

1-1-2001

Variables that affect the amount of the consent that clinical research subjects read

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VARIABLES THAT AFFECT THE AMOUNT OF THE CONSENT
THAT CLINICAL RESEARCH SUBJECTS READ

by

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Bachelor of Science
University of Nevada, Las Vegas
1994

A thesis submitted in partial fulfillment
of the requirements for the degree of

**Master of Science Degree
Department of Nursing
College of Health Sciences**

**Graduate College
University of Nevada, Las Vegas
May 2001**

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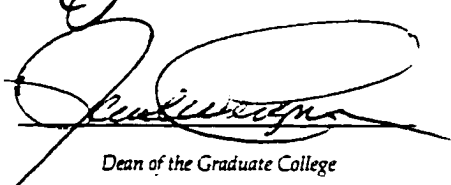
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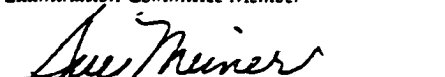
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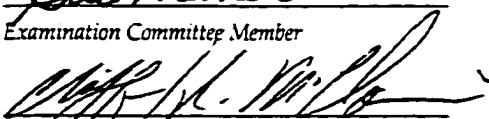
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ABSTRACT

Variables That Affect the Amount of the Consent That Clinical Research Subjects Read

by

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Professor of Nursing
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Various codes, regulations and guidelines have been established that outline what information must be provided to human subjects to insure that their participation in clinical drug studies is informed as well as voluntary. Recently questions have been raised as to whether written consent forms guarantee participants are making autonomous, informed decisions. The purpose of this study was to determine how much of the consent research subjects read in relation to selected variables. Seventy-seven percent of the participants reported that they read the entire consent form, but results suggest that 30-40% may not understand the study they are in. A question not answered is, do research subjects in clinical drug studies know information pertinent to the study in which they are participating.

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ACKNOWLEDGMENTS

I want to thank my Chairperson and friend Dr. Margaret Louis, Ph.D. for her time, expertise and encouragement. This paper would not have been completed without her support. Also, thanks to my other committee members for their time and guidance.

Finally, thank you to my family and friends you have my love and gratitude for being there whenever I needed you.

CHAPTER 1

INTRODUCTION

Background and Significance

**“Any Research Project Utilizing Human Subjects Requires
the Informed Consent of Those Subjects”**

(Federal Regulations Governing Human Experimentation, 46.116)

The Doctrine of Informed Consent was created to protect the rights and welfare of human subjects participating in clinical research. Various ethical codes, federal and state regulations and professional guidelines have been established that explicitly outline what information must be provided to human subjects to insure that their participation is informed as well as voluntary (Piper, 1994, Cassidy & Oddi, 1986).

Informed consent is a concept developed from the moral principal of self-determination or autonomy (Roach 1990). “Autonomy means that persons have the right to determine their course of action on the basis of a plan that they have developed for themselves” (Davis, 1989, p.448). Additionally those patients who acquire more information are able to make better decisions (Beisecker & Beisecker, 1990). “Despite the fact that many individuals express a desire for more information and involvement in the health care process, it remains to be seen if they have adopted a more participative approach by becoming involved in decisions made about their health” (Brashers, Haas & Neidig, 1999, p.97). Research shows that not all individuals are willing or able to

actively participate in health care decision making (Brashers, Haas & Neidig, 1999; Beisecker & Beisecker, 1990; Hinckly, Craig & Anderson, 1989).

There are several ways to obtain a subject's consent, but almost all of them involve written documentation (Federal Regulations Governing Human Experimentation, 46.117(a), so the most common method of obtaining informed consent is through the use of written consent forms. However, questions recently have been raised as to whether or not this method guarantees that research subjects are making autonomous, informed decisions (Tenthorey, & Dison, 1996; Marwick, 1998; Energy Times, February, 2000).

Problem

A recent article indicated that research subjects typically read less than fifty percent of a written consent form (New York Times, May 1999). There are several results from this: Subjects are not truly knowledgeable about the study they are agreeing to participate in, dissatisfaction with the consent process, lawsuits by clinical research subjects (Kaplan & Brownlee, 1999; Las Vegas Review-Journal, December 9, 1999), and in extreme cases even injury or death (Las Vegas Review-Journal, May 24, 2000).

Significance

The need for the protection of human subjects involved in research was brought to the world's attention after World War II, during the Nuremberg trials. The first effort to establish formal ethical standards for human subjects research is known as the Nuremberg Code (Iserson, 1999). Nearly every major ethical code or guideline for human research developed since the Nuremberg trials has been based, at least in part, on

the Nuremberg principles. It is only in the last 20 years that most of these codes and guidelines have been enacted (Grundner, 1986).

Despite the existence of regulations, codes, and guidelines, abuses in human research continue to take place. In 1963 twenty-two subjects were injected with live cancer cells without being informed at the Jewish Chronic Disease Hospital in New York (Grundener, 1986). An audit by the Food and Drug Administration of studies conducted between 1977 and 1983 revealed that more than 10 percent of clinical drug studies had deficiencies in one or more of the following areas: subjects' consent, accountability for drugs, adherence to research protocol, and accuracy or availability of protocols for the study (Hammerschmidt, 1992). Recently the problems with patients rights have resulted in the closure of studies at well-respected universities: Duke and the University of Pennsylvania (Kaplan & Brownlee, 1999; "FDA: Teen too sick", 1999).

One of the methods developed to protect the rights of research subjects is the informed consent document. The goal of this document is to provide potential research subjects with all the information they need to make an informed autonomous decision about participating in a research trial.

Nurses working in the field of clinical research often have the responsibility of administering the informed consent document and insuring that potential research participants understand the information in the consent prior to signing it. The problem is that even with encouragement potential subjects do not always read the entire clinical drug trial consent form.

Purpose

The purpose of this study was to identify how much of the consent form clinical research subjects read when they agree to participate in clinical drug studies. An additional goal of this study was to learn more about why research subjects read or do not read all of a consent form.

CHAPTER 2

REVIEW OF RELEVANT LITERATURE

Introduction

A review of the relevant literature covering clinical drug studies was conducted to identify which variables were most likely to have an influence on the amount of the informed consent that was read. A brief historical overview of the development of informed consent in clinical drug trials is presented first to give the reader background on informed consent and protection of subjects rights.

Historical Overview

The Federal government regulates clinical research involving human subjects by enacting a statute (law) and then delegating to a government agency the responsibility to define and enact the law by issuance of regulations (Wing, 1985). These regulations, authorized by statute, are published (Annas et al., 1981) and implemented under statutory law. Such regulations are part of that law and violation of the regulation is a violation of the law (Wing, 1985).

In the United States federal regulation of research was originally done by the Department of Health, Education and Welfare (now the Department of Health and Human Services,DHHS). Its actions and authority are in accordance with its powers under the Public Health Act to regulate the research for which it provides funds. The

Federal Drug Administration and the Public Health Service (PHS) are agencies of the DHHS whose regulations are now the standard for protecting human subjects in the United States (Veatch, 1987). These regulations go beyond the standards set by the Nuremberg Code and the Declaration of Helsinki, specifically regarding the requirement that all investigations be reviewed by an independent committee prior to being started. In addition, the FDA establishes standards for the research protocols that it will accept as evidence of the safety and efficacy of drugs (Hershey & Miller, 1976).

The Food and Drug Administration (FDA) is the agency responsible for consumer protection in the use of cosmetics, foods, and drugs, and was the first agency in the DHHS to regulate clinical investigations. The first congressional policy on informed consent was the Drug Amendment Act of 1962 that came into being after the Thalidomide disasters (Oddi & Cassidy, 1998). The Kefauver-Harris amendments of 1962 required that informed consent be obtained from potential human subjects prior to their participation in the testing of investigational drugs. These amendments were limited though because the FDA did not want to interfere with doctor-patient relations and waived consent if the doctor did not believe it was in the patient's best interest to know he/she was in a study, or if it was not feasible to gain informed consent from subjects (ACHRE Report p.1). Formal department policies were published in 1967, and additional regulations were added in 1971 (Hershey & Miller, 1976) that covered potential subjects rights.

In 1974, Title II of the National Research Act was signed into law. This act established a National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research to investigate, develop guidelines, and make recommendations

concerning human subjects involved in research sponsored by the federal government (Veatch, 1987). Proposals by this commission were part of the 1981 regulations published by the DHHS. This commission also identified three moral principles, known as the Belmont principles, as the framework for guiding the ethics of research involving human subjects. The Belmont principles are respect for persons, beneficence, and justice. The commission was required to examine the “nature and definition” of informed consent and argued that the basic justification for the obligation to obtain consent is the moral principle of respect for persons (ACHRE chap 3).

In 1995 President Clinton established the National Bioethics Advisory Commission (NBAC) to review how human subjects rights were protected. The Office for Protection from Research Risks (OPRR) is within the National Institute of Health which funds much of the research that OPRR oversees. OPRR was criticized by the NBAC for its lack of ability to carry out investigations (Marwick, 1998).

In addition to federal standards, professional organizations have established guidelines for clinical and other research. One organization, The American Nurses’s Association, has developed standards for nurses conducting research which includes the “Code for Nurses With Interpretive Statements” and the “ANA’s Human Rights Guidelines for Nurses in Clinical and Other Research” (ANA Guidelines on Ethical Values, Nursing Research 1968).

