously with language and with nonverbal objects and events. Moreover, the language system is peculiar in that it deals directly with linguistic input and output (in the form of speech or writing) while at the same time serving a symbolic function with respect to nonverbal objects, events, and behaviors" (p. 53).

Research by Paivio and others supported his theory (Clark & Paivio, 1991). For example, in an experiment where participants had to determine the roundness of an object, the objects were presented as words, pictures, or word-picture pairs. Participants were asked to indicate which member of the pair (e.g., tomato, goblet) was rounder. Response times were measured and found to be slowest for word-word pairs, intermediate for picture-word pairs, and quickest for picture-picture pairs.

In the VVQ, the scoring system is suspect since it implies that learners have a strong preference toward one type of learning and would not be equally adept in both

domains. Research and analysis by Kirby and colleagues (1988) showed no evidence to support the single bipolar score and led them to question the validity of the VVQ. Their new instrument was constructed so that items reflected "as much as possible the underlying constructs of preference for verbal or visual learning" (p. 174). Subsequent analyses did show, in fact, that visual and verbal styles are separate factors and not opposite ends of a single dimension.

In testing with college students and army recruits with the Verbal/Visual Learning Styles questionnaire, college students had higher scale scores on both scales (verbal, $F(1,356) = 17.04$, $p < .0001$; visual, $F(1,356) = 11.41$, $p < .001$). The college students, who were still in school, had greater learning preferences than the army group. Within the army recruits, age differences approached significance for verbal preference ($p < .07$) and visual ($p < .06$). College students did not differ significantly by age or sex.

Learning Style and Comprehension

Perhaps the broadest application of learning styles' research has been in education. Conflicting models aside, most researchers agree on the existence of individual differences in learning (Dunn, et al., 1981). With these differences in mind, the Dunns have advocated that learners should always be taught through their strengths because learning preferences "make identical instruction effective for some students and ineffective for others" (Dunn & Dunn, 1993, p. 5). When accommodated, one's style of learning can result in "improved attitudes toward learning and an increase in productivity, academic achievement, and creativity" (Griggs, 1991, p.1).

Educational leaders have recognized that the process of learning is vital and that understanding how individuals learn is the key to educational improvement (Griggs, 1999). Studies have identified several connections between cognitive style and learning (see Messick, 1976). The stronger the preference, the more important it is to provide compatible instructional strategies. In addition, it is more important to accommodate learning style preferences in less academically successful individuals (Dunn, et al, 1995). Significant achievement gains have been found in students with learning disabilities and low literacy levels when instructional methods are in accord with their learning style.

"From a learning perspective, reading is closely related to many other cognitive processes or domains including: attention, concept formation, imagery, language, memory, and perception" (Theories in Print, 2000). Text integrated with pictures has been found to enhance learning by Imagers (closely related to visual learners) compared to when the same content was presented in text format only (Riding & Ashmore, 1980; Riding & Douglas, 1993). "Individuals confronted with instruction which is incongruent with their cognitive style experience great difficulty in comprehending the information" (Pillay, 1998, p. 172).

In summary, based on the relevant literature, examining the role of learning style preference on comprehension of written informed consent documents appears justified. This study was designed to explore possible relationships between verbal and visual learning style preference and comprehension of written consent information.

CHAPTER III

RESEARCH METHODOLOGY

The study was a cross-sectional, post-test only design. The purpose of this study was to examine whether verbal or visual learning style preference influenced comprehension of information in an informed consent document for research involving human subjects. This chapter describes the sample population, sampling procedure, human subjects' issues, research procedures, instrumentation, treatment of data and statistical methods.

Population and Sample

College women age 18 and above who were enrolled in undergraduate health-related courses at Texas Woman's University comprised the population. Convenience sampling was used to obtain the study sample ($\underline{n} = 92$). Two participants provided incomplete data and 6 participants were male. These 8 subjects were excluded from the data analysis yielding a study sample of 84.

Description of Sample

Texas Woman's University is a state-supported institution, primarily for women. According to the Office of Institutional Research and Statistics' Fact Book (1998), TWU enrolled over 9,000 students on its three campuses. In 1998, over 95% of the 4,454 undergraduates enrolled on the Denton campus were female. While Caucasians accounted for 66.3% of undergraduates, African-Americans (17.0%) and Hispanics

(9.3%) were also well represented. Asians/Pacific Islanders accounted for 5.7% of the student body while American Indian/Alaskan Natives and International students accounted for less than 1% each. The majority of undergraduate students were between the ages of 20 and 29 years of age, with almost half of the subjects falling between 20 and 24 years of age. The University's General Division is composed of the College of Arts and Sciences, the College of Education & Human Ecology, and the School of Library & Information Studies. The Institute of Health Sciences includes the College of Health Sciences, the College of Nursing, and the Schools of Occupational and Physical Therapy.

Protection of Human Subjects

An application was filed with the TWU Human Subjects Review Committee (HSRC) for approval to conduct the study. Based on the information submitted, the HSRC determined the study was exempt from further review (Appendix A).

Potential participants were read verbal instructions (Appendix B) which outlined the general nature of the study. They were advised that their participation was voluntary, and that no names would be collected with the study data. As required by the HSRC (2000, p. 4), the statement, "The return of your completed questionnaire constitutes your informed consent to act as a participant in this research" was included at the top of all data collection forms.

Research Design & Procedures

Beginning in March 2000, the researcher designed the demographic questionnaire, adapted the consent form for use in the study, and developed the Informed

Consent Comprehension Test. After piloting the comprehension test, data collection began.

The researcher approached instructors who were teaching undergraduate health-related courses during the Spring and May Mester 2000 semesters to obtain permission to speak to their classes about participating in this study. Data collection occurred between May 1 and May 22, 2000. With the class instructor out of the room, the researcher explained the study to the class, advised the students of their rights as research subjects, and asked for volunteers.

