COMMUNICATING INFORMED CONSENT WITH LEP PARTICIPANTS DURING CLINICAL TRIALS: A CASE STUDY

by

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COMMUNICATING INFORMED CONSENT WITH LEP PARTICIPANTS

DURING CLINCIAL TRIALS: A CASE STUDY

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ABSTRACT

Healthcare systems are under pressure to eliminate disparities of care. Communication methods used with Limited English Proficiency (LEP) patients was presented in the literature as an essential component to deliver quality and equal care. Several strategies have been implemented to assess and target the communication methods between patients and health care teams. The challenge for health systems workers is to address communication barriers to eliminate disparities of care and medical errors. The purpose of the present qualitative case study was to explore if communication barriers affect the understanding of LEP research participants while participating in the informed consent process during clinical trials. Communication barriers during the informed consent process may affect clinical trial outcomes. In the study, the use of a triangulation data gathering method was associated with a qualitative case study. Data regarding barriers of communication during the informed consent process were gathered by performing semistructured interviews. The study population included six principal investigators, five interpreters, and nine LEP research participants. Data analysis involved reviewing the emerging themes from participants' responses. Results indicated four major themes supporting communication challenges. The themes included authority figure, cultural sensitivity, communication barriers, and education. The study suggested the need for further research regarding communication barriers during the clinical trials process.

Keywords: informed consent process, clinical trials, communication barriers, limited English proficiency

DEDICATION

This dissertation is dedicated to the LEP parents of children with an illness, many of them immigrants who work passionately and tirelessly to provide a good life for their children so they can experience the highest level of success in life. Many of these individuals encounter difficult news during their medical appointments. This difficult news many times requires decisions they need to make with only a limited understanding of the information they have received and their trust in the medical system of the United States. These parents' hopes are for their children to get well.

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I want especially to thank the parents of the patients who took time from their busy lives to share their experiences and emotions that they endured during their medical appointments. During this transition, they let me see how difficult is to take care of their little ones while trying to make decisions with limited information and understanding of their children's illnesses. They shared how scared they were each time they had to cross the facility doors not knowing what to expect yet hopeful that their children would recuperate from illness.

My wife, children, and my parents have provided me with a lifetime of unconditional support, encouragement, and belief that I could achieve this milestone. I want especially to provide infinite gratitude to my wife because she has been with me

every step of the way, supporting, encouraging, and providing her hand and thoughts throughout the process. I appreciate her patience, understanding, and endurance to support me through this long process.

TABLE OF CONTENTS

LIST OF TABLES

Chapter 1

Introduction

The barriers of communication between providers and research participants are affecting the informed consent process during clinical trials (Flores, 2006). The problem of barriers in communication has been identified and has resulted in alternatives to improve the quality of the medical processes (Flores, Torres, Holmes et al., 2008). Clinical trials are part of the improvement of scientific treatments (U.S. National Institute of Health, 2007). Clinical trials are "carefully controlled studies conducted in human volunteers to answer specific health questions and are the safest method to find treatments that work in individuals and improve health" (U.S. Food and Drug Administration [FDA], 2010, para. 1).

Drugs in the United States undergo three phases of clinical trials before approved for general use, which will be discussed in detail in Chapter 2. Research organizations engaged in clinical trials have established Independent Review Boards (IRB), governed by the FDA Rule 45 CFR 46 (Poitras, 2009). ISBs approve, monitor, and review biomechanical and behavioral studies to protect the rights and well-being of human participants (U.S. Department of Health and Human Services [DHHS], 2009).

Biomedical organizations have accreditation standards for patient safety, adverse event management reporting systems, mandatory reporting laws, and policies (Devers, Pham, & Liu, 2004). Research groups have created Data Safety Monitoring Boards (DSMB) to review and manage research events and decision making of ongoing studies in relation to outcomes (National Institutes of Health [NIH], 2008). The DSMB is an independent group of experts serving as advisers to research investigators. The DSMB

reviews and evaluates the accumulated study data for participant safety, progress, and appropriate efficacy of studies (NIH, 2008).

Scientific research is important to the continuous innovation of treatments and understanding of illnesses. The communications process during clinical trials manifests how well participants understand the aims and protocol procedures of a study during the informed consent process. The informed consent process is the key factor of research seeking to support the ethical value of voluntary participation (Nishimura et al., 2013). This research studied how clinical trials' personnel administer and manage informed consent procedures when language may present a communication barrier to the clinical trial processes.

Background

Significant numbers of patients participate in clinical trials in the United States every year. The NIH provides a registry of federally funded and private supported studies conducted in the United States and other countries, has registered 154,225 trials with 185 countries (U.S. NIH, 2011). Communication barriers may be a possible cause of not understanding trial procedures, aims, benefits, and possible risks (Resnik & Jones, 2006). Possible miscommunication during the informed consent process may result in adverse events. Inadequate communication may develop negative medical consequences (Flores, 2006). Communication barriers may delay treatments or initiate treatment errors when facts are not present and may contribute to the deficiency of Limited English Proficiency (LEP) patients in clinical trials studies.

LEP is defined "as a limited ability or inability to speak, read, write, or understand the English language" (Jacobs, Agger-Gupta, Piotrowski, Chen, & Hardt,

2003, p. 60; cf., DHHS, 2013). In one study, 49.1% of LEP patients' adverse events involved physical harm in comparison with 29.5% of patients who spoke English fluently (Divi, Koss, Schmaltz, & Loeb, 2007). The study showed adverse events occurred to LEP patients as result of communication errors (52.4%) in comparison with English speakers (35.9%) (Divi et al., 2007). The informed consent form represents one part of the process occurring between the research participant and research team. The informed consent document and the process should be transparent and clear to the future research participants (U.S. DHHS, 2013a).

The process of obtaining informed consent represents a dialog of the study procedures between a potential participant and research team. The informed consent represents the ethical documentation of health care treatments (Kluge, 2007). Informed consent provides the patient explanations about the interventions, consequences, nature of the study, visit schedule, possible side effects of the drug or device, and available alternative treatments. The informed consent provides understanding to patients. Patients can make an informed decision about acceptance or refusal to participate in a particular trial. In research, informed consents are monitored and ethical concerns are raised when the investigator may be the primary provider (Kluge, 2007).

The ethical standards for informed consents in clinical trials are higher because research involves investigation with human participants. Clinical trials follow The Joint Commission on Accreditation of Healthcare Organizations rules and Good Clinical Practices standards of care procedures for research. According to the U.S. NIH (1999), effective July 1, 1999, all multi-site trials with DSMB are expected to provide reports of adverse events to the IRB practicing clinical trial studies. The DSMB reports assist

health care organizations in reviewing medical errors to develop avoidance strategies of similar consequences at other research sites. Good Clinical Practices are "standard for research design provides assurance that data and reported results are correct in addition to reviewing the rights, integrity, and confidentiality of participants" (Global Harmonization Task Force, 2008, p. 4).

Participant understanding of the parameters of clinical trials increases the possibilities of clean data for analysis (Kerrison, Laws, Cane, & Thompson, 2008). Lack of understanding increases the possibilities of adverse event reporting and early withdrawals from studies. Limited investigations have studied communication initiatives taken by hospital leadership and IRB groups to identify and correct problems contributing to possible adverse events related to barriers of communication during clinical trials (Lidz & Appelbaum, 2002; Resnik & Jones, 2006).

Problem Statement

Communication barriers are a significant problem in the understanding of informed consent processes during clinical trial practices among Limited English Proficiency (LEP) participants. According to the U.S. 2010 Census, 59 million Americans speak a language other than English at home and 25.2 million have LEP (U.S Census 2010). Twenty percent of the U.S. population over the age of five does not speak English at home according to 2007 Census Data (Shin & Kominsky, 2010), This statistical percentage does not include undocumented immigrants, who are estimated at 40 million people accounting for 13.8% of the U.S. population (Justich & Ng, 2005). Among these undocumented immigrants, it is estimated that 5.5% have LEP (Resnik & Jones, 2006).

Data from other information sources provide diverse measurements of the size of the undocumented immigration population indicating that the current size may range 11.7 million. Statistics by the U.S. Census Bureau, Department of Labor, and Pew Hispanic Center estimated 10.3 million unauthorized immigrants in 2004 reaching 11 million in 2005 (Kohut, Suro, Keeter, Doherty, & Escobar, 2006). Twelve million people are the estimation of undocumented immigrants in the United States accounting for 13.8% of the U.S. population (Pew Research Institute, 2012). Based on the 2009 census of U.S. hospitals performed by the American Hospital Association, of the 641,000 daily inpatients, 128,000 are LEP requiring professional interpretation services (Flores, 2005; Karliner, Jacobs, Chen, & Mutha, 2006).