Some states have also developed regulations governing human research, but state regulations tend to focus on specific issues rather than broad areas. California statutes are found in the California Penal Code, 1977, and the California Health and Safety Code 1978. New York has Public Health Laws published in 1975 concerning human research.

One thing that federal laws, state laws and professional guidelines have in common, is that they all emphasize that research can be conducted only after informed consent is obtained, which is the “autonomous authorization by individuals of a medical intervention or of involvement in research” (Beaucham & Childress, p. 143 1994).

The specific federal laws that govern informed consent are found in the Code of Federal Regulations, Title 21, parts 50, 56, and 312, revised April 1, 1998. Part 50, Subpart A defines the scope, what or who the regulations apply to and also gives definitions. Subpart B deals specifically with the informed consent by human subjects, general requirements for informed consent, exception from general requirements, exception from informed consent requirements for emergency research, elements of informed consent, and documentation of informed consent. Subpart B, 50.20 states that “no investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject’s legally authorized representative”. Additionally “the information given to the subject or the representative shall be in language understandable to the subject or the representative”. Subpart B, 50.27 states that except in certain cases outlined in 56.109, informed consent shall be documented by the use of a written consent form, and either the subject or the subject’s representative shall have adequate opportunity to read the consent form before it is signed.

The above provisions are pertinent to this paper because they specifically outline what written information must be given to a potential research subject and how it should be given. The problem remains, however, that even if adequate information is provided, subjects who do not read or understand the information can not give true informed

consent . The next sections discuss factors that have been found to impact comprehension of what people read.

Comprehension Factors

Informed consent forms are used to convey information to potential research subjects so they can reach a decision about whether they should participate. Department of Health and Human Services Regulations for the Protection of Human Subjects require that study information be presented at a level that is easily understood by the subjects who will be reading it (Tarnowski, Allen, Mayhall and Kelly 1990). The next sections offer factors that have been identified as affecting reading comprehension and have potential to prevent or impede a potential subject from reading an informed consent document and understanding its content.

Readability

Readability is the reading grade level required to understand any given document (Grundner, 1986) and may influence how much of a consent form is read. Spadero (1983) found comprehension tests showed that about 50% of patients in general were not able to read, or had difficulty reading instructional materials written at the fifth grade level or greater. The study findings were that readability of the written patient material showed most to be above the eighth grade level. Goldstein, Fraiser and Curtis (1996) reviewed 284 consent forms for clinical research and he found that the average form was written at a twelfth grade level, with less than ten percent written at the tenth grade level or below. Another study using the Gunning Fog Index and Flesch-Kincaid Formulas for readability found that 100% of the 137 consent forms for research studies analyzed were

written at grade level 11.1 to 14.1 (Grossman, Piantadosi and Covahey 1994).

Seventy-one consent forms selected from research proposals on IRB agendas had grade level fifteen as the norm, and of sixty-four proposals approved only eleven had improved readability as recommended (Hammerschmidt, 1992).

Studies by Lawson and Adamson (1995), LoVerde, Prochazka and Byyny (1989), Morrow (1980) and Murgatroyd (1991) reached similar conclusions as the before mentioned studies, that the readability of informed consent material was at a grade level higher than that attained by the average research subject. Only two studies found no or only slight problems with readability. An attitudinal survey of 45 oral surgeons in Canada found that only 63% percent of their patients could both read and understand consent forms used by the surgeon (Freedman & Dunn, 1984).

An additional problem with readability is that self-reported educational status may not accurately reflect actual reading ability. Even when patients correctly report last grade completed in school this does not indicate actual reading ability (Davis et. al., 1991, Davis, Long, Jackson, Mayeaus 1993). Patients in studies by Davis, Doak, Jacson and Gault read four to five grade levels below the last grade they attended (Murphy, Cavis, Long, Jackson, Decker 1993).

The importance of readability is that written informed consent documents are used to covey specific study information. If the information is not at a level that is easily understood by the potential subjects he/she may not be able to arrive at an informed decision concerning their willingness to participate.

Format

A second variable that may influence how much of the consent form is read is the format. Format refers to the way the consent is arranged and can include type size, order, spacing, font, and style. Taub, Kline, and Baker (1981) discussed size of typeface as a potential problem for older volunteers. A later study by Taub and Sturr (1990) again identified format problems with older subjects due to vision problems. Length of the form has also been found to affect reading in a study of patients in chemotherapy trials when 75 women were tested for their preferences for short, medium, or long consent forms. Most patients preferred long forms with more information but those receiving the long forms had the most difficulty answering basic questions about the study (White, Muss & Micheiutte, 1984).

Another area identified by Cardinal, Martin and Sachs (1996) was that most forms were not “user-friendly”. That is they do not use formats such as double spacing and large type size. Epstein and Lasagna (1996) gave consent forms of different lengths to 66 subjects, and concluded that comprehension and retention was greatest when the information was clearly and briefly stated.

A study by Peterson, Clancy, and Champion (1992) used computer programs to improve the readability of consent forms. The computer corrections gave little improvement in readability scores but evaluations by volunteers rated the graphically improved versions as easiest to comprehend.

The importance of format is similar to the importance of readability. If the consent form is a written document and because of print size or other problems with format the information is not easily understood it can interfere with potential research

subjects understanding the information they need to make an informed decision.

Comprehension

Comprehension is the measure of the understanding of the information potential subjects have received. A review of the literature on comprehension of informed consent documents confirmed that research subjects do not have enough understanding of what they read to make informed decisions. Miller, Searight and Grable (1994) conducted a study of 168 patients enrolled in a clinical trial. A telephone survey was used to evaluate recall of study information from the informed consent. Most patients rated themselves as well-informed about the study but were not able to recall important study information.

Fifty patients participating in twenty-three different research protocols were evaluated for understanding of the consent forms and only one-half were rated as adequately informed (Schultz, Pardee & Ensinnck 1999). A study, conducted in Veterans Administration hospitals involving 156 research patients, revealed that of 40 consent forms analyzed, a college-level education on the average was required for adequate comprehension (Riecken & Ravich, 1982). McCormack, Evoy and Mulcahy (1997) tested 50 patients who had consented to orthopedic procedures during their post-operative stays. Most of the patients showed limited understanding of the terminology used in the consent forms they had signed, indicating they may have consented to procedures they did not really understand. Waggoner and Mayo, (1995) and Waggoner and Sherman (1996) conducted studies to evaluate the understanding of 25 commonly used words in clinical research consent forms. The first study involved 287 subjects, the second 302 subjects. In both studies, understanding of the words was highly variable with those subjects who had higher educations doing better overall.

Problems with readability and format can prevent potential research subjects from receiving important study information. Research on comprehension is important since it has been shown that readability as the sole measure of patients' comprehension of medical consent forms is not a sufficient measure of potential research subjects ability to understand the information that is provided in the informed consent process (Mariner & McArdle, 1985).

Subject Satisfaction

The literature also suggests a relationship between satisfaction with the research study and the participant's knowledge of the study. Research concerning subject satisfaction with the consent process was found in only three studies. Tabak (1995) interviewed 66 patients, most stated they did not have sufficient time to decide if they wanted to participate, and a small majority responded they felt pressured to consent. Verheggen, Jonkers and Kok (1996) interviewed 198 patients involved in clinical trials in the Netherlands. Overall the patients reported being satisfied with both oral and written consent procedures. Williams, French and White (1997) surveyed fifty-nine patients who were asked to participate in a clinical trial and they stated they were satisfied with their decision to participate.

Consent Process

Another variable that may influence how much of the consent form is read is the process, specifically how the form is presented to a potential subject. Morrow, Gootnick and Schmale (1978) did not determine how much of the form 77 subjects read, but did report a higher comprehension in patients who took the form home to read prior to consenting. In contrast to the Morrow, et al's findings, no difference was found in

comprehension scores or level of satisfaction between two groups of out-patients who either received a consent form 24 hours before the procedure and those who received it immediately before the out-patient procedure (Neptune & Hopper 1996).

Patient Advocacy

A final factor that may influence the amount of the consent form that is read by potential clinical research subjects is their degree of patient advocacy. Stress caused by chronic or life-threatening illnesses can cause a “self-help” response (Brader, 1990) in which patients are more likely to become “activists” or active agents (Thouts, 1994) in managing their illness. Brashers and Klinge (1992) maintain that activists are more involved in decisions about their health care. This involvement can be described as self-advocacy. Self-advocacy behaviors are used to represent “one’s own interest in decision-making processes” and can result in a change in physician-patient interactions (Brashers, Haas & Neidig, p. 99, 1999).

Ballard-Reisch (1990) suggested a model of physician-patient interaction that would be different from the traditional encounter where the physician has the power over the patient. She purposed that physicians and patients share responsibilities for decisions using open communication. Beisecker and Beisecker (1993) see this change in communication style between physician and patient as a shift from a paternalistic to a consumeristic model of interaction. They also suggested that individuals following the consumeristic model desire more information from their health care provider.