The researcher administered the testing. A unique study number was used to identify study forms and answer sheets for each participant. Participant answers remained anonymous and no record was made to link participant names with their identifier. Subjects were asked specifically not to enter their name on any of the study forms.

First, participants were given 10 minutes to read the informed consent document (Appendix C) as if they were considering participation in the outlined research project. Questions about the information in the consent form were not answered until after all testing was complete.

The consent form used in this research study was adapted from one approved by the TWU HSRC and was previously used for participants enrolling in "The Pioneer Project—a longitudinal study on women's health across the lifespan". The TWU Institute for Women's Health (formerly the Center for Research on Women's Health) is conducting this study. (An updated and modified version of this consent form is currently

being used for the Pioneer Project.) The researcher is a co-investigator on the Pioneer Project and permission to use the consent form was obtained from the principal investigator, Charlotte (Barney) Sanborn, Ph.D. (Appendix D). The Pioneer Project is an observational rather than an intervention study which should have made it easier for participants to envision actually enrolling in the study and making the informed consent document more meaningful. In order to shorten the consent form for use in this study, several paragraphs describing various questionnaires were removed from the original consent. A fictitious name was also substituted for that of the principal investigator. A former chair of the HSRC reviewed the original and shortened versions and established that the new form was equivalent to the original in terms of required information and still met all HSRC requirements for approval (J. Engelbrecht, personal communication, April 25, 2000).

Using the readability tools in Microsoft Word '97, the revised consent form had a Flesch-Kincaid Grade Level score of 12.0 and 45.8 as the Flesch Reading Ease score. (The Flesch-Kincaid formula determines readability based on average sentence length and the average number of syllables per word, and tends to score low (Hochhauser, 1997). Flesch scores ranged from 0 to 100, and are divided into 7 categories ranging from very easy to very difficult.) This form contains 2124 words in 83 sentences with an average of 22.5 words per sentence and 4.8 sentences per paragraph. The Flesch-Kincaid Grade Level score for the original form was 12.0 and the Flesch Reading Ease scale score was 48.1. There were 2888 words in the consent form with 110 sentences, an average of

21.9 words per sentence, and 4.4 sentences per paragraph. Most participants were able to read the study consent form in 5 to 10 minutes.

After the consent forms were read and returned, the participants completed the Verbal and Visual Learning Style questionnaire (Kirby et al., 1988) (Appendix E). Answers (true or false) were recorded on a separate answer sheet. Completion time was approximately 10 minutes. Participants also completed a short demographic data sheet (Appendix H) that included a qualitative research question. Completion time for the demographic form was less than 5 minutes.

Finally, participants completed a multiple-choice test (Appendix I) to assess their comprehension of the material in the informed consent document they read. Completion time for this test was 5 to 10 minutes. The researcher collected all study forms that were later scored and coded. The researcher performed appropriate data analyses.

Instruments

Instruments in this study included a demographic data sheet and qualitative research question, the Verbal and Visual Learning Styles questionnaire (Kirby et al., 1988), and a multiple-choice comprehension test. The demographic information sheet (Appendix H) collected information on age, gender, ethnicity, education level, academic major, and previous exposure to informed consent documents. In addition, a research question was included which asked for suggestions to make the consent form easier to understand. Descriptions of the other instruments follow.

Verbal and Visual Learning Styles Questionnaire

Permission to use the Verbal and Visual Learning Styles Questionnaire was obtained from the author and the publisher (Appendixes F, G). This questionnaire contains 20 randomly presented true/false statements (Appendix E). Half of the questions are phrased positively and half negatively. For each scale, a point is scored for each true response to positively phrased statements and for each false response to negatively phrased statements. The test produces two scale scores: verbal learning preference and visual learning preference, and resulting scores for each scale can range from 0 to 10. For the purposes of this study, participants who had equal scores on the verbal and visual scales ($n = 10$) were not classified as to learning type and were thus omitted from the statistical analysis for null hypothesis 1.

In a sample of female college students ($n = 98$), the mean verbal score was 6.27 ($SD = 2.216$) and the mean visual score was 7.94 ($SD = 1.54$) (Kirby et al., 1988). The verbal and visual scales showed adequate internal-consistency reliability with alpha coefficients of .70 and .59 respectively. Principal component analysis showed good construct validity and face validity was also achieved "as the verbal and visual style items range across a broad spectrum of aspects relevant to those constructs" (p. 179).

Informed Consent Comprehension Test

The researcher developed the comprehension (recall) test (Appendix I). The 15 questions for the multiple-choice test were based on the requirements for adequate informed consent documents as addressed in the Code of Federal Regulations-Protection of Human Subjects (1991) and the TWU HSRC policies and procedures manual (1994).

These criteria include (a) study purpose, (b) time involvement, (c) nature of subject participation, (d) risks, (e) benefits, (f) voluntariness, (g) confidentiality, and (h) anonymity. Similar tests have been developed for use in other studies of informed consent comprehension (Silva, 1985; Sorrell, 1991). One point was scored for each correct answer and participants were assigned a corresponding percentage score (number of correct responses/total number of questions x 100).

Three experts with extensive knowledge of informed consent requirements and/or test construction reviewed the test for face and content validity. According to Stephen Freeman, Ph.D. (personal communication, May 2, 2000), the test had adequate face validity and the test questions covered the intended content. (Dr. Freeman is an associate professor and licensed psychologist with training and expertise in psychometrics.) The other experts agreed (L. McFarland, personal communication, May 3, 2000; J. Engelbrecht, personal communication, April 25, 2000). (Ms. McFarland is the manager of oncology clinical research operations at Dallas area academic hospital and has over 10 years of experience preparing and reviewing informed consent documents for research. Dr. Engelbrecht has previously served as a member and chair of the TWU HSRC.) Changes were made to the test to assure random presentation of possible answer choices. The instrument was piloted with a group of 12 female undergraduate students. The mean comprehension score was 10.9 (72.8%), standard deviation 1.75, and range 8-14 (53.3% - 93.3%).