The U.S. DHHS responded to the need of minorities and LEP people accessing the health care system to receive equal and quality care in response to the changing demographics in the United States. To accomplish quality and equal care, the DHHS Office of Minority Health issued the National Standards for Culturally and Linguistically Appropriate Services in Health Care (CLAS) (U.S. DHHS, 2001a, 2013c). The intention of the Minority Health Office was to advance equality, improve quality care, and eliminate the U.S. disparities in health care (U.S. DHHS, 2013c). CLAS responded to the diversification of cultures and practices, patients' primary language health education, and other communication needs. The Office of Minority Health worked on CLAS standards from 2002 through 2012. The enhanced standards were published early in 2013. The standards sustained governance performance through policy development, practice, and the allocation of resources. Demographics from the U.S. census 2010 confirmed a large number of Limited English Proficiency (LEP) people in the United States. Clinical trials

in the United States include LEP participants (Resnik & Jones, 2006). Statistics of cancer trials demonstrated less than 3% of patients with cancer enroll in clinical trials. Statistically, clinical trial participants are represented by, married, middle class, highly educated Caucasians (Giuliano et al., 2000). The participation of LEP diagnosed with cancer is much lower (Resnik & Jones, 2006).

The presentation and signing of the informed consent prior to the start of a research study is paramount to the patient-doctor relationship (Roe, 2009). Interpreters, investigators, and LEP patients, participating during the informed consent process is imperative to make the communication understandable throughout the clinical trial process (Jacobs, Chen, Karliner, Agger-Gupta, & Mutha, 2006). The problem is that communication barriers between providers and LEP trial participants affect the informed consent process. The deficiencies of clear methods of communication during the informed consent process may affect the trial process and outcomes.

Purpose

A qualitative case study was used to describe the communication barriers during the informed consent process at a North Texas Research Institution (NTRI). The name of the institution was not used to protect the confidentiality of outcomes at the organization's request. The purpose of the present qualitative case study was to explore if communication barriers affect the understanding of LEP research participants while participating in the informed consent process during clinical trials. Data analysis involved reviewing the emerging themes from participant's responses. Audio recording and note taking took place during the interviews with subsequent transcriptions of the interviews, ensuring capture of accurate responses. Data were collected by using open-

ended semistructured interviews with six principal investigators with diverse medical backgrounds, nine LEP participants, and five interpreters from the Language Assistance Program at NTRI. The study included a pilot study to determine feasibility of interviews, audiotape, and transcript of interviews, and patient's medical records to corroborate previous clinical trial participation. The first participant of each group participated of the pilot study. For the purpose of the study, the unit of analysis included five PIs, four interpreters, and eight LEPs.

Significance of the Study

Scientific research is an important part of medical innovation (National Academies Press, 2002). The recruitment of diverse ethnic groups and cultures in clinical trials provides abundant information for the development of new alternatives of treatment (Kao, Hsu, & Clark, 2004). The importance of maintaining mutually beneficial, clear, and efficient communication during the informed consent process facilitates research study outcomes (Helgesson, Ludvigsson, & Gustafsson, 2005). Maintaining clear communication throughout phases of information exchange during the informed consent processes is important to the clinical trials industry because misunderstanding may jeopardize outcomes.

Misunderstanding of informed consent processes may increase chances for serious adverse events with possibilities of hospitalization, early withdrawal from study treatments, incomplete data, financial losses for sponsors, and ethical concerns of research participation (Dixon-Woods et al., 2007). For example, adverse events represented 32% of financial expenses in a HIV clinical trial; this expense has caused related concerns to the outcomes and marketing of a new product (Chou et al., 2007).

Results of the current study may inform leaders of the medical research industry to promote clear communication environments increasing research participation, clear data, and scientific improvements.

Quality improvements during the informed consent processes of clinical trials increasing knowledge about communication barriers are important to conduct safe, scientific investigations. Many studies revealed poor comprehension of informed consent by participants; in fact, some participants may not even be aware of their participation in research (Joffe, Cook, Cleary, Clark, & Weeks, 2001a). Limited information was available in the literature concerning quality improvements implemented by organizations in an attempt to identify and correct problem areas contributing to communication barriers during clinical trials (Jones, 2006). Even though many studies have investigated LEP participation in clinical trials and informed consent processes, evidence of communication process improvement has not emerged from the studies (Berntsen, 2004; Young, D., 2005).

Finally, the study will contribute to the knowledge related to the methods and effectiveness of leadership quality improvement processes in completing the informed consent when communications barriers are present during clinical trials. The main purpose of a clinical trial is to find methods to improve treatments or treat diseases through research (University of Texas Southwestern [UTSW], 2006). The results of the present study will assist in the development of IRB-informed consent approval strategies to continue safer scientific investigations and encourage research investigators to maintain and develop strategies of clear communication with LEP participants. Investigators may use results to elaborate the communication parameters during informed

consent presentations to LEP participants and create educational strategies for scientific researchers involved in clinical trials.

Nature of the Study

The current qualitative case study obtained data from a convenience sample of clinical trial participants at NTRI. Exploratory case studies allow for the contemporary examination of phenomena during concurrent episodes (Creswell, 2005). The nature of this study section will represent a discussion of why qualitative case study was appropriate, instead of quantitative research methods as the selected design. The purpose of the present qualitative case study was to explore if communication barriers affect the understanding of LEP research participants while participating in the informed consent process during clinical trials. The case study design requires investigators to work with a variety of observational evidence, development of research questions, and creation of research design standards. In contrast to exploratory qualitative designs, quantitative methods are necessary when measuring specific quantifiable data to answer explicit questions (Creswell, 2005). The quantitative research design collects numeric data from research participants and applies statistical analysis (Creswell, 2005). Quantitative studies are common to determine statistical measurements of variables, relationships of variables, and outcomes that will test theories in large populations. The qualitative research method was appropriate because the data consisted of participants' views and experiences generated as transcribed data from an interview process (Creswell, 2005).

According to Yin (2003), qualitative case study designs are the preferred research method to answer how and why questions. To answer these questions it is important to

explore data generated over time and not in frequencies. Case studies are used to explore, describe, and explain a social phenomenon (Neuman, 2003).

One of the reasons this research was a case study was that behaviors of interest were not manipulated. Sponsors require different methods of data reporting and informed consent processes. The IRB requires preparation of informed consent using an eighth-grade level of writing, Spanish short forms, and depending on the risk of the study, a full translation of the informed consent. The U.S. federal government provides guidance to mitigate language barriers in clinical trials. According to the Federal Drug Administration Rule 45 CFR 460116 and 21 CFR 50.20, information given to a research participant during informed consent "should be in a language understandable to the subject or representative." This policy implies that the communication during the informed consent process must take place in a language understandable by the participant (Resnik & Jones, 2006).

According to Creswell (2005), qualitative research includes the need to listen, ask questions, and often advocates for the betterment of the community; in the case of this study the informed consent process. In this qualitative study, the focus of the research was to explore the reasons LEP clinical trial participants encounter obstacles that inhibit clear understanding of informed consent processes during clinical trials. The forms of data collection included interviews, questionnaires, document analysis, and behavioral observations. Case studies are capable of dealing with a variety of evidence (Yin, 2003). The employment of diverse sources of data collection provides a comprehensive study of an event (Creswell, 2005).

The informed consent process is a social activity where patients volunteer to participate after communication of the parameters involved in a study protocol. The patients gathered the information provided by the investigators to make a voluntary decision to participate. These types of behaviors and communication are in a social context conducive to a qualitative exploratory case study.

Research Questions

The purpose of the present qualitative case study was to explore if communication barriers affect the understanding of LEP research participants while participating in the informed consent process during clinical trials. The central questions of this study were:

RQ1. To determine communication barriers during the informed consent process among principal investigators, interpreters, and LEP clinical trial participants. The study determined if language barriers affected the understanding of the informed consent process.

RQ2. To determined what other factors, such as culture, experience, education, religion, and social economic status, clinical trial participants attributed to communication barriers.

RQ3. To discover precedents that may emerge as negative procedures in the informed consent process with LEP participants.