Related to self-advocacy is the level of desire to participate in medical decision making by patients. Strull, Lo, and Charles (1984), assessed patient’s preferences for participating in medical decision making. Of 210 hypertensive patients interviewed less

than half of the patients requested more information about their disease. In this study it was determined that clinicians overestimated their patients desire to be involved in therapeutic decisions.

Robinson (1986) analyzed taped informed consent discussions with 644 patients prior to cardiac surgery. Twenty-five percent of the patients refused to hear part or all of the informed consent information. Beisecker and Beisecker, (1990), Thompson, (1994), and Waitzkin (1985) question whether patients are taking a more participative approach in decision making about their health despite the fact that patients express a desire for more information. Research by Hinckley, Craig and Anderson (1989) indicates that in actual practice the majority of patients are not willing or able to take an active role in health care decision making. Of the patients who do desire more information about health care and participate more in the decision-making process about care Beisecker and Beisecker (1993) saw a switch by these patients from a paternalistic to a consumeristic model of decision making. Braden (1990), described a “self-help” response to chronic or life-threatening illnesses where patients were more likely to become “active agents” related to their illness. Even though it is recommended that patients should become more involved in health care decisions little research has been done to determine if patients are or desire to be more active (Brashers & Klinge, 1992).

Summary

The extensive literature search of Medline, Cinahl and government Internet sites found only a small number of studies addressing how much of the informed consent document is actually read by clinical research subjects. Of the studies that were found it

can be concluded that research subjects have limited understanding and comprehension of the study they are agreeing to participate in if they do not read the informed consent document. This also means they can not give true “informed” consent to participate. These findings are supportive of a need for further study to better understand why research subjects do or do not read consent material and how it may affect subject satisfaction with the study as well as impacting study data.

CHAPTER 3

FRAMEWORK

This chapter presents the theoretical framework used in this study, research questions, theoretical definitions, operational definitions and assumptions.

During the review of literature variables were identified that might influence how much of the informed consent document is read by potential research subjects. The type of relationship potential research subjects have with their health care providers has been suggested as one of the variables that influence how much of the consent form is read. Asymmetric or paternalistic interactions where the health care provider has the majority of influence in the encounter is usually the most common type of interaction (Guttman, 1993; Treichler, Frankel, Kramer, Zoppi, & Beckman, 1984). However the relationship can vary between the extremes of paternalism and consumerism (Gadow 1983).

The Existential Advocacy model proposed by Gadow (1983) was chosen as the framework for this study because it stresses the principle of self-determination in patient health care decisions while allowing for a variety of interaction types. Gadow proposes that in “any given encounter the patient and nurse can freely decide whether their relationship shall be that of child-and-patient, client-and-counselor, friend-and-friend, colleague-and-colleague, and so on through the range of possibilities” (p. 42). The type of relationship may determine how much information the potential subject wants to receive.

Theoretical Framework

Gadow defines existential advocacy as “the nurse’s assistance to individuals in exercising their right of self-determination, through decisions which express the full and unique complexity of their values” (1983, p.55). Informed consent can be defined as the consent of an individual or his or legally authorized representative to participate in research without undue inducements or any form of fraud, deceit, duress, or other constraint or coercion (Southwick, 1988; Bok, S. 1992). Government regulations mandate what information must be presented to the potential research subject to enable them to give informed consent. Legal obligations can be met by giving information to potential research subjects in the form of a written document (Code of Federal regulations, Title 21). However, the review of literature has identified several variables that can interfere with potential subjects receiving the information that they need to make a truly informed consent. Gadow recognizes that there are a variety of interaction types between health care providers and patients because each patient has “unique strengths and complexity” (1983 p. 43).

Gadow states that the concept of existential advocacy is the “opposite of paternalism”. She defines paternalistic acts as those which “limit the rights of individuals in their own interests”(p.43). Another view of paternalism is that it is sometimes better for the patient if the person who makes the decisions is the one who is most knowledgeable in the situation. The intent of informed consent is not met during a paternalistic type interaction.

Although advocacy is opposite from paternalism it is not consumerism. Gadow considers consumerism a form of paternalism where individuals must make decisions

with “technical” assistance only, where information is given but no recommendations are provided. Existential Advocacy’s goal is to “help persons become clear about what they want to do” by being interested in the other’s good more than their own (Gadow p.44-45).

The object of this study was to determine if subjects made informed consent decisions to participate in clinical drug studies based on how much of the consent form they read and their level of self-advocacy. According to Gadow’s self-advocacy framework the potential subject has varying needs at any given time concerning the amount of help needed for informed decision making.

Research Questions

Research questions for this study were developed from Gadow’s theory of Existential Advocacy (1983) and findings from the literature review.

1. How much of the written consent form do clinical research subjects read?
2. What is the relationship between how much of the consent form clinical research subjects read and self-advocacy?
3. What is the relationship between how much clinical research subjects read and the variables of sex, age, ethnic group, gender, marital status, educational status and occupation?
4. What reasons do clinical research subjects give for reading or not reading the informed consent document?
5. Do clinical research subjects who read all or nearly all of the consent form have different reasons for participating in clinical research trials than those who indicate that they read little or none of the consent form?

Definitions

Informed consent is the intentional autonomous authorization, with substantial understanding and lack of substantial control by others (Beauchamp & Childress, 1994). Informed consent was operationalized in the clinical drug studies as the process of receiving, reading, and signing the study information (Beauchamp & Childress, 1994). It was fulfilled if a research subject received a consent document that had been approved by an institutional review board after fulfilling all government and or local regulations. A witnessed signature on the informed consent was necessary, but no requirement to verify that the consent was read, or was understood.

Existential advocacy is a process that involves the nurse and the patient deciding what the relationship will be in health care encounters (Gadow, 1983). The patient and health care provider's relationship can vary from paternalism to consumerism (Brashers, Haas & Neidig, 1999). Existential advocacy was operationalized by the summed score from the participants responses on the Patient Self-Advocacy Scale which measured the level of self-advocacy on a continuum from paternalism (not an advocate) to consumerism (active self-advocacy).

Clinical research subject is an individual participating, or who has participated in a pharmaceutical drug study.

Readability is the reading grade level required to understand an informed consent document.

Format is the way the consent form is arranged including type size, order, spacing, font and style, measured by question two in the demographic data form.

Comprehension is understanding of information presented in an informed

consent document, measured by question three in the demographic data form.

Subject satisfaction is whether or not clinical research subjects received the amount of information about a study that they desired, measured by question seven on the demographic data form.

Assumptions

Study participants will honestly answer questions regarding how much of the consent form they read and why or why not.

Summary

Existential Advocacy was chosen as the framework for this research study because it stresses the principle of self-determination in patient health care decisions. Research subjects have the right to know what they are getting into and the right to say no for good reasons, bad reasons or no reason and the consent process has been developed to insure that this right to make an independent decision is honored.

CHAPTER 4

METHODOLOGY

This chapter describes how the study was conducted. The subsections covered include study design, population, sample, setting, procedure, tools, statistics, and human subject rights.

Design

A comparative descriptive design that examines and describes “differences in variables in two or more groups that occur naturally in a setting”, was used (Burns & Grove, 1997). The design was used to examine and describe differences in variables between those subjects who read all of the consent form and those who did not read all of the consent form.

Population

The target population was any person age 50 to 75, who signed an informed consent document and agreed to participate in a clinical research trial for a pharmaceutical company. Excluded groups were vulnerable populations, cancer and HIV trial participants. The accessible population was people who had signed an informed consent document within the previous year and agreed to participate in a clinical research

trial, were still participating in the research trial and were being seen at one of the three research centers where data were collected.

Sampling

Convenience sampling was used to identify the first one hundred usable responses by people in the before mentioned groups who volunteered to be part of this study.

Setting

The sample was obtained from three privately owned for profit research centers located in Ohio and Nevada. The three sites were similar in size, subject population, had a single investigator and two research coordinators. Persons asked to participate in this research study were subjects enrolled in the same clinical drug trials and who had the same informed consent documents.

Procedure

Research subjects who were currently taking part in a clinical drug trial were approached after all visit procedures were completed when they came to one of the centers for their regularly scheduled appointment. The purpose of this study was explained to the subject by a research coordinator who was trained by the principal investigator. The same procedure was followed at each site. If the person expressed interest in participating in this study they were given a consent document to read. If the subject consented to participate they signed the informed consent. Next the subjects were given two questionnaires to be completed at the site. The first questionnaire was

the demographic data form (DDF) and the second questionnaire was The Patient Self-Advocacy Scale (PSAS). After completing both items the subject was asked to place the questionnaires in a plain envelope and seal it. The envelopes were stored in a locked cabinet until they were mailed or delivered to the principal investigator. After it was verified that the consent form had been signed the questionnaires were separated from the consents to maintain patient confidentiality. The data were transferred to a computer spread sheet. The completed questionnaires and Patient Self-Advocacy Scales will be destroyed after a minimum of three years.

Tools

Data were collected using two tools. The first tool was the Demographic Data Form (DDF), found in appendix A. This form was developed by the researcher and reviewed by two expert nurses for clarity and conciseness after which modifications suggested by these nurses were made. The purpose of the DDF was to obtain basic demographic information about the sample such as age, marital status, educational level, and gender. These questions were identified as possible influencing factors based on the Strull (1984) study in which a correlation was found between degree of decision making and gender, age, race and education level. In addition to the previous questions subjects were also asked how much of the clinical trial consent form they had read and why. Three items, questions 3, 4 and 5, dealt with the subjects' subjective opinion of their comprehension of the consent form and possible variables that may have interfered with comprehension. Item 6 on the form asked for reasons the subjects had for participating in the clinical drug trial.