Design and Analysis

Descriptive statistics in terms of frequencies and percentages were compiled to provide a profile of participants' demographic information. Participant responses to the qualitative question were analyzed using taxonomic analysis as described by Spradley (1980). Themes were developed from the domain analysis and a taxonomy was established (Appendix J). The taxonomic relationship is used to show relationships among the items within the domain and is based on semantic relationship. According to Snow and Anderson, (1993), this taxonomy, or typologizing, allows the researcher to categorize items by their likeness and difference.

An independent t-test was used to determine whether learning style preference (verbal learner versus visual learner) had a significant effect on comprehension scores. The magnitude of the relationship between verbal learning preference, visual learning preference, and comprehension was assessed using Pearson correlation coefficients. A standard multiple regression analysis was used to determine whether verbal and/or visual learning style preference scores were predictive of comprehension scores. All hypotheses were tested at the .05 level using the statistical software program, SPSS 10.0.

CHAPTER IV

PRESENTATION OF THE FINDINGS

Inferential and descriptive statistics were used in the data analyses. The descriptive characteristics of the study sample and descriptive analyses of the variables will be reported in this chapter. In addition, the results of the independent t-test, correlation, and regression analyses will be presented. Finally, the findings of the taxonomic analysis of responses to the qualitative research question will be outlined.

Description of the Participants

The study sample (n = 84) consisted of undergraduate college women between the ages of 18 and 54 with a mean age of 25.9. The self-reported ethnicity of the sample is shown in Table 1. Though Caucasians comprised 71.4% of the sample, the heterogeneous sample included Black or African-Americans (14.3%), Hispanics (2.4%), Asians (4.8%), and participants of mixed or other ethnic groups (7.1%).

Table 1

Number and Percentage of Subjects by Ethnicity

Ethnic Group	n	%
Caucasian	60	71.4
Black/African-American	12	14.3
Hispanic	2	2.4
Asian	4	4.8
Other	6	7.1
Total in sample	84	100.0

As Table 2 indicates, the education level of the participants was evenly distributed between freshmen, sophomores, juniors, and seniors. Over 46% of the respondents identified themselves as majors in the College of Health Sciences and 28.6% were majors in the College of Arts and Sciences (Table 3).

Table 2

Number and Percentage of Subjects by Education Level

Education Level	n	%
Freshman	18	21.4
Sophomore	20	23.8
Junior	24	28.6
Senior	22	26.2
Total in sample	84	100.0

Table 3

Number and Percentage of Subjects by Academic Major

Academic Major	n	%
College of Arts and Sciences	24	28.6
College of Education & Human Ecology	15	17.9
School of Library & Information Studies	2	2.0
College of Health Sciences	39	46.4
College of Nursing	4	4.8
Total in sample	84	100.0

Only 28.6% of participants answered yes to the question, "Have you ever read or signed an informed consent document for a research study?" (Table 4). Of those

responding affirmatively, the majority of the students reported participating in research conducted at a college or university.

Table 4

Number and Percentage by Exposure to Informed Consent for Research Document

Previous Exposure to Informed Consent	n	%
Yes	24	28.6
No	60	71.4
Total in sample	84	100.0

Based on the results of the Verbal and Visual Learning Styles questionnaire (Kirby et al., 1988), the visual learners outnumbered the verbal learners almost three to one (Table 5). Participants whose scores were equal for verbal and visual preference (n = 10) were not included in the learner type analysis. As seen in Table 6, the mean verbal score of the sample was 7.3 and the mean visual score was 8.3. The mean score of the sample for the comprehension test was 71.9%.

Table 5

Mean Comprehension Percentage by Learner Type

Learner type	n	x	SD	Range
Verbal	20	70.3	17.8	40-100
Visual	54	72.4	13.5	33.3-100
Total	74			

Table 6

Verbal and Visual Learning Preference and Mean Comprehension Percentage

Score type	n	x	SD	Range
Verbal	84	7.3	1.7	2.0-10.0
Visual	84	8.3	1.7	3.0-10.0
Comprehension (%)	84	71.9	14.4	33.3-100.0

The sample in this study scored slightly higher on both verbal and visual scales compared to Kirby and colleagues' (1988) sample of female college students ($n = 98$, mean verbal score = 6.3, mean visual score = 7.9). However, both samples had higher visual preference scores than verbal scores.

On average, participants in this study answered incorrectly on between 4 and 5 of the 15 comprehension test questions. Assuming that total comprehension would result in a perfect score, incorrect responses to one-third of the questions represents an unacceptable level of comprehension.

Tests of Hypotheses

Prior to hypothesis testing, data were explored using SPSS 10.0, (1999) to assure assumptions were met for each statistical test. Assumptions include normality, randomness, homogeneity of variance, and independence. The data followed a normal distribution that was slightly skewed to the right. The assumption of linearity was met as required for correlation. Based on statistical and visual analyses, extreme values did not

qualify as outliers and were not removed from the data analyses. Therefore, all assumptions were met. All hypotheses were tested at the .05 level of significance.

$H_0$1: Learning style preference has no statistically significant effect on comprehension scores. ACCEPTED

An independent t-test was used to determine the effect of being a verbal (n = 20) or visual learner (n = 54) on comprehension scores. Equal variances were assumed based on Levene's test for homogeneity of variance (p = .119). The results (Table 7) revealed no significant difference between comprehension and type of learner (72) = -.532, p = .596.