RQ4. To determine if emerging characteristics were shared among the three groups investigated.

Theoretical Framework

Hospitals in America are encountering adverse events and quality problems in relation to health care treatment and research (Kohn, Corrigan, & Donaldson, 2000). Organizations are creating policies for patient safety and interventions to improve health treatments. The present research was necessary to investigate the quality improvement process implemented by review boards of scientific research to determine effective communication procedures during informed consent processes.

The study involved an exploration of ways communication barriers affected the understanding of risks, benefits, and procedures of clinical trials detailed during the informed consent process. Limited information was available concerning quality improvement of the informed consent process that organizations have implemented by identifying and correcting problem areas in clinical trials (Becher & Chassin, 2001). Many studies have been performed investigating the relationship and frequency of adverse events during standard of care practices (Berntsen, 2004; Young, D., 2005).

Recommendations from the Department of Health and Human Services

The U.S. DHHS Office of Minority Health published Culturally and Linguistically Appropriate Services (CLAS) in 2000 and later updated in 2013 the enhance standards of a 10-year study of the equality of the U.S. health care system (U.S. DHHS, 2013c). Report recommendations explained that health systems personnel needed support to develop data management programs. CLAS included metrics to monitor performance and demographic changes in the U.S. health care system in culturally and linguistically diverse situations. The report encouraged the development of tools for appropriate services focusing on implementation strategies for senior leaders,

administrators, and clinicians. The report detailed the need to develop cultural and linguistic strategies of care to eliminate disparities of care to patients of diverse ethnicities and cultural backgrounds (U.S. DHHS, 2013c). Other needs included improving quality of service, establishing accreditation mandates, addressing competition, and decreasing liability claims. The importance of documenting and recognizing emerging communication problems during the informed consent process in clinical trials will assist health care organizations, research institutions, and research lenders in creating and implementing effective policies and training for the protection of participants.

Communication and Transition of Information Theory

Communication barriers may be a cause in overlooking important details during the informed consent process that may consequently lead to misunderstanding of the informed consent. The evolution of the significant factors of clear methods of communication, beneficence, justice, competence, autonomy, perception, risk, and benefits formed the framework to support this research study (Quinn, S., 2004). Communication theory is framed in a social and cultural context of transmitting a message (West & Turner, 2004). Communication is fundamentally the ability to understand conversations through the transition of information as a social process in which individuals employ symbols to institute, interpret, and understand events (West & Turner, 2010). Communication is essential to the interaction in which providers offer medical advice to patients in relation to treatment and diagnosis (Blanquicett, Amsbary, Mills, & Powell, 2007).

Communication theory argues that during communication interactions individuals will try to accommodate to the style and speaking ability of the receiver (Craig & Muller, 2007). Communication involves meaning, symbols, environment, social environments, and processes. Identification of participants' communication will initiate a process of cognition, demanding tasks, such as recognition of language differences, to enhance the process during informed consent procedures. Recognizing the communication differences will assist providers in making decisions about integrating, interpreting, or excluding participants from research studies. The process of informed consent necessitates an exchange of clear communication parameters between investigators and participants. The interchange of information during the process establishes a relationship between the investigator and the participant for the duration of the study procedures.

Social Exchange Theory

Social exchange theorists posit that the interchange of information builds relationships in economic terms (Hepworth, Rooney, Strom-Gottfried, & Larsen, 2010). Individuals count the cost of a connection and compare it to the rewards obtained by working in a particular relationship. Based upon the social exchange theory, the worth of a relationship influences the outcomes (Monge & Contractor, 2003). Building a relationship of understanding during clinical trials procedures is paramount to comply with the standard procedures of the research protocols and to avoid negative outcomes in relation to communication that can jeopardize results (Smith, Thomas, & George, 2002). Building a relationship requires time and effort with clinical trial participants (Hepworth, Rooney, Strom-Gottfried, & Larsen, 2010). The relationship between provider and research participants requires trust. To acquire trust, both groups spend time

communicating and building a relationship through the consent process. Based upon the social exchange theory, to maintain trust, the time spent building a relationship through communication is viewed as a cost. The consent process required an exchange of communication, which can be complicated if the participant has LEP.

Title VI of the Civil Rights Act of 1964

The U.S. Department of Justice defines LEP individuals as people whose primary language is not English (Donelan et al., 2009). Title VI of the Civil Rights Act of 1964 prohibits discrimination based on national origin (U.S. Department of Justice, 2000). Executive Order No. 13,166 (2000) mandates that persons with LEP have access to federally funded programs (U.S. Department of Justice, 2000). This order specifies provisions requiring language services for LEP patients. Previous research indicated interpretation is not formalized into practice because of the lack of standard of care trainings and licensure for the interpretation processes (Dysart, 2007). Health care institutions offer language access services to LEP patients by employed certified bilingual personnel (Donelan et al., 2009).

Simon, Kodish, Zyzanski, and Durand (2006) conducted a study involving an exploration of the use of professional interpreters during informed consent dialogues. The results confirmed the use of medical jargon, length of sentences, and lack of knowledge concerning the cultural perspective of the patient caused miscommunication during the transfer of information between the investigator and the participant. Communication and understanding is important in the patient-investigator relationship to treat, prevent, and gather past medical data useful to treatment plans. Keatinge et al. (2002) conducted a study in Australia resulting in proof that nurses' perceptions of

partnerships with patients were diverse. The researchers identified communication as the principal barrier to relationship development, an important finding because lack of clear communication may jeopardize patients' treatment while in hospital care.

Clinical trial teams have diverse methods of introducing research studies to participants. Each method is governed by the Federal Drug Administration Rule 21 CFR 50.20 of the informed consent documentation. The findings from this qualitative case study may serve as the basis of education for institutions practicing clinical trials in which LEP patients are part of the participatory culture as well as a reference for future studies and informed consent procedures.

Since 1990, medical research has grown globally and the numbers of investigations have multiplied (Stober, 2003). Title VI of the Civil Rights Act of 1964 changed institutional mechanisms that allowed discrimination of minorities to the services of organizations that received federal funding; this included the practice of research (Bustillos, 2009). In 2000, President Clinton ordered organizations to remove language barriers for people with LEP enhancing access to services for individuals with LEP (Bustillos, 2009).

Language and cultural differences among research participants may present proof that organizations need to acquire and educate research teams in communication development. Interpreters not trained with the proper scientific and research terms are a probable cause for poor communication during the informed consent procedures (Donelan et al., 2009). The results of a study of language barriers in a pediatric emergency facility demonstrated an increase of $38 in charges for testing and longer waiting periods (20 minutes or more) than compared to patients without language barriers

(Hampers, Gutglass, Binns, & Krug, 2002). A study geared toward enhancing interpreter services intervention in hospitals demonstrated the intervention did not significantly influence measurable outcomes. The cost of the interpretation services was estimated at $234 per intervention, representing 1.5% of the average hospital cost (Jacobs, Sadowski, & Rathouz, 2007). The study demonstrated that the interpretation services increased patient satisfaction and reduced emergency visits; reducing hospital cost by $92 per Spanish-speaking patient (Jacobs, Sadowski et al., 2007).

Hospitals in the United States participate in clinical trials and in many cases have internal institutional review board departments (Steinbrook, 2002). Hospitals and organizations vary in size, organizational structure, and are influenced by accreditation standards such as FDA, Joint Commission, state and government laws, Good Clinical Practices, sponsors regulations, and public concerns that determine feasibility, security, and credibility of trials.

Understanding the Informed Consent Process

The success of clinical trials requires participants to understand the methods and research design of the protocols. The informed consent is the main tool for understanding; it provides details of the purpose, objectives, procedures, and risks of the studies. Communication barriers during the informed consent process are obstacles to clear outcomes. Available data suggest that participants of prospective research studies may regularly not understand information relevant to clinical trials in the informed consent form (Flory & Emanuel, 2004). This is the case of patients understanding the informed consent communication about randomized trials. A study conducted with cancer patients who were asked to participate in randomized trials demonstrated patients

lack of understanding of the randomization procedures (Behrendt, Golz, Roesler, Wunsch, 2011). The results of the present qualitative study supported the needs of patients to have adequate time with experienced and trained research teams to understand trial procedures. Systematic data reviewed of interventions in randomized trials from 1961 to 2006 demonstrated that 54 % of research participants understood the objectives of the protocol, 50% understood randomization, 47% understood the voluntary participation concept, 50% understood risk, and 57% understood the possible benefits of the study (Nishimura et al., 2013). The study demonstrated that forms and methods of conversation are important during the informed consent process. The percentages described above limited the specifications of language barriers to overall consent understanding among trial participants. A collection of data performed using the terms informed consent and clinical research from 1966 to 2004 demonstrated efforts to improve consent understanding failed (Flory & Emanuel, 2004). Data collection findings demonstrated that research members who spend quality time with research participants face-to-face had effective communication and understanding of the research processes (Flory & Emanuel, 2004). The time spent with the participants could consist of one hour to several meetings before the consent was signed. Clear communication is an important piece during the research presentation and gathering of information. The first conversation is the preamble to what could represent clean data outcomes of a clinical trial. The following definitions are concepts used in clinical trials that assist the understanding of the current study. The investigators use the concepts to assist in communication with sponsors, coordinators, and research personnel, accessing a universal language to determine the stages and processes of the clinical trials.