The second tool used was the Patient Self-Advocacy Scale (PSAS), (Brashers, Haas & Neidig, 1999). Patient Self-Advocacy was identified as a possible variable influencing the amount of the clinical trial consent form subjects read. The PSAS was used to measure patient involvement in health care decision making and scores of possible low of 18 reflecting low self-advocacy or paternalism to a possible high of 90 for self-advocacy (Brashers, Haas & Neidig 1999). The PSAS was developed because of some questions raised in a 1984 research study concerning shared decision making by patients and clinicians. Strull, Lo and Charles (1984), found that although shared decision making had been identified, little was actually known about how much decision making patients actually prefer. The PSAS was chosen as a tool because of the framework selected for this study, existential advocacy. Gadow (1983) states that at any given time the potential subject has varying needs concerning the amount of help they want with health care decision making, an opinion shared by Ingelfinger (1980).

The Patient Self-Advocacy Scale is an 18 item questionnaire answered in a 5-point Likert format (Brashers, Haas & Neidig 1999). To test the validity of the PSAS the authors used several other measures. Discriminant Validity was evaluated by the Desire for Control Scale (Burger, 1992), Health Opinion Survey Instrument (Krantz, Baum & Wideman 1980), Desire for Autonomy Scale (Ende, Kazis, Ash & Moskowitz 1989), and Health Locus of Control Scale (Dahnke, Garlick & Kazoleas, 1994). A combined sample of 392 subjects was used to evaluate the tool, 174 adults from an HIV-AIDS population and 218 adults from a general population. Conclusions by Brashers, Haas, and Neidig (1999), were that “this was a reliable and valid means for measuring patient involvement in health care decision making and that measuring self-advocacy is

important because it may be associated with increased health care participation” (p.113).

To assess efficacy of the measurement tools for this study a pilot study was conducted consisting of 5 individuals age 50 to 75 who had previously participated in a clinical drug study. They were asked to review the questionnaires and make suggestions regarding readability, comprehension and format. The pilot group requested changes in font size (larger), and terminology. Specifically they suggested referring to the studies they had participated in as “drug” studies. Changes were made to the questionnaires following their suggestions.

Analyses

Nominal and ordinal data were collected for this study. Both descriptive and inferential statistics were used to analyze the data and because of the data collected nonparametric tests were used. The SPSS computer program used descriptive statistics including measures of central tendency and measures of distribution to describe the sample obtained.

Research question number one, How much of the written consent form do research subjects read? was answered by question one on the DDF. Research question two, What is the relationship between how much of the consent form clinical subjects read and self-advocacy? was answered by obtaining the PSAS total summed score of items and then looking for a relationship between PSAS scores and the amount of the informed consent that was read. Research question three, What is the relationship between how much clinical research subjects read and the variables of gender, age, ethnic group, marital status, educational status and occupation? was answered by items 10

through 15 on the DDF and item one on the DDF. Research question four, What reasons do clinical research subjects give for reading or not reading the informed consent document? was answered by the second part of question 1 and question 2 on the DDF. Research question 5, Do research subjects who read all or nearly all of the consent form have different reasons for participating in clinical research trials than those who indicate they read little or none of the consent form? was answered by question 6 on the DDF.

Human Subjects Rights

Human subjects rights approval was obtained from the Department of Nursing and the Human Subjects Rights Committees at the University of Nevada, Las Vegas, (see Appendix A). Prior to participation in this study all subjects were given an informed consent document to read that explained the purpose of the study, potential risks, possible benefits, and that their participation was voluntary (Appendix B). Participants were told that they could withdraw at any time without penalty and without affecting their participation in the drug study. Subjects who agreed to participate received a signed copy of the consent document. No minors or vulnerable populations, including cancer patients, intellectually impaired, HIV positive, nursing home residents, or non-English speaking patients were included. All data were kept in a locked cabinet, and only numbers were used on the questionnaires for identification. Data were accessible only to the study personnel. There was no direct benefit to the subjects of participation in this study, but the results may benefit future clinical research participants. No risks related to participation in the research study were identified, the risk-benefit ratio was neutral, and the only cost to participants was the 30 to 45 minutes needed to complete the forms.

CHAPTER 5

RESULTS

This chapter discusses the findings of this study. Included is a description of sample and setting, the data analysis procedures and the results obtained from these analyses.

Sample

The target population for this study was any person age 50 to 75 who had signed an informed consent document and agreed to participate in a clinical research trial for a pharmaceutical company. One hundred and five subjects at three research centers agreed to participate in the study and returned informed consents, demographic data sheets and Patient Self-Advocacy Scales. Sites one and two were located in Las Vegas, site number three was located in Ohio. Site number one had forty-two participants, site number two had twenty-two participants and site number three had thirty-seven participants. Participants at all three sites were reflective of the people recruited into the clinical research trials showing no significant differences demographically in regards to age, gender, education, marital status, race or occupation. All three sites were conducting the same research studies in therapeutic areas for hypertension, arthritis, female incontinence and diabetes. Although all the subjects suffer from chronic conditions none were life-threatening at the time of the study. These clinical research trials were testing drugs that had not yet been approved by the Food and Drug Administration and were available only

to participants in clinical research trials. Consent forms for the clinical drug studies the subjects were participating in were evaluated using the Flesch Readability Formula (Grundner, 1986) and had readability scores ranging from grade 10.3 to grade 12.

Eight subjects were initially excluded from the study. Four subjects did not meet the inclusion criteria for age. Four subjects were excluded from the study due to incomplete questionnaires. After reviewing the data from the eight excluded subjects the four originally removed due to age were returned to the sample when it was determined that they were age 75 when they originally had entered into the clinical research studies giving a total of 101 participants.

Demographics

The characteristics of the sample population were obtained through the use of the Demographic Data Form. The ages ranged from 50 to 76 years, with a mean age of 62.90. Descriptive statistics were used to organize the data regarding, gender, marital status, educational status, occupation and ethnic group (see Table 1). Of the total participants 78 (77.2%) had never been in a clinical drug study before, 23 (22.8%) had previously been in a clinical drug study. A crosstabulation was done to determine if there was any difference between those who had been in a study before and those who had not in relation to the amount of consent read. The analysis showed that of the 78 who had not been in a study before 78.2% read all the consent, and of the 23 who had been in a study before 73.0% read all the consent. The conclusion was that there was no difference between the two groups due to previous study participation in relation to the amount of the consent form that was read.

Research Questions

Research Question Number One

How much of the written consent form do research subjects read? This question was answered with data from question one on the Demographic Data Form. Seventy-eight (77.2%) of the one hundred and one participants answered that they read all of the consent form. Nineteen (18.8%) of the participants said they read most of it ($\frac{1}{2}$ to $\frac{3}{4}$), three (3.0%) responded that they read some ($\frac{1}{4}$ to $\frac{1}{2}$) and one (1.0%) read a little ($\frac{1}{4}$). No one responded that they read none of the consent form.

Research Question Number Two

What is the relationship between how much of the consent form clinical subjects read and self-advocacy? The relationship between how much of the consent was read and self-advocacy was answered by first obtaining the total summed score of the eighteen items on the Patient Self-Advocacy Scale (PSAS). Question number 2 also asked participants how much of the consent form they understood (see table 6). Brashers (1999) study showed that the PSAS was able to discriminate between self-reported activist and nonactivist participants. The possible scores on this form range from eighteen to ninety with a score of ninety representing the highest level of self-advocacy. The sample's scores ranged from a low of 42 to a high of 82. The mean score was 62.67 (SD = 6.68). Because of the small number (4) of subjects who responded that they had read less than most of the consent form it was decided that data from this question would be recoded to two groups. One group represented those who read all of the consent form and the other group was those participants who read less than all of the consent form. The seventy-eight participants who read all of the consent form had a mean score of 63 on the PSAS

and a standard deviation of 6.31. The twenty-three participants who read less than all of the consent form had a mean score of 61.57 with a standard deviation of 7.85 on the PSAS. Anova results for read versus not read on self-advocacy was $F = 0.94$, ($df\ 28, 72$), $P = .55$ (see table 2).

This finding supports the position there is no relationship between PSAS scores and amount of informed consent read.

Research Question Three

What is the relationship between how much of the consent form clinical research subjects read and the variables of age, ethnic group, gender, marital status, educational background and occupation ? As in the previous question participants response to how much of the consent form did you read was recoded to those who read all of the consent form and those who read less than all of the consent form. Crosstabulations were done comparing all the above variables and read all the consent form or did not read all the consent form. No significant differences were found regarding age, gender, ethnic group, marital status or educational background. The variable of occupation had six categories casino, clerical, construction, homemaker, professional and retired. Of the six only one category showed a significant difference, and that was construction where 75% did not read all of the consent while 25% did read all the consent, however, this group only had four members so it is not possible to conclude that construction workers in general do not read all of a consent form. The conclusion is that the amount of the consent form read by this sample was not related to the variables of age, gender, marital status, occupation, ethnic group, or educational background. See table 3 for details.