Table 7

Comprehension Percentage Scores for Verbal and Visual Learners

Learning Type	df	t	p (2-tailed)
Verbal Visual	72	-.532	.596

$H_0$2: There are no significant relationships between verbal learning preference, visual learning preference, and comprehension scores. REJECTED

A Pearson r was calculated to identify any significant relationships between learning preference scores and comprehension percentage scores (n = 84). While the results (Table 8) show no meaningful relationship between verbal learning preference and comprehension scores, a small but significant correlation (r = .214, p = .05) was found between scores for visual learning preference and comprehension.

Table 8

Correlation Between Verbal Learning Preference, Visual Learning Preference, and Comprehension Percentage Scores

Score	x	SD	r	p
Verbal	7.27	14.42	.114	.302
Visual	8.33	1.74	.214*	.050*
Comprehension (%)	71.86	14.42	---	---

Note: *p = .05

$H_0$3: Learning preference is not predictive of comprehension score. REJECTED

As shown in Table 9, a standard multiple regression analysis revealed a small though significant predictive relationship between visual learning style score and comprehension percentage score (r = .214, p = .05). Independence of variables was assumed based on the Pearson correlation between verbal and visual scores (r = -.107, p = .166). No other significant relationships were found.

Table 9

Standard Multiple Regression: Comprehension Percentage Scores, Verbal and Visual Learning Preference Scores

Model	r	r^2	Adjusted r^2	p
1	.214*	.046*	.034*	.050*
2	.255	.065	.042	.066

Note: *p = .05
Model 1 predictor = visual score
Model 2 predictors = visual score, verbal score
Dependent variable = comprehension

Research Question

Suggestions for changes to the consent form to improve understanding of the information were provided by 51 of the participants. A taxonomic analysis was conducted of participant responses to the qualitative research question. As Figure 1 shows, two major themes emerged: (1) elements of the consent form perceived as barriers to understanding and (2) suggestions for additions or changes that would aid understanding.

Too Much (What Impedes Understanding)

In replying to the question of what could be done to improve the consent form, participants indicated aspects of the document that could be categorized as impediments to understanding. These included the length of the document, what they perceived as repetition of information, complexity of wording and sentence structure, typographical errors, and monotony. Respondents described the form as "ambiguous", "boring", "wordy", and "overwhelming" and suggested condensing the form. One participant recommended using two forms—one complete and one with the basics condensed to one page, noting that readers could then decide for themselves how much information they wanted.

Too Little (What Would Aid Understanding)

Though the form as written was described as long and boring, the responses also indicated that participants wanted more specific information in some areas. For example,

the analysis showed respondents wanted more detail about the time commitment for the study and the reasons why the study was being conducted. Participants said they were "unclear on the length of the study" and "not clear on benefits". They were also interested in definitions of medical terms and examples of medications in excluded drug categories (i.e., antihypertensives, corticosteroids). Changes in the format were also recommended such as using charts, lists, graphs, bolding, and larger type.

Figure 1

Theme: Suggestions to Improve Understanding of The Informed Consent Document: Too Much and Too Little

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A. Too Much (What Impedes Understanding)

1. Length
2. Repetition
3. Complexity
4. Typographical errors
5. Monotony

B. Too Little (What Would Aid Understanding)

1. Detail about time commitment
2. Explanation and justification of the research purpose
3. Visual aids
4. Formatting
5. Examples/Definitions

CHAPTER V

SUMMARY, DISCUSSION, CONCLUSION, AND RECOMMENDATIONS FOR FURTHER STUDIES

Even when changes are made to enhance the readability of consent forms, research has shown that comprehension and understanding of the information is poor (Byrne, Napier, & Cuschieri, 1988). To date, little research has focused on possible reasons for findings of differences in levels of comprehension when supplemental materials or alternate methods of information-giving are used in the informed consent process.

Research in the fields of education and psychology has shown that individuals differ in their preferred method of processing information and that their preferred style may impact learning (Das, Kirby, & Jarman, 1979; Van Wynen, 1997). Since instructional methods and learning styles have been found to interact in educational settings (Stawar, Stemm, & Truett, 1992), it is reasonable to hypothesize a link between learning style and comprehension of written informed consent documents.

With this hypothesis in mind, the purpose of this study was to examine whether verbal or visual learning style preference influenced comprehension of information in an informed consent document for research involving human subjects. The convenience sample ($\underline{n} = 84$) was composed of college women age 18 and above who were enrolled in

undergraduate health-related courses at TWU in the spring and May semesters of 2000. After volunteering to participate, the women were asked to read an informed consent document as if they were considering participation in the outlined research project. After the consent forms were read and returned, the participants completed the Verbal and Visual Learning Style questionnaire (Kirby, et al., 1988) followed by a short demographic questionnaire and qualitative research question. Finally, participants completed a multiple-choice test that assessed their comprehension of the information in the consent.

Summary of the Findings

Descriptive statistics for the sample were compiled for age, ethnicity, education level, academic major, and previous exposure to informed consent documents for research. In ancillary analyses, there was no significant difference in comprehension scores by age, education level, academic major, or for participants who indicated they had signed a consent form before and those who had not. Overall comprehension of the consent information was 72% (measured as percentage of correct responses on the multiple-choice test). When participants with a learning style preference (as determined by a greater verbal or visual score) were grouped as verbal ($\underline{n} = 20$) or visual ($\underline{n} = 54$) learners, comprehension scores for the verbal learners did not differ significantly from those of the visual learners. The 10 participants scoring equally on verbal and visual scales were not classified as either type of learner and were thus omitted from this analysis.

The Pearson correlation coefficient was significant ($p = .05$) for visual score and comprehension score, meaning this correlation accounted for less than 5% ($r^2 = .046$) of the total variance in comprehension scores. However, the adjusted r-square, which compensates for the optimistic bias of r-square (SPSS 10.0, 1999) showed even less of the variance accounted for by the verbal learning style preference score. There was no significant correlation between verbal score and comprehension.

Discussion

Though statistical analysis resulted in the rejection of two null hypotheses, the practical impact of these findings is difficult to predict. The generalizability of the findings is limited by small sample size, nonprobability sampling, and the instruments used in the study.