Definitions

The meaning of the terms used through the document is vital in order to interpret the scope of a research study. The following definitions are used through this case study:

Adverse event--any undesirable medical experience or investigation associated with the use of a medical product in a patient (FDA, 2009, p. 2).

Clinical trial/study—According to the U.S. DHHS (1996), a clinical trial or study refers to,

> any investigation in human subjects intended to discover or verify the clinical, pharmacological, and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. (p. 3)

Contract research organization (CRO)--person or an organization contracted by the sponsor to perform sponsor's trial-related duties and functions (U.S. DHHS, 1996, p. 3).

Data Safety Monitoring Board--A group of individuals with expertise that reviews data from ongoing clinical trials, creating awareness of potential concerns that may arise during the investigation (U.S. DHHS, 2001b).

Good Clinical Practice (GCP)--According to the U.S. DHHS (1996), good clinical practice refers to a,

> standard for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials that provides assurance that the data and

reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected. (p. 4)

Informed consent--A process by which a participant voluntarily confirms his or her willingness to participate in a particular trial, after been informed of all aspects of the trial relevant to the participant's decision to participate. Informed consent is documented by means of a written, signed, and dated informed consent form (U.S. DHHS, 1996, p. 5)

Institute of Medicine--Established in 1970 by the National Academy of Science to develop and examine public health policy (Kohn et al., 2000).

Institutional Review Board--an independent body composed of medical, scientific, and nonscientific members, who have the responsibility to ensure the protection of the rights, safety, and well-being of human participants involved in a trial (UTSW, 2008).

International Conference on Harmonization-founded in 1990 was established to develop unified clinical research standards for the United States, Europe, and Japan (Global Harmonization Task Force, 2008).

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO)-The JCAHO is an independent accrediting and certification not-for-profit organization for organizations and programs in the United States (The Joint Commission, 2008).

Limited English proficiency (LEP) is defined "as a limited ability or inability to speak, read, writes, or understands the English language" (Jacobs, Gupta, & Chan, 2003, p. 60).

Language access services (LAS) is defined "as the availability of bilingual staff who can communicate directly with patients/consumers in their preferred language" (Office of Minority Health, 2001, p. 8).

Medical error--Reference to "failure of a plan to be completed as intended or the use of a wrong plan to achieve a specific objective (error of planning or execution)" (Kohn et al., 2000, p. 54).

National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care (The National CLAS Standards)--"are intended to advance health equity, improve quality, and health eliminate care disparities in health care organizations to implement "culturally and linguistically appropriate services" (U.S. DHHS, 2013b, p. 9).

National Institutes of Health--steward of medical and behavioral research for United States (NIH, 2008).

Patient safety standards--developed by The Joint Commission on Accreditation of Healthcare Organizations as measures of accreditation of health care organizations (Joint Commission, 2008).

Principal investigator--"the primary individual in charge of a research grants or sponsored project" (U.S. DHHS, 1996, p. 5).

Protocol-Investigators describe in this document the objective(s), design, methodology, statistical considerations, and organization of a trial (U.S. DHHS, 1996, p. 6).

Serious Adverse Event (SAE) or *Serious Adverse Drug Reaction* (Serious ADR)-"Any untoward medical occurrence associated with the use of a medical product in a patient who, at any dose, is life-threatening, requires new or existing hospitalization, or results in death, a significant disability/incapacity or a congenital anomaly/birth defect" (U.S. DHHS, 1996, p. 7).

Vulnerable subjects—A term referring to

> patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent. Vulnerable subjects applies to individuals whose willingness to volunteer in a clinical trial may be improperly influenced by the expectation, whether justified or not, of benefits associated with participation or of a retaliatory response from research team members in case of refusal to participate. (U.S. DHHS, 1996, p. 8)

Assumptions

The present study included the following assumptions. The first assumption pertained to the number of participants needed for data saturation to be adequate and representative of the clinical trials population at the NTRI. This assumption was based on the numbers of studies IRB approved per department and recruiting standards at the NTRI. The NTRI IRB approved over 20 studies per department yearly, and each study varied in recruitment parameters. Interventional studies could involve from one to five patients yearly. The number of participants interviewed in each group provided ample information with repetitive concepts. A semistructured interview was used to collect the data from the sample population.

The second assumption pertained to the participants' responses. The assumption was that participants would answer the demographic questionnaire and provide honest responses related to their experiences during the informed consent process. The assumption was participants would provide honest responses because participants

understood how the contribution of their experiences possibly would benefit others who participate in future clinical trials. The participants provided real experiences from their clinical trials informed consent participation. The participants integrated their experiences during the interviewed process in relation to the informed consent process participation.

The third assumption pertained on the way the sample groups would provide interview responses based on their desire to have positive workable experiences during informed consent processes with LEP trial participants. The participants demonstrated concern regarding their role during the informed consent process and the way their communication and interpretation would affect the understanding of the informed consent. Principal investigators are responsible for creating conditions of collaboration during the communication of the informed consent procedures in which interpreters are assigned to aid the interpretation process. The principal investigators trust the expertise of the interpreter to communicate the informed consent process clearly to research participants.

Scope

The study investigated the effects of communication barriers presented during the informed consent process for clinical trials. The goal of the study was to investigate how communication barriers were perceived as contributors to the understanding of the informed consent concepts and possible subsequent consequences. The investigation included the ability of the research team to communicate the informed consent process to the NTRI research participants whose primary language was not English. The study included the development of communication through the presentation of the informed

consent process and perceptions of the effectiveness of the conversations with research participants during the trials. The investigation also evaluated the effects of clinical trials and possible adverse events in relation to communication barriers between research teams, interpreters, and participants. The study included an evaluation of the perceptions of research participants of the informed consent process after the informed consent was signed and research details explained.

Limitations

Semistructured interviews were used to evaluate the consequences of communication barriers during informed consent processes. Limited and comparable information exists in the literature; the data collected from the questionnaire was difficult to compare and contrast with other literature. The elements and conclusion of this study must be re-evaluated in the future and expanded to other institutions because to the lack of comparative information from previous studies.

NTRI was selected as the organization of interest to develop the study because of accessibility and the researcher's knowledge of the governance of the organization in regard to clinical trials. The NTRI represented a comparable sample size of health centers dedicated to research and education around the United States. The NTRI has clinical trials currently active in diverse scientific specialties. As part of the research team, the study required Institutional Review Board approval before implementation. Other hospitals were not included in this study, and the data obtained may not represent other institutions informed consent practices during clinical trials. The focus of this study was to identify the progress of research teams in implementing communication processes during clinical trials. The focus did not include a study of specific situations that may

exist during standards of care practices, which could lead to improved effective methods of consent management.

Delimitations

The present study did not involve an investigation of standard of care policies and procedures that exist in the hospital's informed consent for treatments or the influence of other regulations that promote safety. Leaders and organizational structures can influence the effectiveness and implementation of the study. The study required an IRB approval process. The approval process required IRB stipulations, which limited the time and population under study.

Summary

The good clinical practices regulations have increased research policies for the protection of human subjects (U.S. DHHS, 2010). The IRB and DSMB groups have increased medical reporting systems to monitor adverse events in research procedures. Despite efforts to monitor effectiveness of communication and adverse events during clinical trials, limited information is known to indicate if this progress is effective. Patient provider communications are critical to eliminate discrepancies and possible adverse events during protocol transitions (Bigby & Ashley, 2008).