Research Question Four

What reasons do clinical research subjects give for reading or not reading the informed consent document? This group was recorded to those participants who read all the consent form or did not read all the consent form. This question was answered on the DDF as an optional part to question number one. Subjects were instructed to select one or more answers if they did not read the entire consent form. One subject who reported not reading the entire form did not answer this question so there is no data as to why her/she did not read the entire consent form. One subject who read the entire consent form answered yes to the choice that “someone in the research department explained the drug study to me so I didn’t think I needed to read the entire consent form”. Of the participants who did not read the entire consent form fifteen (65.2%) responded that “someone in the research department explained the drug study to me so I didn’t think I needed to read the entire consent form”. Four (17.4%) of the group who did not read all of the consent responded that “my doctor suggested I take part in the drug study and I trust his/her judgment so I didn’t read the entire consent form”. Two (8.7%) of the respondents who did not read the entire consent said “a friend or family member read the consent form and explained it to me so I didn’t read the entire form”. One (4.3%) participant responded, “got information from a source other than the consent form” and two (8.7%) responded, “I wasn’t in the mood to read the entire drug study consent form”. Seven (30.4%) answered “other”, for the reason they did not read the entire consent form. Only three who answered other wrote in a reason for not reading the entire consent. One fifty-four year old female wrote in that she did not read the part pertaining to females of childbearing age. A fifty-two year old male who answered that he read some of the

consent (1/4 to 1/2) and that someone in the research department explained the drug study to him wrote in that he “read the first form completely”. It is not known what he was referring to as none of the studies these participants were in had more than one consent form. The last “other” wrote in “bad eyesight” and also answered that a friend or family member read the consent form and explained it to me so I didn’t read the entire consent.

Based on the data collected the conclusion is that those who did not read the entire consent form got the information from another source, most often from someone in the research department.

Research Question Number Five

Do clinical research subjects who read all or nearly all of the consent form have different reasons for participating in clinical research trials than those who indicate that they read little or none of the consent form? Data to answer this question were obtained from question one on the DDF and question six on the DDF. Participants had the option of choosing more than one answer for the reason they entered a drug study. The data regarding the amount of consent form read were again collapsed into two groups, those who read all of the consent and those who did not read all of the consent.

Crosstabulations were done to determine if there was any significant difference in the reasons participants gave for agreeing to be in a drug study who read all the consent form and participants who did not read all the consent form. Of the 19 who responded the study gave them a chance to get medical care they could not afford 6 (31.6%) did not read the entire consent. Of the 17 who responded that they entered the study because it paid money 6 (35%) did not read the entire consent. Of the studies that the sample was drawn from only one study had a patient stipend for participation. Of the forty-eight who

responded they had tried every other treatment and it had not helped, 13 (27%) did not read all the consent form. The most frequent reason given for participating was that it was an opportunity to obtain medication not otherwise available 59 (58%). The answer “I’ve tried every other treatment or medicine and nothing else has helped was selected by 48 (47.5%) of the participants. A crosstabulation showed 70.8% of the participants that choose the opportunity to obtain medicine also choose no other treatment or medicine has helped. Participants who entered the clinical studies for money or to obtain medical care were less likely to read the entire consent form than those who entered the studies for other reasons. See details in Table 3.

Additional information was obtained from the DDF. Question number 2 and 4 asked general information about the consent form relating to readability. The results are in Table 4. Question three on the DDF asked how much of the consent form did you understand. Table 5 summarizes how much the participants understood and how much of the consent they read. It should be noted that the amount of consent form understood was not validated with an actual check of the participants knowledge of the study.

Not all the subjects who participated in the study had the same consent form for their drug study. No data were collected regarding which form they read. There were a total of four different consents that were created by four different pharmaceutical companies. All the consents were similar in length and reading grade level 10 to 12. The general information in the consents was the same as mandated by FDA guidelines.

Of the total participants 78.3% percent of those who did not read the entire consent and 89.7% of those who did read all answered that they received all the information that they wanted from the consent. However, 73.9% of those who did not

read all the consent, and 83.3 % of those who did read all the consent said they asked questions before they signed the consent form. Another question asked the participants if they would be in a drug study again. Of those who did not read the entire consent, 87% responded that they would be in another study, 8.7% might be in another study, and 4.3% would not be in another study. Of the participants who read the entire consent form 74.4% would be in another study, 21.8% might be in another study, and 3.8% would not go in another study.

Summary

The answer to research question one, how much of the written consent form do research subjects read, is that of the 101 participants 77.2% said they read all of it. Question number two, asked what is the relationship between how much of the consent form clinical research subjects read and scores on the PSAS (self-advocacy). In this sample there was no difference in PSAS scores whether the participant read all or less than all of the consent form. Question number three, what is the relationship between how much of the consent form is read and the variables of age, ethnic group, gender, marital status, educational background and occupation.? Only one variable showed a relationship, with those in construction reading less of the consent than those in other occupations or retired. However there were only 4 members in this group so it is not possible to generalize this finding to construction workers in general. What reasons do clinical research subjects give for reading or not reading all the consent form was research question number four. Since this was an optional items on the DOF not all participants responded.

Of those who did answer the most frequently chosen reason for not reading the entire consent was that they received information from someone in the research

department, perhaps leading them to believe it was not necessary to read the consent. The final research question was did research subjects who read all of the consent form have different reasons for participating in the research study than those who did not read all the consent form. More than a third of those who were in a clinical research study because it paid money, or they received medical care they could not otherwise receive, did not read all of the consent form.

CHAPTER 6

DISCUSSION

The purpose of this descriptive study was to answer questions related to the informed consent process in clinical drug studies, specifically how much of the informed consent document is read and variables related to how much is read. This chapter discusses the major findings in relation to the research questions, study framework and previous research. Limitations that were identified are discussed as well as implications for nursing and recommendations for further research.

Research Questions

How much of the written consent form do clinical research subjects read? Of the one hundred and one participants who responded to this question seventy-eight (77.2%) answered that they read all of the consent. These results contradict previous reports that research subjects read less than fifty percent of a written consent (New York Times, May 1999). This is also in contrast to the researcher's personal observations that research subjects do not read all of the consent form and FDA audits of research sites from 1977 to 1984 that cite the most violations of FDA regulations to be in the area of informed consent (www.fda.gov/cder). Possible explanations for these findings may be that the participants observed by the researcher were not typical, participants may pretend to read the consent form (Tenthory & Dixon, 1996) and that the FDA audits may reflect problems with the consenting other than the amount of the document that is read.

The answer to the second research question, what is the relationship between how much of the consent form clinical research subjects read and self-advocacy was that no relationship was found. There was no significant difference in self-advocacy scores whether the participant read all, most, or some of the consent. The mean PSAS was 62.67 with a standard deviation of 6.68. Two of the participants with the lowest scores on the PSAS, 42 and 49 reported reading most of the consent form. The third participant who scored 51 on the PSAS reported reading all of the consent form. A possible explanation for this finding may be that research subjects as a group may be more assertive in regards to health care than individuals who do not participate in clinical research studies. In addition, this sample may not be representative of the average research subject. During the literature search no studies were found that addressed this issue, so this remains an area that needs further research.

The third research question asked, what is the relationship between how much clinical research subjects read and the variables of sex, age, ethnic group, gender, marital status, educational status and occupation. Because of the small number of subjects who read less than most of the consent the four groups were collapsed into two groups, those who read all the consent and those who read less than all the consent. No statistical differences were found regarding the above variables regardless of the amount of consent that was read. Additionally no statistical differences were found on PSAS scores, the amount of the consent that was understood or the reasons for participating in a clinical study regarding the variables of sex, age, ethnic group, gender, marital status, educational status or occupation. A possible explanation for these findings may be the homogeneous

nature of the participant sample. The majority of subjects were retired, married Caucasians, with some college education. About two-thirds were female.

Research question number four, what reasons do clinical research subjects give for reading or not reading the informed consent document? The results from this question are inconclusive possibly because of the way the question was asked on the demographic data form. It was an optional part to the question that asked how much of the consent was read. It said that if you did not read the entire consent form check all the answers that apply. Since 77.2% of the participants answered that they read all of the consent form limited data were obtained. However 65.2 % of those who answered that they did not read the entire consent said that the reason was because someone in the research department explained the drug study to them. This was actually only fifteen participants in the study, but is valid because all fifteen also said that they asked questions about the study before they signed the consent. However, IRB's give approval based on the written material not that the researcher will provide oral information to all of the potential research subjects reading the form. Of concern is the possibility that information will not be provided because of a conflict of interest due to that fact that investigators in clinical drug studies usually receive payment based on the number of subjects who agree to participate in a study.

Do clinical research subjects who read all or nearly all of the consent form have different reasons for participating in clinical research trials than those who indicate that they read little or none of the consent form was the final research question. Again the respondents were collapsed into two groups, those who read all the consent and those who read less than all the consent. Slightly more than 30% of those who entered clinical trials

for money or because they could not afford to get medical care elsewhere did not read the entire consent form. This finding is bothersome because they may in fact represent a vulnerable population, the poor or uninsured and may not be giving true informed consent. A second group, those who have tried every other treatment or medication with no success and are now seeking medication that is not available except in clinical trials are also vulnerable. Although the majority of this group did respond that they read all of the consent, is their desire for relief influencing their decision to participate to a point where they may be willing to take risks that another individual who felt they had other options might not take. Also, at risk subjects consent forms do not differ from not at risk subjects in relation to IRB approvals.