The qualitative analysis supported the findings of other studies. Participants generally agreed that the form was too long and complicated. As Hopper et al., (1998) noted, "a consent form that contains every detail of every eventuality would likely be unread, not understood, and self-defeating" (p. 501). However, in somewhat of a contradiction, the respondents in this study found the form not detailed enough in certain areas. Perhaps participants were more interested in the aspects of the study that more directly affect them, such as time commitments. A surprising finding was that potential volunteers wanted to know more about the purposes of the study, beyond that provided by the required purpose statement. Based on this emphasis and that of time commitments, participants seemed to be looking for information to justify the research and balance that against the time commitment. This finding could be related to the fact

that the research project outlined in the consent form was not a treatment study and offered little in the way of direct benefits to the participant. Therefore, potential research participants might use a different type of risk versus benefit equation in decision-making for non-intervention studies, especially those that are longitudinal in nature. More research in this area should be designed to measure the key aspects of how a person decides to participate in a longitudinal, non-treatment study. These findings could lead to improved trial design, which might lead to increased enrollments, in addition to better understanding.

The findings are further limited by the instrumentation used in the study. The Verbal and Visual Learning Style Preference questionnaire was chosen based on the fact that it was designed to be administered to a group, was short and thus took little time to complete, and had adequate reliability and validity data for college students. However, more information might have been gleaned from the use of another instrument that measured all four learning types: verbal, auditory, tactile, and kinesthetic. This could be especially meaningful as many researchers group verbal learning with visual learning. In addition, the instrument may not have actually measured the constructs of learning preference that directly impact comprehension. As Kirby (1988) wrote "it may be, for instance, that the essence of the 'visual' style is not the visual modality, but rather the type of processing which such input tends to encourage" (p. 182). Future research could control for this possibility with the use of multiple measurements of learning style, larger sample sizes, and random assignment to presentation groups. Different presentation groups could be given the informed consent information using various methods such as

reading only, listening only, reading and listening, or with videos or other supplemental materials. When comprehension scores are compared, main effects and interactions between the various learning style scores and method of presentation might reveal the true relationship this study was just beginning to explore.

The consent form chosen for use in this study could also have affected the outcome. This particular form was chosen based on the fact that it was a consent form that had been approved for use by an IRB and met the federal requirements for informed consent documents. Plus, the consent form described a non-treatment longitudinal study for women, thus making it more plausible for the study participants to read as if they were considering enrolling. Using a consent document that was shorter and written at a lower reading level may have led to significantly different results. However, based on other research in this area, this consent form was typical of those in use throughout the research community.

Additionally, the comprehension test itself could have also led to error in the study findings, although a measure such as this is an accepted method of assessing comprehension (Faden & Beauchamp, 1986). Though it was reviewed for content and face validity, and created in a manner similar to that of other researchers, no item analysis was performed. In addition, the instrument was fairly short and multiple-choice (again due to time considerations and ease of scoring). Perhaps the use of a standardized comprehension assessment could at least decrease the error introduced by this measurement component.

Finally, the question of defining and measuring comprehension is itself a factor in all research conducted in this area. Different researchers define comprehension in different ways, from "understanding" to "recall" to "knowing" (Meisel & Roth, 1981; Silva & Sorrell, 1984). Meisel and Roth recognized that the "threshold problem of any study of what patients understand is to specify what the term 'understanding' means" (p. 2474). However, "recall may not be equivalent to understanding or it may be merely one kind of understanding, and not even the one most relevant to the informed consent issue" (p. 2474). In addition, researchers have found that the timing of the assessment of understanding also makes a difference. For example, in a study of 106 neurosurgery patients, the mean score on testing for immediate retention was 43.5% (Herz, Looman, & Lewis, 1992). Six months later, the score had dropped to 38.4%. However, in a re-analysis of earlier studies, Yanics (1996) found that while recall on some information decreased over time, recall of some of the informational content actually increased with time. Clarification and research of the issues regarding how and when to measure comprehension should result in more meaningful findings in future research in this area.

Conclusion

Within the limitations imposed by this investigation, it can be concluded that learning style preference may have a significant effect on comprehension of information in informed consent documents. Based on the findings of a slight, but significant correlation between visual learning style preference and comprehension score, the role of learning style in the ability to comprehend informed consent documents for research deserves more rigorous and thorough investigation. In addition, if other studies find that

learning preferences do affect comprehension, then methods of increasing comprehension for different learning types need to be explored.

Recommendations for Further Studies

The following recommendations are suggested as the focus of future research:

1. Item analysis of answers to Informed Consent Comprehension Test used in this research to identify trends or relationships.
2. Identify particular aspects of learning at work in reading and comprehending informed consent documents.
3. Define comprehension and the most appropriate time(s) in the process to measure this variable.
4. Using a basic design similar to this study, examine the relationship between learning style and comprehension with larger and more diverse samples, randomization to methods of presentation, and multiple learning styles measurements.
5. Investigate the decision-making processes and determinants involved in decisions to participate in longitudinal, nonintervention studies.

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APPENDIX A

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APPENDIX B

Transcript of Verbal Instructions

My name is Lynda Owen and I am conducting research for my dissertation in Health Education. I am interested in the way that people learn and process information. Completing the questionnaires for this study will take approximately 30 minutes. You have the right to choose not to participate and the right to not answer any questions you choose. However, if you choose to participate, I ask that you complete all of the questionnaires to the best of your ability so that the results—and thus your participation—will be meaningful. I will not collect your names, so please assure that all of your forms are identified with the same ID#. I will be glad to answer any questions you have about the purpose of the research or the content of the questionnaires after all testing has been completed.

For this research, you will be asked to read a document, complete 2 short questionnaires and a demographic data sheet. Total time is about 30 minutes.