A representative sample from NTRI was studied. The purpose of the present qualitative case study was to explore if communication barriers affect the understanding of LEP research participants while participating in the informed consent process during clinical trials. Health care and government organizations dedicated to research and policy development may benefit through the information obtained. The present research may provide an opportunity to initiate studies related to communication barriers and

adverse events during clinical trials procedures. Organizations can determine if efforts, regulations, and language interpretation programs implemented are enough to improve and make effective clinical trials informed consent procedures.

A detailed literature review was performed of the existing research related to clinical trial regulations and developments, informed consent processes, adverse events, and management systems during the clinical trials practice. The literature reviewed includes an overview of government, institutional review boards, accreditation procedures, and clinical trials processes. The literature review in Chapter 2 also includes sources on regulatory procedures and management of policies to protect research participants.

Chapter 2

Literature Review

The purpose of the present qualitative case study was to explore if communication barriers affect the understanding of LEP research participants while participating in the informed consent process during clinical trials. Chapter 2 includes a historic overview, current findings, and gaps in the literature pertaining to communication barriers of clinical trial participants. A literature review was conducted on communications barriers with LEP patients, including searches in topical areas of informed consent procedures. Chapter 2 includes a review of literature pertaining to two research questions: (a) How do LEP clinical trial participants (providers, patients, and interpreters) perceive the communication methods used during the informed consent processes at the NTRI? (b) Do principal investigators, participants, and interpreters consider communication barriers as a possible cause of medical error during the informed consent process? Chapter 2 includes communication theories that can be used to explain the informed consent process and explore the historical perspective of clinical trials and development of scientific regulations.

The study for themes in the literature review included *legal and ethical approaches in clinical trials, history and perspective of research, the importance of research for science and medicine,* and the *definition of clinical trials*. Other search topics included the *Joint Commission, health care research and quality, clinical trials development, the Institutional Review Board, Informed consent, principal investigators and research participant's interactions, provider's conflict as principal investigators, communication,* and *primary language of research participants*. Sources included peer-

reviewed journals from University of Phoenix, the U.S. Library of Medicine, books, and medical regulatory websites such as the FDA, NIH, and the DHHS.

Clinical trials are composed of a series of steps involving accreditation standards, good clinical practices, IRBs, and communication strategies between research teams and participants. The exercise of communication through the informed consent process is the method by which patients and investigators interchange information relevant to the studies. The process includes future visits associated with the study, responsibilities, risks, benefits, randomization, compensation, and communication parameters. The research involved an investigation of communication barriers during the scientific research process, specifically during the informed consent process between the research team and LEP participants.

Legal and Ethical Approach

The U.S. population is continually increasing and diversifying (Bustillos, 2009). More than one sixth of the U.S. population speaks a language other than English (Shin & Bruno, 2000). According to the 2010 Census, 59 million Americans speak a language other than English at home, an increase from 7.3 million. The statistic does not include illegal immigrants who are estimated at 40 million, accounting for 13.8% of the U.S. population. Previous reports showed 20% of patients reported communication barriers with health care providers (Bustillos, 2009). Clear channels of communication are critical to ensure safety and deliver care effectively.

Clear channels of communication during the informed consent process include understanding risks and benefits, adherence to protocols processes, research goals, and treatment regimes. Providing clear communication during the informed consent process

so the informed consent is understood and effective is paramount for the exchange of communication required by the informed consent process guidelines ensuring protection to human subjects. LEP patients may experience an inability to understand, which could lead to unnecessary errors (Flores, Barton-Laws, Mayo et al., 2003).

Because LEP patients are accessing health care facilities, data indicated that the population could be recruited to participate in clinical trials (Wilson, Chen, Grumbach, Wang, & Fernandez, 2005). LEP patients without adequate communication skills are embarrassed and attempt to compensate by respecting without question the principal investigators; the LEP patients tend to consent to participate in clinical trials without adequately understanding the processes (Wolf et al., 2007). To offset the inherent disadvantages LEP individuals and other groups experience, the Title VI Civil Rights Act of 1964 restricted institutional mechanisms that allowed discrimination of minorities. Title VI Civil Rights Act prohibits facilities that receive federal funding to deny services to anyone.

During President Clinton's administration in 2000, an executive order was issued for all federally funded organizations to remove language barriers for LEP individuals (Bustillos, 2009). Exec. Order No. 13,166 (2000) included a stipulation that each organization receiving federal funding should have published guidelines to provide access to LEP patients in compliance with the Civil Rights Act of 1964. This order includes mandates for organizational leaders to provide communication tools to LEP patients accessing medical services.

Providing communication tools to LEP is important because the involvement of communication tools in the exchange of communication in health care facilities promotes

understanding of clinical and research procedures. In 2003, the executive order directed the DHHS to develop guidelines outlining the responsibility of federally funded agencies to prohibit discrimination on the grounds of color, race, and national origin from participation or denial from its program or activities (Bustillos, 2009). In April 2013, the revised policies and practices, known as *National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care: A Blueprint for Advancing and Sustaining CLAS Policy and Practice*, were published by The Office of Minority Health of the DHHS (2013c).

The CLAS policies and practices have been enhanced with 15 revised standard practices, a multiyear process involving several organizations and individuals across the United States. The guidelines by the DHHS indicated organizations funded by federal agencies that perform research must include LEP and minorities in clinical trial procedures if candidates from the special population qualify for the clinical trials. Limiting clinical trials participation of special populations such as LEPs sacrifice benefits and a general view of research outcomes (Resnik and Jones, 2006). The involvement of diverse ethnicity in clinical trials enhances the diversification of sound research discoveries in studies on genetic comparison and analysis (Beckman, 2006). LEP participation is critical for the comparative effectiveness of research and improvement of qualitative data.

Historical Perspective of Research

Scientific knowledge is developed through studying the effectiveness and efficiency of medical innovation by using volunteers for clinical trials (FDA, 2009). A clinical trial is a research study in which human volunteers respond to health aims (FDA, 2008). Clinical trials are the methods used to find treatments that work and improve health in humans (NIH, 2009). Clinical trials are performed to investigate the safety and effectiveness of drugs or devices on humans, analyzing different methods to use standard treatments for effectiveness and to decrease adverse reactions. Trials are governed by rules created to protect the research participants (FDA, 2009).

The Global Harmonization Task Force (2008) was created in 1992 to "achieve uniformity within national medical regulatory systems to enhance patient safety and increase access to safe, effective, and clinically beneficial practices around the world" (para. 1). Although rules and regulations are written to govern and protect research participants, the protections are a result of previous human subject abuse discussed in the human protection guidelines.

The first human protection statement emerged from the Nuremberg Trials in Germany. During World War II, Nazi scientists and physicians conducted experiments using concentration camp victims without gaining participants' informed consent (Trials of War Criminals, 1949). The Nuremberg Code outlined the policies and rules of research protection of human subjects. During World War II, physicians in Nazi Germany conducted clinical research on prisoners in concentration camps without consent, involuntary participation to victims who died as a result of the research. After

the war, physicians were tried at the Nuremberg trials for their crimes committed on individuals who involuntarily participated in studies.

The results of the Nuremberg trials influence the creation of the Nuremberg Code in 1948. This document addressed the importance of ethics in medical research. The document stated voluntary participation was mandatory for all clinical trial participants. Voluntary participation meant that participants were able to consent without coerciveness and understood the risk and benefits involved. The Code was adopted by the United Nations in 1948.

From 1932 to 1972, the United States had a controversial study known as the Tuskegee Syphilis Study (National Cancer Institute, 2008). The Tuskegee Study followed low-income African American men with syphilis without obtaining informed consent, communicating information about their diagnosis, or providing any antibiotic treatment for the disease. Several men died of syphilis, wives contracted the disease, and children were born with congenital syphilis because of the lack of communication and treatment. For these reasons, regulations and policies were developed to secure the information of benefits, risks, and purposes to research participants (DHHS, 2001b).

Investigators enrolled in the study 600 impoverished from Macon County, Alabama, without informed consent. Participants received medical care, meals, and free burial assistance for participation. Participants were never informed of their syphilis or threated for disease. Participants were informed that their treatments were related to a diagnosis of bad blood (Center for Disease Control and Prevention, 2013). The Tuskegee project lasted 40 years and raised ethical standards primary because investigators knowingly failed to treat participants appropriately after 1940 approval of penicillin as an

effective drug to cure the disease. This led to major laws for the protection of human subjects in clinical trials requiring informed consent.