Study Framework

The framework for this study was existential advocacy. The goal of existential advocacy is to “help persons become clear about what they want to do” stressing self-determination in health care decisions (Gadow pp. 44-45). The PSAS was used to identify the participant’s degree of self-advocacy. The scores of this group on the PSAS reflect their high level of involvement in health care decision making . This sample showed their involvement by reading most or all of the consent form, and responding they understood most or all of the consent form and that they received all or most of the information they desired. Additionally, 81.2% of the participants answered that they asked questions before signing the consent. Verheggen, Jonkers & Kok (1996) interviewed 198 patients in clinical trials and found that overall they were satisfied with informed consent. He found that this satisfaction was influenced by attitudes toward medical care, research and trust in their physicians. Of the participants in this study 49.5% answered that one of the

reasons they went into the study was because their doctor said it would be a good idea reflecting their trust in their physicians. If Gadow (1983) is correct this would be also be an example of the physician acting in the interest of the patient's good. However it is unknown what the physician's motivation is, it may be the patient's best interest, or it may also benefit the physician if he is being paid for conducting the clinical trial. In addition, this study did not identify if the research subject was made aware of the latter fact.

Previous Research

The results of this study appear to contradict other previous research in addition to those studies dealing with the amount of consent form read. In comprehension studies, Riecken and Ravich, (1982) and Miller, Searight and Grable, (1994) concluded that subjects do not have an adequate understanding of the informed consent documents yet 62.4% of the participants in this study reported they understand all of the consent, while 30.8% understood most of the consent, and 4.0% understood some of the consent form. A limitation with this study is that there was no objective test of participants understanding of the consent form information. Their response was a subjective opinion of what their level of understanding was.

Implications for Nursing

Evidence in case law documents show health care professionals are legally liable for adverse outcomes by patients who do not understand important health information (Brandes, Furnas, McCllan, Haywood, Oheme-Frempong, & Taylor-Watson, 1996). Also, if a nurse, in lieu of a physician, explains a medical or surgical intervention to gain a patient's informed consent they can be held to the same standard as court would hold a physician (Curran, 1982). The signature of a low health-literacy patient on a consent form

may not indicate informed consent (Cassileth, Zupkis, Sutton-Smith & Morch, 1980). The legal validity of the consent may be questionable even if the patients have read the form if there is incomplete comprehension of the material (Powers, 1987). Patients with poor health literacy that prevents their comprehension of the informed consent may also have problems understanding and following instructions concerning the clinical study they are participating in leading to poor compliance with the study requirements (Spandorfer, Karras, Hughes & Caputo, 1995). In addition such may also limit their reporting of serious events that may have an impact on approval of the drug by the FDA. If serious events are not reported and approval is given open public use may result in injury or even death due to lack of full and accurate reporting in the clinical trial.

Limitations

This study was limited to three research sites that were extremely similar as far as patient population and method of obtaining informed consent. The participants were for the most part patients of the physicians conducting the clinical drug study and had some type of patient/ health care provider relationship with the research staff. At these sites R.N's are consenting the patients and this may not be the norm for all research centers. Additionally this was not a diverse group in many areas such as age, race, education or occupation. There were problems identified with the DDF. Information was lost by making some answers dependent on the answer to the previous question. No general conclusions can be drawn from this study.

No information was obtained as to what type of research study the participants were taking part in. For example some participants were in a hypertensive study where numerous alternative medications are available to the public. Therefore it was not

necessary for them to participate in a clinical study to obtain medication for their medical condition. However the females participating in the urge incontinence study did not have the same number of alternatives available as those in the hypertension study. There are no medications currently available that are comparable to the one that was being test in the clinical trial. These differences may cloud some of the data.

The PSAS, which was used to test patient self-advocacy, had not previously been used on clinical research subjects. Because of what appeared to be some contractions in responses to questions regarding why the participants went into the study and high scores on the PSAS (my doctor suggested I enter the study), it might be that the tool is not discriminating enough for this group.

Conclusions

The results from this study cannot be generalized to all clinical research subjects. Results would indicate that this sample which was mostly retired, married, female, Caucasians with some college read and understood most of the consent form. They thought the form was boring but they received all the information they wanted. This groups main motivation for entering a clinical study was to get medication that is not yet otherwise available, and they also though it might help other people. Additional reasons for participation that were frequently chosen were that it would be interesting, their doctor thought it would be a good idea, and no other treatments were working.

Recommendations for Further Research

Based on the overall findings in this study the following recommendations are made.

1. Check the participants understanding of the consent form by asking a few pertinent questions about the consent after it has been signed. For example ask the participant to name two potential drug side effects, how many visits will be required and who to contact in an emergency.
2. Obtain the sample from a more diverse number of sites, such as for profit, non-profit, university based and centers that obtain research subjects through advertisements only
3. Obtain the sample from sites where the consent process is conducted by nurses and non-licensed research coordinators.
4. Obtain a more varied sample in regards to age, race, education and reason for participation such as patient payment.
5. Have the subjects take a health literacy test such as the Rapid Estimate of Adult Literacy in Medicine (REALM) which can identify patients with low reading levels in relation to health terminology (Davis, Long, Jackson, Mayeaux, George, Murphy & Crouch 1993).

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APPENDIX I

TABLES

Table 1 Participant Demographics (N=101)Age Range 50-76 Mean= 62.90

<u>Gender</u>	<u>Frequency</u>	<u>Percent</u>
Male	37	36.6
Female	64	63.4

<u>Marital Status</u>	<u>Frequency</u>	<u>Percent</u>
Single	15	14.9
Married	56	55.4
Divorced	12	11.9
Widowed	18	17.8

<u>Highest Education</u>	<u>Frequency</u>	<u>Percent</u>
Less than high school	4	4.0
High school	24	23.8
Some college	43	42.6
College degree	16	15.8
Some graduate study	5	5.0
Graduate degree	4	4.0
Technical training	5	5.0

<u>Ethnic Group</u>	<u>Frequency</u>	<u>Percent</u>
African	5	5.0
American Indian	4	4.0
Caucasian	87	86.1
Hispanic	3	3.0
Other	2	2.0

<u>Occupation</u>	<u>Frequency</u>	<u>Percent</u>
Casino	3	3.0
Clerical	8	7.9
Construction	4	4.0
Homemaker	8	7.9
Professional	13	12.9
Retired	41	40.6
Sales	4	4.0
Service	3	3.0
Technicians	12	11.9
Other	5	5.0

Table 2 ANOVA Results for Read vs. Not Read on Self-Advocacy

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	4.771	28	.170	.944	.553
Within Groups	12.991	72	.180		
Total	17.762	100			

Table 3 Crosstabulations Between Variables of Age, Ethnic Group, Gender, Marital Status, Educational Background, Occupation and Amount of Consent Form Read

<u>Occupation</u>	<u>Did not read all of consent</u>	<u>Read all of consent form</u>
Casino	0	3
% within occupation		100%
Clerical	2	6
% within occupation	25%	75%
Construction	3	1
% within occupation	75%	25%
Homemaker	2	6
% within occupation	25%	75%
Professional	3	10
% within occupation	23.1%	76.9%
Retired	6	35
% within occupation	14.6%	85.4%
<u>Gender</u>	<u>Did not read all of consent</u>	<u>Read all of consent form</u>
Male	7	30
% within gender	18.9%	81.1%
Female	16	48
% within gender	25%	75%
<u>Marital Status</u>	<u>Did not read all of consent</u>	<u>Read all of consent form</u>
Single	4	11
% within marital status	26.7%	73.3%
Married	14	42
% within marital status	25%	75%
Divorced	1	11
% within marital status	8.3%	91.7%

Table 3 (continued)

Widowed	4	14
% within marital status	22.2%	77.8%

<u>Education</u>	<u>Did not read all of consent</u>	<u>Read all of consent form</u>
------------------	------------------------------------	---------------------------------

Less than High School	1	3
% within education	25%	75%
High School	9	15
% within education	37.5%	62.5%
Technical Training	1	4
% within education	20%	80%
Some College	8	35
% within education	18.6%	81.4%
College Degree	3	13
% within education	18.8%	81.3%
Some Graduate Study	1	4
% within education	20%	80%
Graduate Degree	0	4
% within education	0	100%

<u>Ethnic Group</u>	<u>Did not read all of consent</u>	<u>Read all of consent form</u>
---------------------	------------------------------------	---------------------------------

African American	1	4
% within ethnic group	20%	80%
American Indian	0	4
% within ethnic group		100%
Caucasian	20	67
% within ethnic group	23%	77%
Hispanic	1	2
% within ethnic group	33.3%	66.7%
Other	1	1
% within ethnic group	50%	50%

Table 4 Cosstabulations Between Participants Reasons for Agreeing to be in a Clinical Drug Study and How Much of the Informed Consent they Read