Prior to reading consent:

This is a consent form for a research study conducted by the TWU Institute for Women's Health. Please read this entire consent form as if you were considering participating in the study. Please note that you are not being asked to participate in this study and will not sign the consent form. I am only using this document in this study as a research tool. You have 10 minutes to read the form before we continue to the questionnaires.

Prior to Verbal/Visual Learning Styles questionnaire:

Please indicate whether the following statements are True or False for you. If the statement is True for you, then circle T on the answer sheet next to the corresponding number. If the statement is False for you, then circle F on your answer sheet. Please make sure your ID# is entered on the answer sheet. When you are done, please raise you hand.

Prior to Demographic Form:

Please answer each question completely. Please make sure your ID# is entered on the answer sheet.

Prior to comprehension test:

Please circle the one best answer for each question below. These questions are based on the informed consent document you read earlier. Be sure to complete the front and back. Please make sure your ID# is entered on the top of the first page.

After testing:

Thank you for your participation in this research project. I will be glad to try to answer any questions you might have about my research or the questionnaires you completed.

APPENDIX C

TEXAS WOMAN'S UNIVERSITY
SUBJECT CONSENT TO PARTICIPATE IN RESEARCH

TITLE: The Pioneer Project: A longitudinal study to explore the general status of women's health across the life span

PRINCIPAL INVESTIGATOR: C. F. Grant, Ph.D., (940) 898-3967

I am being asked to participate in the Pioneer Project, a longitudinal study of women's health. The purpose of the study is to help us better understand the health status and relationships of components of health among women across the life span. I understand that to be selected as a participant I must be an apparently healthy adult female between the ages of 18 and 60.

If I agree to participate, I will be asked to return to the Pioneer Clinic on the TWU campus to complete physical tests or to complete questionnaires in a location of my own choosing, for as long as the study is funded. The completion of tests at the Pioneer Clinic may require 2 or 3 visits within 4 weeks but this 4 week period will occur no more often that once per calendar year. I will be asked to return to the Pioneer Clinic to complete physical tests in my first year of the research study and then every third year thereafter. I understand that this consent form will be considered valid for a four-year period and that I will be asked to renew my consent by signed a form when I return to the Pioneer Clinic for physical testing.

I understand that my time commitment will be as follows: testing at the Pioneer Clinic on the TWU campus will be approximately 7 hours in the first year. I understand that completion of the questionnaires will require approximately 2 hours of my time but that the questionnaires may be completed in privacy at a location of my choosing. The 7 hours at the Pioneer Clinic will be divided into two or three clinic visits. The second and third clinic visits must be completed within 30 days of the first visit. Testing in subsequent years will take from 2 to 5 hours, depending upon the tests for which I am scheduled in that year.

Exclusion Criteria

I should not participate in this study if:

- I am not a female age 18 to 60
- I am not willing to undergo required testing at yearly intervals
- I do not expect to reside in this geographic area for at least next 2 years

- I am not able to comprehend and give informed consent
- I am not in generally good health

I should not participate in this study:

- If my resting blood pressure is greater than 200 systolic or greater than 115 diastolic
- If I weigh over 275 lbs.
- If I am pregnant or attempting to become pregnant
- If I gave birth in the last 6 months
- If I cannot stand without assistance

I should not participate if I have had any of the following types of surgery:

- Organ transplantation
- Intestinal bypass
- Cardiac bypass
- Heart valve replacement

I should not participate if I am taking any of the following types of mediations:

- Corticosteroids
- Thyroid hormone replacement
- Heart medications
- Anticoagulants (blood thinners other than aspirin)

I should not participate if I have been in a drug research study within the last 90 days.

Procedures and Risks

Privacy

I understand that, due to the ongoing nature of the Pioneer Project, the data will be kept indefinitely. To safeguard my privacy, data will be available only to Texas Woman's University Pioneer Project research staff, the Texas Woman's University Human Subjects Review Committee or to researchers approved by the primary investigator of the Pioneer Project and the Texas Woman's University Human Subjects Review Committee after a written request is made. No other persons will have access to the data without my approval. Pioneer Project data records and questionnaires will contain only subject identification numbers and not my name. All data will be kept in a locked file in a secured room accessible only to the research personnel noted above. A master list that shows my name and my subject number will be kept by the primary investigator and the Texas Woman's University Human Subject's Review Committee. At no time will my identity or my participation in the Pioneer Project be revealed without my express written permission.

Resting Electrocardiogram (ECG)

I understand that I will be asked to undergo a resting ECG. For this test, I will be asked to remove my blouse and bra in private and put on a paper gown. I will lie on a flat padded table. A female assistant, trained in the performance of resting ECGs will apply the ECG electrodes to my chest, arms and legs. I understand that there is no physical risk to me during this test and that I will feel no discomfort or abnormal sensation of any kind from this test.

Graded Exercise Stress Test (Aerobic Capacity Test)

I understand that I will be asked to complete a test on a treadmill to evaluate the maximum amount of oxygen consumed by my body during exercise. I understand that this test will be conducted in accordance with the guidelines for such testing as established by the American College of Sports Medicine (ACSM). I understand that during the test I will be asked to walk on a treadmill. To collect the air that I exhale, I will breathe room air through a rubber mouthpiece and that the air I exhale during the test will be collected continuously. I understand that during the treadmill test, my heart rate will be continuously during the test and that my blood pressure will be taken immediately before and after the test. I understand that, after completion of the exercise stress test, I will be monitored until my heart rate returns to 120 beats per minute or less. The technician will be present at all times while I undergo the stress test. I understand that a physician will be present throughout the test if I am 50 years of age or older.