As a result of the Tuskegee Syphilis Study, the National Commission commissioned the Belmont Report, which led to the creation of the Office of Human Research Protections (OHRP) and the requirements of the Institutional Review Board (IRB) for studies involving human subjects (Office of Human Subjects Research, 1979). The principles are divided into three categories: respect for persons, benefits, and justice. Organizations performing research studies are required to follow these regulations in compliance with Good Clinical Practices.

Importance of Research for Science and Medicine

Research is important for the development of medical knowledge to extend life (NIH, 2008). Scientific research is used by health care providers to identify the parameters of medical treatments, drug development, medical devices, and the study of side effects. Health care providers need researchers to prove the effectiveness and efficacy of treatments on humans. Research studies form the steps to discover many mysteries of medicine. The evolution of scientific research has helped in the development of antiretroviral medications for HIV, treatments for cancer, diabetes, and other illnesses that had high mortality rates (Weijer & Miller, 2004). Results of research are essential for decision makers as the best predictors of outcomes and regulating monetary spending (MacPhail, 2008). Research engages people of diverse areas around the world to study common illnesses.

Researchers use outcomes to present arguments concerning health research benefits and possible issues that may arise. Clinical research creates strategic

opportunities to develop medical alternatives for patients (Girot, 2008). Research is an important piece of informative science that supports opportunities to discover the risks and benefits of medical practices, such as risks of radiation when radiation can potentially save lives (Wood, Prior, & Gray, 2003). Research allows patients, providers, and health care communities the best available scientific information to make informed decisions for medical treatment.

Scientific research creates and constructs databases to support decision making and prolongs updates for future studies (Uddin & Martin, 1997). Databases assist by determining inclusion criteria for later prospective studies and identifying common variables leading to continued retrospective research. The development of science improves medicine through the practice of clinical trials and the results they yield.

Clinical Trials

According to the FDA (2009), clinical trials are research studies in which human volunteers answer specific health questions. Clinical trials comprise a safe method to acquire and generate knowledge about new and effective treatments to improve health. Clinical trials are developed to prevent illness, create new treatments, and find innovative methods of existing treatments (FDA, 2009). Clinical trials improve medical screenings, diagnostic techniques, quality of life for serious medical conditions, and measure the effectiveness of new drugs and devices in humans. Clinical trials compare treatments to measure efficacy and effectiveness while recording side effects. Diverse populations are studied during the clinical trials process. Investigators develop trials with the interest of increasing knowledge in the scientific and medical community. Clinical trials expose participants to potential benefits and unknown risks associated with the study.

A principal investigator designs a protocol with the aim of studying a particular medical condition. The research team submits the protocol for review and approval by the IRB of the research organization. The process of the IRB approval depends on the magnitude of risks to the participants. The identification of risks to participants can be physical, psychological, social, or economic (DHHS, 2009). Full board review is the approval process for studies that involve more than minimal risk (UTSW, 2007).

The composition of the IRB review group includes physicians, scientists, nonscientists, and community members who serve to protect the rights and welfare of research participants in accordance with the DHHS and the FDA policies and procedures (UTSW, 2008). The IRB reviews the study procedures including the protocol, objectives, and informed consents that will be used during the research process. These documents and research procedures must comply with the good clinical practices regulations. After the IRB approves the study, the research team is ready to start recruiting individuals for participation (Flynn, Hahn, Kramer, Check, Dombeck, Bang, Perlumutter, & Weinfurt, 2013). Research studies are reviewed by the IRB for continued approval processes.

"Good Clinical Practices (GCP) is an international ethical and scientific standard for proposing, conducting, recording, and reporting trials that involve the participation of humans" (DHHS, 1996, p. 4). Compliance with the GCP policies ensures stakeholders that the rights, safety, and protection of research participants are embedded in the study. Clinical trials are conducted in accordance with ethical principles originated from the Declaration of Helsinki and are consistent with the requirements of the GCP. According to the DHHS Clinical Practice Consolidated Guidelines (1996), the regulatory requirements are stipulated.

1. Before a trial starts, foreseeable risk and inconveniences should be discussed and studied against the anticipated benefits of the research participant and society; a trial should be initiated only if the benefits justify the risks.

2. The rights, safety, and well-being of the participants are the highest consideration and should prevail over the interest of science and society.

3. The available non-clinical and clinical data on an investigational product should be adequate to support the proposed clinical trial.

4. Clinical trials should be scientifically sound and described in detail in a written protocol.

5. A trial should be conducted in compliance with the IRB-approved protocol and independent ethics committee.

6. The medical care given to participants and decisions made on behalf of participants should always be the responsibility of a qualified physician or dentist.

7. Individuals involved in a clinical trial should be qualified by educational training and experience.

8. Informed consent should be obtained prior to clinical trial participation.

9. Clinical information obtained from a trial should be safely recorded and allow accurate reporting, interpretation, and verification.

10. The confidentiality of participants' records should be protected at all times.

11. Investigational products should be manufactured, handled, and stored in accordance with the good manufacturing practice and used following the protocol instructions.

12. The creation of safety and procedures to ensure quality should be implemented.

Research organizations are rigid by accreditation standards dedicated to improve the quality of care provided to patients; the Joint Commission provides oversight of organizations' accreditation procedures. Before a clinical trial investigator commences with the study visits, the informed consent must be discussed and signed. Each organization conducting clinical trials must place documentation of the signed consent

form in the patients' medical record. The Joint Commission during regulatory and accreditation surveys investigate the documentation and procedures of the informed consent forms.

The Joint Commission

The Joint Commission for Accreditation is an independent organization dedicated to continually improving the safety and quality of care assists organizations with performance and support (The Joint Commission, 2008). In 1917, the American College of Surgeons (ACS) established the first set of standards for patient safety and began inspections of organizations for compliance in 1918. At the time, only 89 of 692 hospitals surveyed met the regulatory requirements for minimum standards. In 1951, The Joint Commission was created as an independent, not-for-profit organization with the primary focus of providing voluntary accreditation. Since then, The Joint Commission has published standards for hospital accreditation manuals used by organizations to meet the requirements.

In 1965, Congress passed the Social Security Amendment Act that required hospitals that participated in government programs and received federal funding to be accredited by The Joint Commission. Since implementation, 5,000 hospitals in the United States have received The Joint Commission Accreditation (The Joint Commission, 2008). After the Institute of Medicine published the report *To Err is Human* in 2000, The Joint Commission used the results to strengthen the accreditation standards for patient safety and reform the organization's approach to investigations.

In 2003, The Joint Commission introduced the national patient safety goals to focus health care improvement efforts on specific problems that organizations were

reporting (Hyman, 2006). The Joint Commission specified that treatments and procedures be explained to the patient and relatives (The Joint Commission, 2008). The risk and benefits must be addressed as well as other alternatives of treatment. The standard practice requires informed consent for all participants of clinical trials.

In an effort to continue the understanding of how hospitals can provide patient and family-centered care, the Joint Commission conveyed an internal advisory group. In 2010, the advisory group and the Joint Commission supported by a grant from the California Endowment developed a document called, *Advancing Effective Communication, Cultural Competence, and Patient-and Family-Centered Care: A Road Map for Hospitals* (The Joint Commission, 2010a). In this document, administrators of hospitals and health care facilities received a description of integrated methods of communication for health care facilities to provided quality and equal care.

The report supported the position that hospitals must include cultural competence and patient-centered care practices to consider the needs of patients and family members to the communities assessing services at each particular facility. The recommendations in the document included issues such as language, culture, health literacy, communication barriers, mobility needs, and concerns regarding the gay, bisexual, and transgender community (Joint Commission, 2010a). An exploratory study by the Joint Commission's Division of Quality Measurement and Research developed a study to establish the baseline of culturally and linguistically appropriate by care facilities in 14 hospitals in the state of Florida (Joint Commission, 2010).

The Joint Commission's study findings indicated hospitals in Florida are provided with resources to meet patient-centered needs. Several inconsistencies demonstrated how

staffs are provided with the resources: sometimes the staff was not aware of the resources. If staff was aware of the availability of the language tools, the staff did not use the tools frequently. The present study demonstrated a gap and barriers to overcome even when programs are established in organizations. The problem is leaders of healthcare facilities are not collecting the necessary data to evaluate cultural and language access programs in their respective facilities (Joint Commission, 2010).