<u>Reason for Participation</u>	<u>Frequency</u>	<u>Did not read all consent</u>	<u>Read all of Consent</u>
Gave me a chance to get medication not available	59	10 (16.9%)	49(83.1%)
I thought it might help other people	58	13 (22.4%)	45(77.6%)
I thought it would be interesting	57	13 (22.8%)	44 (77.2%)
My doctor said it would be a good idea	50	9 (18%)	41 (82%)
I've tried every other treatment nothing works	48	13 (27%)	35 (73%)
Family said it was a good idea to enter study	29	7 (24%)	22 (76%)
Other reasons	22	7 (32%)	15 (68%)
Chance to get medical care	19	6 (32%)	13 (68%)
Study pays money	17	6 (35%)	11 (65%)
I did not want to go against my Dr. or nurses recommendation	4	1 (25%)	3 (75%)

Table 5 Crosstabulation Readability Questions About the Consent Form and Read or Did Not Read All of The Consent Form

<u>Readability of Consent Form</u>	Did not read all	Read all
The consent was too long	7	11
The type in the consent was difficult to read	3	0
Did not have enough time to read the entire consent	3	4
I felt rushed to read the consent form	2	2
The consent form was boring	10	20
The consent form was clear	17	61
I received all the information I wanted	18	70

Table 6 Crosstabulation Between How Much of the Consent Form Did You Understand and How Much of the Consent Form Did You Read

	Did Not Read All of Consent	Read All of The Consent
Understood Some ($\frac{1}{4}$ to $\frac{1}{2}$) 3.5% total sample	1%	3%
Understood Most ($\frac{1}{2}$ to $\frac{3}{4}$) 33.5% total sample	10%	23.5%
Understood All 63% total sample	12%	50.5%
	<u>23%</u>	<u>78%</u>

APPENDIX II

PERMISSIONS

Subj: Re: Self-Advocacy Scale
 Date: 4/10/00 2:12:13 PM Pacific Daylight Time
 From: dbrasher@uiuc.edu (dale brashers)
 To: JHRLV@aol.com

File: Unknown (11160 bytes)
 DL Time (28800 bps): < 1 minute

Joanne: I would be happy for you to use the patient self-advocacy scale in your thesis. I would appreciate hearing the results of your study when available.

We have two other publications in the works—one is the background for the scale (in press at Human Communication Research) and one that will soon be submitted. Also, the scale is being used in several other studies, including a study of HIV vaccines being conducted by the CDC.

We also are testing an expanded version of the PSAS. From our tests so far, it has better reliability for the subscales, but complete validation and reliability information is not available. I'm attaching a copy of the expanded PSAS.

Please let me know if I can be of further assistance.

Dale

>Dear Mr. Brasher, My name is Joanne Robinson and I'm pursuing a master degree
 >in nursing at the University of Nevada at Las Vegas. I recently read your
 >article "The Patient Self-Advocacy Scale: Measuring Patient Involvement in
 >Health Care Decision-Making Interactions" I would like to use the PSAS in my
 >masters thesis. The primary purpose of my thesis is to determine how much of
 >the informed consent document clinical research subjects read, and whether
 >there is a correlation between how much of the document is read and what
 >degree of responsibility research subjects take when making health care
 >decisions. I would appreciate any assistance you could give me regarding
 >obtaining information about the PSAS and permission to use it.

>
 >Thank you, I can be reached at my home e-mail JHRLV@aol.com office e-mail
 >NCRLV@aol.com or office work number Nevada Clinical Research 702-471-7288
 >

>My thesis chair is Dr. Margaret Louis University of Nevada Las Vegas
 >Department of Nursing 702-895-3812

Headers

Return-Path: <dbrasher@uiuc.edu>

Received: from nty-zc05.mx.aol.com (nty-zc05.mail.aol.com [172.31.33.5]) by air-zc04.mail.aol.com (v70.20) with ESMTP; Mon, 10 Apr 2000 17:12:13 2000

Received: from stat2.cso.uiuc.edu (stat2.cso.uiuc.edu [128.174.5.53]) by nty-zc05.mx.aol.com (v71.10) with ESMTP; Mon, 10 Apr 2000 17:11:43 -0400

Received: from [128.174.167.95] (walt1.spcomm.uiuc.edu [128.174.167.95])
 by stat2.cso.uiuc.edu (8.9.3/8.9.3) with ESMTP id QAA18622
 for <JHRLV@aol.com>; Mon, 10 Apr 2000 16:11:37 -0500 (CDT)

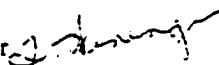
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DATE: September 26, 2000

TO: Joanne Robinson
Nursing
M/S 3018

FROM: Dr. William E. Schulze, Director 
Office of Sponsored Programs (x1357)

RE: Status of Human Subject Protocol Entitled:
"Variables Related to How Much of the Informed Consent Document is Read by
Clinical Research Subjects"

OSP #501s0900-089

This memorandum is official notification that the protocol for the project referenced above has been approved by the Office of Sponsored Programs. The approval is for a period of one year from the date of this notification and work on the project may proceed.

Should the use of human subjects described in this protocol continue beyond a year from the date of this notification, it will be necessary to request an extension.

If you have any questions or require assistance, please contact the Office of Sponsored Programs at 895-1357.

cc: OSP File

Office of Sponsored Programs
4505 Maryland Parkway • Box 451037 • Las Vegas, Nevada 89154-1037
(702) 895-1357 • FAX (702) 895-4242



PROTOCOL FORM APPROVAL SHEET
FOR RESEARCH INVOLVING HUMAN SUBJECTS

Log Number: 12 September 2000

Title of Project:

Variables related to how much of the informed consent document is read by clinical drug research subjects

Investigator: Joanne Robinson

After reviewing this proposal, the members of the Department of Nursing, Human Subjects Rights Review Committee has indicated below their approval/disapproval of this proposal.

Signature of Committee Members	Approve	Disapprove
<u>[Signature]</u>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<u>[Signature]</u>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<u>[Signature]</u>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<u>[Signature]</u>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

The above named project is hereby approved/disapproved (circle one).

Date: 12 Sept 2000

[Signature]
Committee Chairperson's Signature

Department of Nursing
4505 Maryland Parkway • Box 453018 • Las Vegas, Nevada 89154-3018
(702) 895-3360 • FAX (702) 895-4807

OHIO CLINICAL RESEARCH

5167 Mayfield Rd., Suite #100, Cincinnati, Ohio 45224
Phone: (440) 684-8900 Fax: (440) 684-8902

October 25, 2000



Joune Robinson, RN
840 S. Rancho Drive Suite 4
Las Vegas, NV 89106-3820

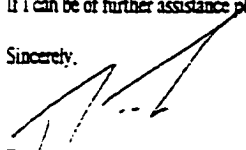
RE: Data Collection

Dear Ms. Robinson,

I received your request to have Holly Renner, RN assist you in data collection for your thesis towards a master's degree in nursing. After carefully reviewing your request, the consent form, and questionnaires supplied, I felt it reasonable that the research be conducted at Ohio Clinical Research, LLC.

If I can be of further assistance please contact me at (440) 684-8900.

Sincerely,


Terence Isakov, MD
Principal Investigator

Cc: Holly Renner, RN

~~CONFIDENTIAL~~

SOUTHWEST MEDICAL ASSOCIATES, INC.

Clinical Trials Department
Stephen H. Miller, M.D. Principal Investigator
2316 W. Charleston Blvd., Suite 280
Las Vegas, NV 89102
Phone: 702-877-8675 Fax: 702-821-1322

October 5, 2000

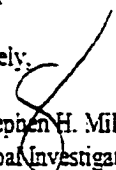
Joanne Robinson
2316 West Charleston Blvd.
Suite 280
Las Vegas, Nevada 89102

Re: Data collection for Master's Thesis

Dear Joanne:

You have my permission to approach patients at this research site for the purpose of obtaining data for your master's thesis on informed consent. It is understood that all patients will be informed that their participation is voluntary and not related to their participation in the pharmaceutical studies.

Sincerely,


Dr. Stephen H. Miller, MD
Principal Investigator

WILLIAM S. BOSSAK, M.D., LTD.

3115 SOUTH EASTERN AVENUE

LAS VEGAS, NEVADA 89109-3387

Telephone 731-1140

October 2, 2000

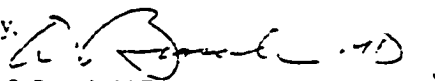
Joanne Robinson
2316 W. Charleston Blvd
Suite 280
Las Vegas, NV 89102

RE: Data collection for master's thesis

Dear Ms. Robinson:

I have considered your request for permission to collect data for you Master's thesis on variables relating to the amount of consent form read by clinical research subjects. You have my permission to approach patients at this site for the purpose of obtaining this data.

Sincerely,



William S. Bossak, M.D.

Principal Investigator

APPENDIX III

FORMS



Research Subject Information and Consent Form

TITLE: Variables Related to How Much of the Informed Consent Document Is Read By Clinical Research Subjects

INVESTIGATOR: Joanne Robinson RN, BSN
Department of Nursing
University of Nevada, Las Vegas

You are being invited to participate in a research study about informed consent in drug studies because you are currently taking part in a drug study. The following information describes the study and your role as a study participant. The research nurse will answer any questions you have about this consent form and about the study. Please read the consent form carefully and do not hesitate to ask questions about the information provided.