There exists the possibility that complications may occur during exercise testing. These include, but are not limited to, muscle sprains, strains, tears, soreness, abnormal blood pressure, and, in extremely rare cases, heart attack, stroke, or death. I understand there is a slight risk of tripping or falling off the treadmill. I also understand that any potential risk will be reduced because I am an apparently healthy female and through screening my medical history questionnaire for cardiovascular risk factors and other abnormalities that might exclude me from this particular testing procedure. In addition, my heart rate will be continuously monitored throughout the test, my blood pressure will be taken immediately before my participation in the test and during the recovery period following the exercise test, and there will be a trained technician in attendance at all times during the test.

Bone Density Measurements

I understand three methods of testing for bone density will be used in this study. An FDA-approved bone density machine, the Lunar IQ, will be used for measurement of the lumbar spine (lower spine), femoral (upper thigh bone), and total body bone mineral density. I understand that I will be

asked to lay face up, fully clothed, on a padded table for about 15 minutes while the scans are made. I understand that another FDA-approved bone density machine, the Norland pDEXA, will be used for measurement of forearm bone density. I understand that, for this test, I will sit in a chair and place my bare forearm on the device, and I will be asked to remain still during the 5- minute test. I understand that an FDA-approved bone density machine, the Norland OsteoAnalyzer, will be used to measure the bone density of the heel. I understand that this test requires me to sit in a chair and place my heel in a water-filled well, and that I must remain still for the duration of the 5-minute test. I understand that a registered technician will perform all bone density measurements, and that I will feel no pain or any other sensations due to the testing.

I understand that these bone density measurements expose me to a small amount of radiation. The risk from the exposure to radiation from the X ray during the bone density tests is very small. The amount of radiation from the bone density test of the spine is 1 microSievert. For the proximal femur bone density test it is also1 microSievert and for the total body bone density test, it is less than 1 microSievert. During the forearm bone density test and the heel bone density test, the radiation exposure is considered biologically negligible. For the sake of comparison, I understand that I would receive a radiation exposure of approximately 80 microSieverts on a transAtlantic airline flight of 8 hours or a dose of 50 microSieverts by staying in a location such as Denver Colorado at an elevation of 5000 feet for approximately 4 weeks. I understand that natural background radiation is approximately 200 microSieverts per month. I understand that if I am pregnant, or trying to become pregnant or suspect any irregularity in my menstrual cycle that might indicate that I am pregnant, I should inform the researchers and that I should <u>not</u> have bone density measurements performed.

<u>Blood and Urine Tests</u>

I understand that I will have blood and urine tests during the first year of the study and periodically thereafter. I understand that I will be asked to take nothing by mouth other than water for 12 hours before the blood is drawn. I understand that the blood samples will be taken from a vein in my arm. The amount of blood drawn will be approximately 3 tablespoons. I understand the risks involved with this procedure include redness, swelling, bruising, and slight discomfort at the site of the blood draw. I also understand there exists the possibility of infection at the site from which the blood is drawn. To minimize these risks, proper techniques for equipment sterilization and storage, as well as cleaning the venipuncture site before the blood draw and applying a bandaid after the draw, will be utilized. There is also the risk of fainting in association with having blood drawn. I understand that I will be asked to provide a urine specimen that I will collect in privacy while at the Pioneer Clinic. Blood will be tested for diabetes and cholesterol abnormalities. Blood and urine specimens

will also be frozen for additional testing when funds become available. This testing will not be done without my additional written consent however.

Questionnaires

I understand that I will be asked to complete questionnaires as part of the Pioneer Project testing. I understand that I will have the opportunity to answer the questionnaires in private and that only my study code number, and not my name, will appear on the questionnaire. I understand that I may complete the questionnaires at the Pioneer Clinic or at a private location of my own choosing. Research personnel will be available in the Pioneer Clinic to answer any questions I may have regarding the completion of the questionnaires.

Personal, family and reproductive medical history questionnaire. I understand that I will be asked questions regarding past and present personal and family medical history and my personal reproductive medical history for the purpose of determining current and past health status and identifying any familial tendencies for diseases. After the first year of the study, I will be asked to complete an interim personal, family and reproductive medical history questionnaire each year.

Cooper Clinic Exercise/Physical activity questionnaire. I understand that I will be asked questions regarding general daily activity patterns for the purpose of determining daily caloric expenditure, general physical activity, and exercise habits, and exploring their relationship to other components of health. I will be asked to complete this questionnaire during the initial testing and then every third year.

Thoughts and Feelings questionnaire. I understand that I will be asked questions for the purpose of assessing general mental/emotional health status of women across the life span and to explore potential relationships between mental health and other components of health and lifestyle. I will be asked to complete this questionnaire during the initial testing and then every third year.

Personal Habits and Lifestyles questionnaire. I understand that I will be asked questions regarding lifestyle behaviors and major health risks for the purpose of better understanding the relationships between lifestyle and disease. I will be asked to complete this questionnaire during the initial testing and then every third year.

Benefits to Participants:

I understand that I will receive the following benefits by my participation in this study:

- I will receive valuable tests and screenings at no monetary cost to me
- I will receive reports of the current findings of the study
- I will have the opportunity to contribute to the advancement of women's health as part of the largest comprehensive, longitudinal study on women's health, to date.

If I have any questions about the research or about my rights as a subject, I should ask the researchers: their phone numbers are at the beginning of this form. If I have questions later, or wish to report a problem, I may call Ms. Tracy Lindsay in the Office of Research and Grants at Texas Woman' University at (940) 898-3377.

The researchers will try to prevent any problem that could happen because of this research. I should let the researchers know at once if there is a problem, and they will help me. I understand, however, that TWU does not provide medical services or financial assistance for injuries resulting from my voluntary participation in this research study.

Voluntary Participation / Withdrawal

I understand that my participation in this study is voluntary. I may decide at any time not to participate or to discontinue my participation in this study without any loss of benefits to which I am otherwise entittled.