Health care leaders seek to have organizations approved by The Joint Commission to obtain financial support. Beaulieu and Epstein (2002) suggested that leaders of health care organizations seek accreditation because of incentives received by participation in government programs such as Medicaid and Medicare (Beaulieu & Epstein, 2002). Based on a study on how accreditation plays a positive role in improving quality care, Medicare and Medicaid legislation stipulate health care organizations must undergo regulatory reviews for their participation in government programs (Evans, 2008). Many states have allowed hospital licensures to be granted based on scores obtained during accreditation standards, because part of the revenue from hospitals comes from government programs (Evans, 2008).

One of the main reasons reported by leaders to continue accreditation was to receive and prolong endorsements and benefits from government programs. Government programs such as Medicare and Medicaid account for 55% of the revenue of the organizations under the study (Rauscher and Wheeler, 2010). Despite the creation of manuals and education from The Joint Commission to make patient medical experience safer, no evidence has been published on prolonged reduction of medical errors as a result of accreditation (Jacott, 2003).

The DHHS agency officials (2000) could implement initiatives and resources to add measures that would promote patient safety not provided by The Joint Commission. A report by the Health Care Financing Administration (2000) requires health care organizations must meet the minimum requirements of the DHHS for participation in Medicaid programs. The surveys conducted by The Joint Commission for Accreditation demonstrated that organizations results determined the ability to obtain Medicare qualifications (DHHS, 2000).

Recent reports published by Health Care Financing Administration and The Joint Commission accountable for their organizations' performance suggested that The Joint Commission should be held responsible for organizations' performances using accreditation standards as measurements by the organization (Moffett & Bohara, 2005). In 2006, with the vision of enforced commitment by health care organizations in promoting safety standards, The Joint Commission conducted unannounced site visits (The Joint Commission, (2008). The Joint Commission has been a continual influence on how organizations engage in determining procedures of patient safety.

In 2003, The Joint Commission published patient safety standards. The patient safety standards include the requirements for medical error management systems (The Joint Commission, 2008). Health care organizations were required to implement the standards for continued accreditation. The patient safety standards follow.

1. Process of data collection to monitor performance (Standard PI.3.1).
2. Create a process to identify undesirable patterns or trends in performance and analyze sentinel events for causes (Standard PI. 4.3).
3. Identify a process for changes in improving performance and safety of patients (Standard PI.4.4).

The Joint Commission exposed the problems of medical errors that continue to make the news and showed how consumers think about the effects of errors during visits (The Joint Commission Resources, 2009). In the latest research by The Joint Commission, researchers emphasized the quality of patient safety issues for organizations. Researchers from The Joint Commission established that organizations followed ground rules to be accredited: prevent medical error events, accurately identify patients, communicate effectively with patients, and reduce delays in patient care (The Joint Commissions Resources, 2002-2008).

Researchers from The Joint Commission (2002) proposed standards for element performance to advance effective communication, cultural competence, and patient-centered care. These were not limited to identifying communication needs, providing language access services, and assessing patient understanding. Health care organizations implemented the patient safety standards regulations to maintain accreditation status and continue with government program services (Devers et al., 2004). The accreditation entitled organizations to an entrée of government programs.

Health Care Research and Quality

Diverse methods can be used to monitor the health care performance of organizations to improve quality in Americans' access to services (AHRQ, 2009). The AHRQ provides comprehensive national overview of the quality services in the United States (2007). In conjunction with the 2005 National Healthcare Disparities Report, a comprehensive national description was presented that measured disparities in health care. The report presented information on how racial, ethnic, and socioeconomic populations were affected. This report was built to measure quality, effectiveness, patient

safety, timelines, and patient centeredness (AHRQ, 2005). The report specified an initiative of awareness toward medical errors and developed reporting systems and national standards for data collection (Tongue, Epps, & Forese, 2005). The report indicated that the data remained incomplete for a comprehensive national assessment of patient safety.

Patient-centered is defined as the establishment of a partnership among practitioners, patients, and their families to ensure decisions, respect, education, and support (AHRQ, 2005). Patient-centered initiatives serve to encourage patients to participate in their own care, improve communication techniques, and promote patient/physician interaction. Patient-centered care can reduce misdiagnosis because communication barriers within care teams are lessened (AHRQ, 2005). Optimal health care requires clear communication and understanding patient diversity, culture, and preferences for best care outcomes.

Studies published by Leape in 1994 suggested that medical errors could be attributed to unintended consequences (VanGeest & Cummins, 2003). Among those unintended consequences are poor communication between patients and staff. In 2002, a study done by the Agency for Health Care Research and Quality revealed that 10.8% of the adult population reported that health care providers sometimes or never listened carefully, explain clearly, respect patient health wishes, and spend enough time participating in consultations (VanGeest & Cummins, 2003). Patient safety is related to quality of care; previous studies have shown that activities that manage quality lack focus on patient safety issues (Agency for Healthcare Research Quality, 2002).

In 2002, the National Patient Safety Foundation (VanGeest & Cummins, 2002) conducted an assessment as part of a study of improvement patient safety through web-based education projects. The objectives of the study were to explore group experiences with medical error, understanding of knowledge of patient safety, and the identification of information and training needs. The study had two phases. The first phase included focus groups with providers and nurses to determine methods of medical error reduction. The second approach used a self-administered survey mailed to physicians and nurses. Physicians were randomized from the American Medical Association (AMA) and nurses were randomized from the American Nursing Association (ANA). The surveys asked both populations to rate the importance of patient safety attitudes toward safety. In the survey, participants were asked about previous education and experiences involving patient safety. Finally, the participants were asked to identify and indicate interest in topics related to patient safety. The results reflected 81.7% of physicians responding to the survey indicated patient safety as a significant issue in health care. The results also showed that 93.8% of responders identified relationships between safety and quality of care. Only 49% of providers indicated patient safety was studied at the organizational level. The focus groups identified the demands of health care and changes in the environment as issues for error (VanGeest & Cummins, 2002). Of the nurses surveyed, 95.2% identified patient safety as important in health care, 83.1% indicated having identified errors during medical practices, and 21% showed participation in trainings and education for patient safety (VanGeest & Cummins, 2002). Based upon study results, although efforts to improve safety in health care are evident, organizations are not improving. The research also indicated obstacles such as communication; cooperation,

technology, and the complexity of the rapidly changing environment in health care are contributors to medical errors.

To err is human. The Institute of Medicine of the United States published a report named *To Err is Human* in 1999 that alarmed health care organizations (Bernsten, 2004; Kohn et al., 1999). The report included collected data that determined deaths caused by preventable medical errors. The report stated that between 44,000 and 98,000 deaths were caused by preventable medical errors yearly in the United States (Bernsten, 2004). The report consisted of a review of the Harvard Practice Study of the cases of more than 30,000 patients from 51 New York hospitals and medical records from Utah and Colorado. The researchers studied admissions and medical procedures to discover medical errors as a leading cause of death in the United States. The report presented a variety of problems created by errors such as disability, injury, and death. The developments of the report represented a serious problem in addition to creating threats for patient safety.

Medical error. Despite continual reports and efforts from organizations to define *error* as a clinical and research priority, the definition of *error* is still inconclusive (Graber, Bohnen, 2005). The cause of multiple definitions for medical error has made organizations collect data for analysis, collaborate with each other, and study the effect of health care delivery. Studies have indicated the measurements of medical error directly because of the broad definitions and causes (Graber & Bohnen, 2005). Researchers have developed alternative measurements such as episodes, critical incidents, potentially comprehensible events, negligence, preventable adverse events, mistakes, and violations (Leape, 1994).

Grober and Bohnen (2005) analyzed the significance of an inclusive and accepted definition for medical error. The study reviewed how the term *medical error* had appeared in literature. The paper described how other safety industries defined error and the effects of the term in health care professions. Grober and Bohnen proposed a new definition and justified the use in clinical practice and research. Researchers had been investigating the impact of medical error; preceding researchers have concentrated efforts on patients' empirical outcomes as consequences of standard of care practices (Leape et al., 1991).

In the early 1950s, medical error was considered a disease of medical progress. Schimmel (1964) adopted the term *noxious episodes* as a surrogate term for medical error and studied the frequency of evidence in patients. Schimmel defined noxious episodes as "all untoward events, complications, and mishaps that resulted from acceptable diagnostic or therapeutic measures" (p. 15; cf. Grober & Bohnen, 2005). In 1970, the California Medical Institute adopted the term *potentially compensatable event* to reflect errors that potentially lead to malpractice (Grober & Bohnen, 2005, p. 40). Potentially compensable was defined as an event because of mismanagement that resulted in disability leading to prolong hospitalization (Grober & Bohnen, 2005). In the 1990s, the Institute of Medicine created the term "adverse event" (Kohn et al., 2000). With the definitions, investigators suggested that only preventable adverse events are attributed to medical error (Kohn et al., 2000). Patient safety professionals have considered adverse events as preventable when there is a failure to follow accepted practices (Wilson et al., 1995).