PURPOSE OF THE STUDY

The purpose of this study is to identify how much of the consent form clinical research subjects read when they agree to participate in a drug study. An additional goal of the study is to learn more about why research subjects read or do not read all of the consent form.

DESCRIPTION OF THE STUDY

After you have completed your routine visit for the drug study you will be asked to complete two questionnaires. It will take you approximately ½ to ¾ hour to complete both. One of the questionnaires will ask questions about how much of the consent form you read for the drug study you are now participating in. The second questionnaire will ask you about health care decision making. After you complete the questionnaire place them in the attached envelope, seal it and return it to the research nurse. Approximately 100 subjects will be enrolled in this study.

POTENTIAL RISKS AND DISCOMFORTS

Risks are minimal. Participants may feel some discomfort answering some of the questions and have the option to stop at any time and not hand in the questionnaire.

POSSIBLE BENEFITS

Information gained may be beneficial to health professionals concerned with the protection of human subject's rights in clinical research studies.

Department of Nursing
4505 Maryland Parkway • Box 453018 • Las Vegas, Nevada 89154-3018
(702) 895-3360 • Fax (702) 895-4807

PAYMENT FOR PARTICIPATION

You will not receive any compensation for participation in this study.

CONFIDENTIALITY

Information from this study will be confidential. Your name will appear on this consent form but not the questionnaires and the consent forms will be kept separate from all other study information and will be stored in a locked cabinet located in the researchers office and destroyed three years after the conclusion of the study. Information from this study may be presented at meetings or in publications; however, your identity will not be disclosed in those presentations.

VOLUNTARY PARTICIPATION/WITHDRAWAL

Your participation in this study is voluntary. You may decide not to participate or you may withdraw from the study at any time without penalty and without affecting your participation in the drug study.

QUESTIONS

If you have questions about this research or your participation in this study contact: Joanne Robinson, the Department of Nursing, UNLV @ 702-895-3360. If you have questions about your rights as a research subject, you may contact: University of Nevada Las Vegas, Office of Sponsored Programs @ 702-895-1357.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

CONSENT

I have read and I understand the information in this consent form describing this study. All my questions regarding the study and my participation in it have been answered to my satisfaction. I freely give my consent to participate in this study until I decide otherwise.

I understand that I will receive a copy of this signed and dated consent form for my records.

Subject Name (Printed)

Subject Signature

Date

Demographic Data Form
By Joanne Robinson

Please indicate your answer to the following questions with an "X". These questions apply to the clinical research study you are participating in for a pharmaceutical company to test a new drug.

1. How much of the informed consent document for the drug study you are participating in now did you read before signing it?

- ☐ I did not read any of the consent form.
- ☐ I read a little of it (1/4 or less)
- ☐ I read some of it (1/4 to 1/2)
- ☐ I read most of it (1/2 to 3/4)
- ☐ I read all of it

If you did not read the entire consent form check all that apply.

- ☐ Someone in the research department explained the drug study to me so I didn't think I needed to read the entire consent form.
- ☐ My doctor suggested I take part in the drug study and I trust his/her judgment so I didn't read the entire consent form.
- ☐ A friend or family member read the consent form and explained it to me so I didn't read the entire form.
- ☐ I got information about the research study from a source other than the consent form.
- ☐ I wasn't in the mood to read the entire drug study consent form.
- ☐ Other _____

2. Please answer Yes or No to the following statements about the consent form for the drug study you are participating in now.

- ☐ Yes ☐ No The consent form was too long.
- ☐ Yes ☐ No The type in the consent form was difficult to read.
- ☐ Yes ☐ No I did not have enough time to read the entire consent.
- ☐ Yes ☐ No I felt rushed to read the consent form.
- ☐ Yes ☐ No The consent form was boring.
- ☐ Yes ☐ No The consent form was clear.
- ☐ Yes ☐ No I received all the information I wanted about the study.

3. How much of the consent form for the drug study did you understand.

- ☐ None of it.
- ☐ A little of it (1/4 or less)
- ☐ Some of it (1/4 to 1/2)
- ☐ Most of it (1/2 to 3/4)
- ☐ All of it.

4. Were there any parts of the drug study consent form that were vague or not clear?

- ☐ Yes
- ☐ No

If you answered yes to the above question please check all statements that apply.

- ☐ The consent form had words or phrases that I did not understand.
- ☐ The consent form described study procedures that I did not understand.
- ☐ I did not have a chance to ask questions about anything I did not understand.
- ☐ I was embarrassed to ask questions.

5. Did you ask any questions about the drug study before you signed the consent form?

- ☐ Yes
- ☐ No

Please go to page 3

6. Why did you agree to be in the drug study? Please check all the reasons that apply.

- ☐ My doctor said it would be a good idea.
- ☐ My family thought it was a good idea.
- ☐ It gave me a chance to get medication that is not available at pharmacies yet.
- ☐ The study pays money to me for participation.
- ☐ I thought it might help other people.
- ☐ I've tried every other treatment or medicine for my condition and nothing else has helped.
- ☐ This is a chance to get medical care that I could not otherwise afford to pay for
- ☐ I thought it would be interesting.
- ☐ I did not want to go against my doctor's or nurse's recommendation to go into the drug study.
- ☐ I thought it would please my doctor or nurse.
- ☐ Other (fill in) _____

7. How much of the information that you wanted about the drug study did you receive?

- ☐ None
- ☐ A little of the information I wanted (1/4 or less)
- ☐ Some of the information that I wanted (1/4 to 1/2)
- ☐ Most of the information that I wanted (1/2 to 3/4)
- ☐ All of the information that I wanted

8. I would participate in another drug study again because of my satisfaction with this study.

- ☐ Yes
- ☐ Maybe
- ☐ No

Please go to page 4

9. Have you ever been in a drug study before?

☐ Yes

☐ No

10. My age is: _____

11. Gender:

☐ Male

☐ Female

12. My marital status is:

☐ Single

☐ Married

☐ Divorced

☐ Widowed

☐ Other: _____

13. The highest level of education I have completed is:

☐ Less than high school

☐ High school

☐ Some college

☐ College degree

☐ Some graduate study

☐ Graduate degree

☐ Technical training

14. Ethnic group

☐ African-American

☐ American Indian/Alaskan

☐ Asian/Pacific Islander

☐ Caucasian

☐ Hispanic

☐ Other

Please go to page 5

15. What is your occupation?

- ☐ Casino
- ☐ Clerical
- ☐ Construction
- ☐ Homemaker, not employed
- ☐ Professional, e.g. architects, engineers, health professional, or teachers
- ☐ Retired
- ☐ Sales
- ☐ Service, e.g. waitress, cook, janitor , hair dresser
- ☐ Technicians, e.g. computer programmer, health technician
- ☐ Other _____

Thank You, you have completed this questionnaire

Patient Self-Advocacy Scale
By D. Brasher

The following questions ask about your feelings about your health care. For each of the following questions, please indicate your level of agreement with the statement by circling either: Strongly agree, Agree, Neutral, Disagree or Strongly disagree.

1. I believe it is important for persons with an illness to learn as much as they can about the disease and treatments.

Strongly agree Agree Neutral Disagree Strongly disagree

2. I actively seek out information on my health.

Strongly agree Agree Neutral Disagree Strongly disagree

3. I am more educated about my health than most U.S. citizens.

Strongly agree Agree Neutral Disagree Strongly disagree

4. I have full knowledge of the health problems of people like me.

Strongly agree Agree Neutral Disagree Strongly disagree

5. I keep notes about my illness and treatment.

Strongly agree Agree Neutral Disagree Strongly disagree

6. I research the latest treatments for my illness.

Strongly agree Agree Neutral Disagree Strongly disagree

7. I don't get what I need from my physician because I am not assertive enough.

Strongly agree Agree Neutral Disagree Strongly disagree

8. I am more assertive about my health care needs than most U.S. citizens.

Strongly agree Agree Neutral Disagree Strongly disagree

9. I frequently make suggestions to my physician about my health care need.

Strongly agree Agree Neutral Disagree Strongly disagree

10. I frequently offer my doctor suggestions about my care and treatment.

Strongly agree Agree Neutral Disagree Strongly disagree

11. I ask a lot of questions of my doctor.

Strongly agree Agree Neutral Disagree Strongly disagree

12. If my physician prescribes something I don't understand or agree with, I question it.

Strongly agree Agree Neutral Disagree Strongly disagree

13. Sometimes there are good reasons not to follow the advice of a physician.

Strongly agree Agree Neutral Disagree Strongly disagree

14. If I am given a treatment by my physician that I don't agree with, I am likely not to take it.

Strongly agree Agree Neutral Disagree Strongly disagree

15. I don't always do what my physician or health care worker has asked me to do.

Strongly agree Agree Neutral Disagree Strongly disagree

16. Sometimes I think I have a better grasp of what I need medically than my doctor does.

Strongly agree Agree Neutral Disagree Strongly disagree

17. My doctor works for me. I would find another doctor if I weren't satisfied with my health care.

Strongly agree Agree Neutral Disagree Strongly disagree

18. I make my own decisions about what treatments I will or will not use, even if my doctor prescribes it.

Strongly agree Agree Neutral Disagree Strongly disagree

VITA

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