I also understand that this study may be stopped at any time because or reasons beyond my control. I also understand that the primary investigator may withdraw me from the study if the investigator believes that it is not in my best interests to continue in the study.
This study, including its risks and benefits, has been explained to me to my satisfaction. I have been given the opportunity to have my questions answered to my satisfaction. I have read and I understand the information in this consent form. I voluntarily agree to participate in this research study. I understand that I will be given a copy of the dated and signed consent form.

_____ _____

Participant's Signature Date

APPENDIX D

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APPENDIX E

Verbal and Visual Learning Styles

(J. R. Kirby et al., in *Contemporary Education Psychology*, Volume 13, 169-184.)

Instructions: Please indicate whether the following statements are True or False for you. If the statement is *True* for you, then circle T on your answer sheet. If the statement is *False* for you, then circle the F on your answer sheet.

1. I have always disliked jigsaw puzzles
2. I enjoy doing work that requires the use of words.
3. I enjoy learning new words.
4. I find illustrations or diagrams help me when I'm reading.
5. I prefer to read instructions about how to do something rather than have someone show me.
6. I have better than average fluency in using words.
7. I don't like maps or diagrams in books.
8. I can easily think of synonyms for words.
9. I dislike looking words up in dictionaries.
10. I have a hard time remembering the words to songs.
11. I don't believe that anyone can think in terms of mental pictures.
12. When I read books with maps in them, I refer to the maps a lot.
13. I read rather slowly.
14. I have a hard time making a "mental picture" of a place that I've only been to a few times.
15. I seldom use diagrams to explain things.
16. I like newspaper articles that have graphs.
17. The old saying "A picture is worth a thousand words" is certainly true for me.
18. I spend little time attempting to increase my vocabulary.
19. I dislike word games like crossword puzzles.
20. I find maps helpful in finding my way around a new city.

The return of your completed questionnaire constitutes your informed consent to act as a participant in this research.

Answer Sheet **ID#:**_____

1.	**T**	**F**
2.	**T**	**F**
3.	**T**	**F**
4.	**T**	**F**
5.	**T**	**F**
6.	**T**	**F**
7.	**T**	**F**
8.	**T**	**F**
9	**T**	**F**
10.	**T**	**F**
11.	**T**	**F**
12.	**T**	**F**
13.	**T**	**F**
14.	**T**	**F**
15.	**T**	**F**
16.	**T**	**F**
17.	**T**	**F**
18.	**T**	**F**
19.	**T**	**F**
20.	**T**	**F**

APPENDIX F

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APPENDIX G

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APPENDIX H

The return of your completed questionnaire constitutes your informed consent to act as a participant in this research.

Demographic Data Sheet ID#: _____

Instructions: Please answer each question completely. Do not put your name on the form.

1. Age: _____

2. Classification: Freshman _____ Sophomore _____
   Junior ____ Senior ____
   Graduate _____ Years of Graduate Study ___

3. Major: _____

4. Gender: Female _____ Male ____

5. How do you describe your ethnic origin? (You may mark more than one)

   ___ Asian/Pacific Islander ___ Black
   ___ Caucasian (non-Hispanic) ___ Scandinavian
   ___ American Indian ___ Hispanic
   ___ Other (please specify _____)

6. Have you ever read or signed an informed consent document for a research study?
   Yes ____ No ____
   If yes, can you give details? (Where, when, what type of research?)

7. Please list **at least one** suggestion you would give to make the consent form you read easier to understand. (Please use the back of the page if you need more room.)

Thank you for your time and participation!!

APPENDIX I

Informed Consent Comprehension

ID#: _____

Please circle the one best answer for each question below. Questions are based on the informed consent document you read earlier. Be sure to complete front and back.

1. What is the purpose of this study?
   a. To study the health status of pre-menopausal women
   b. To better understand the health status of women across the lifespan
   c. To collect data for future studies with post-menopausal women

2. Which risk is involved in Aerobic Capacity Testing?
   a. Tripping or falling
   b. Exposure to small amounts of radiation
   c. Bruising from blood draws

3. What does your participation in this study involve?
   a. 2 or 3 visits to the clinic for the entire study
   b. 2 or 3 visits to the clinic over 4 weeks
   c. 2 or 3 visits to the clinic per year

4. Approximately how long will your participation in this study take?
   a. 7 hours for 2-3 visits
   b. 4 hours for 2-3 visits
   c. 5 hours for 2-3 visits

5. When can you withdraw from this study?
   a. Not until the study is finished
   b. Whenever I choose
   c. After I have completed the first year of testing

6. How will your name be associated with the study data?
   a. On all my study forms
   b. On data reported to journals
   c. On a list kept by investigators

7. With whom will the study information not be shared?
   a. Faculty researchers
   b. Project Research Staff
   c. Human Subjects Review Committee

8. What direct personal benefits will come to you as a result of participating in this study?
   a. Monetary compensation
   b. Payment for injuries
   c. Test results

9. Who may not participate in this study?
   a. Women over age 50
   b. Women taking vitamins daily
   c. Women with diabetes

10. How much radiation will participants be exposed to during bone density testing as compared to a transatlantic airline flight of 8 hours?
    a. Less radiation
    b. More radiation
    c. The same radiation

11. When will urine collected during the study be tested?
    a. Routinely with bloodwork
    b. Only with my additional consent
    c. When I develop a new medical problem

12. What risk might you experience during the resting ECG (electrocardiogram)?
    a. Abnormal sensations
    b. Slight discomfort
    c. No physical risk

13. What is the status of the machines used for bone density testing?
    a. Approved for experimental testing
    b. FDA approved for testing
    c. Not approved for testing

14. What amount of blood will be drawn for testing?
    a. 3 teaspoons
    b. 3 tablespoons
    c. 3 tubes

15. Who should I contact if I have questions about my rights as a research subject?
    a. Texas Department of Health
    b. Office of Research and Grants
    c. Office for Protection from Research Risks