The events of negligence and preventable adverse events characterized in the Harvard publications, show that Utah and Colorado defined negligence as failure to meet the standards of care (Brennan et al., 1991). Leape (1994) defined adverse negligence as "injury caused by standard medical management events" (p. 11) (as cited in Grober & Bohnen, 2005). Injuries to patients occur when circumstances arise that cause problems of protection for patients (Grober & Bohnen, 2005). Based upon the study, Grober and Bohnen (2005) suggested a definition of medical error to capture systematic problems that cause error, irrespective of outcomes. Errors that could have adverse reactions and consequences but did not finish in negative outcomes are known as near misses. Other definitions for medical error, such as the use of an incorrect plan to achieve a goal, were suggested (Reason, 1990). The study exposed the idea that each industry defines error differently.

Grober and Bohnen (2005) proposed to define error as an act of oversight or commission in a plan or execution contributing to an unintended result. In conclusion, the present study reflects the importance of defining medical error as part of a public health concern that potentially poses a serious threat to patients. To understand the concepts of medical error applied to the research study, it is important to comprehend clinical trials and the functions involved in the process informed consent.

Clinical Trials Development

Clinical trials are scientific, biomedical, or health-related research studies involving humans (DHHS, 2009a). Clinical trials are followed by a written, detailed protocol, known as the study plan, prepared by an investigator. The protocol is carefully designed for safety, includes the goals, and provides a detailed description of the

procedures, background, possible risks, benefits, and the statistics to be measured (DHHS, 2009a). Clinical research can cover various types of studies such as treatment, intervention, and observation to measure outcomes. Clinical trials consist of specific guidelines to determine participation. The sponsors or creators of the research determine study participation by inclusion and exclusion criteria in relation to the disease or device and the volunteers. The criteria include factors such as age, gender, the type and stage of a disease, previous treatment history, and other medical conditions. These factors assist in producing clinical outcomes. The development of clinical studies requires participants with specific health characteristics related to a study to qualify for a research. During trials, teams of researchers are involved in the process. This team consists of doctors, nurses, social workers, coordinators, and other health care professionals (National Cancer Institute, 2008).

Participants in clinical trials are entitled to all the information and procedures that will be performed be deciding upon participation. The instrument used to initiate the process of learning the facts of a clinical trial is known as informed consent. Informed consent helps potential participants understand the process of the study in detail (Porter, 1995).

Clinical trials have benefits and risks, associated with procedures, both of which are unknown prior to the beginning of the clinical trial. Clinical trials are complex, and it is imperative that participants know as much as possible about the trials (Barrett, 2005). The determinations of trials are divided into phases. The following are the phases of clinical trials obtained from the clinical trials website at the National Cancer Institute (2006, para. 4):

Phase I trials--Researchers test an experimental drug or treatment in a small group of people (20-30). This phase determines safety, dosage, and the identification of side effects.

Phase II trials--The experimental drug or treatment is given to a larger population (100-300). This phase evaluates effectiveness and safety.

Phase III trials--The experimental drug or treatment is given to an even larger population (1,000-3,000). Phase III research is used to confirm the effectiveness, monitor side effects, compare treatments, and collect information for safe use of the drug or treatment.

Phase IV trials--These are known as postmarketing studies to obtain additional information including risks, benefits, and use.

Clinical trials are developed to maintain an open knowledge of new and existing treatments and to determine the effectiveness and efficacy of drugs. For a protocol to be part of a scientific trial, an IRB reviews and approves or disapproves the study. The IRB continues reviewing the studies and applying modifications emerging during the trial (FDA, 2009).

Institutional Review Board

The FDA (2009) defined the IRB as an appropriately constituted group nominated to examine and monitor biomedical research involving human participants. The IRB is composed of members with different backgrounds, including individuals interested in science and other disciplines. FDA Rule 42 CFR 56.107 (2007) includes the requirement that at least one member of the IRB must have primary expertise in the scientific area and one member must have nonscientific expertise. Rule 42 CFR 56.107 includes the

requirement that the IRB have diverse members based on race, gender, cultural, and community backgrounds. The FDA regulations also stipulate that the IRB has the authority to approve, modify, or reject studies. The main purpose of the IRB is to protect the rights and welfare of human participants (FDA, 2008). The DHHS includes an Assurance with the IRB for research involving human participants. The institution must comply with the rules and regulations associated with Good Clinical Practice. The process of obtaining IRB study approval varies with the severity and risk of the study (FDA, 2012).

The types of studies include expedited reviews. The expedited review is a procedure in which IRB members approve documents without convening a full board review meeting (UTSW, 2008). FDA Rule 21 CFR 56.110 (2007) includes the concept of the expedited review; it does not require an IRB-expedited review for certain categories of research if the study under review involves no more than minimal risk. These reviews are performed by the IRB chairperson or by an appointed person. The group members of the committee reviewing the documentation must still convey disapproval of a study (FDA, 2007).

Communication is an important tool established between the research team, specifically the principal investigator, and the IRB. The communication parameters include adverse events reporting and continuous progress reports. One of the main means to establish a relationship with research participants and investigators during clinical investigations is through informed consent. Informed consent is reviewed, approved, or disapproved by the IRB. Informed consent is the key to understanding the research purpose and factors involved during the research process (Hubbard, 1982; Meade, 1999).

Informed Consent

Informed consent is a written summary of the study information provided to research participants (National Cancer Institute, 2006). Investigators use informed consent to communicate the parameters of the research study. The informed consent details the purpose of the research, importance of the research, risks, benefits, and volunteer statements (FDA, 2011). The consent gives the research participants adequate information of the study objectives and procedures, providing the tools to comprehend what the research study will entail. The informed consent process should provide enough time for the participant to review, understand, and formulate questions before an agreement is made. The signature of the participant is the agreement to participate and to receive and provide information (Darrow, 2014; FDA, 2011).

Many IRBs have consent form templates. The IRB should review a completed form for each study, taking into consideration the study developments and the population background under the research. The document must be clearly written at an eighth grade level for clear understanding (FDA, 2002).

During the document exchange, a research team member should conduct the presentation of informed consent to the research participants or caregivers. The FDA does not require a third person to witness the consent interview unless the participant has not had the time to read the consent. Each IRB has stipulations for consent presentation and approval processes. Some IRBs require that the investigator be present during the consent process (FDA, 2007).

On many occasions, the informed consent is not written in the primary language of the research participant. The wordiness and complexity of the consent is difficult to

understand for some individuals without medical knowledge. The FDA has certain parameters for consent presentations. The federal government has provided guidelines to include Limited English Proficiency participants in research studies.

According to the regulations, known as the Common Rules, the information given to the research participant should be in a language comprehensible by the participant or representative (Resnik & Jones, 2006). These guidelines imply that communication during the informed consent process should be in a language the participant can understand. Under the FDA Rule 21 CFR 50.27 (b) (2009), illiterate persons who understand English may have someone read the consent to them (FDA, 2002). The signatures of the witness and interviewer must appear in the document. If a short form is used, the interviewer's signature and interpreter's signature must be present in the document. According to the Rule 21 CFR 56.111 (b) (2007), the IRB must review and add safeguards to informed consent when researchers recruit illiterate and vulnerable persons (FDA, 2002).

FDA Rule 21 CFR 50.20 (2009) includes the requirement that the consent be in a language understandable to the research participants. If a participant speaks a language other than English, investigators must translate the document into the language of the participant and submit the document for IRB approval. In other cases, the IRB will consider use of a short form, which is a summary of the English consent form. The IRB should require the investigator conduct an open discussion of the research process when the short form is used. The short form must be approved by the IRB through continued reviews. The IRB requires a translated consent form professionally prepared for nonEnglish-speaking participants (FDA, 2009). Interpreters are required to participate in

the informed consent process when the participant's primary language is different from the research team. One possible problem that could arise during the interpretation process is if interpreters do not have the correct scientific or medical preparation and education to interpret the documents and conversation accurately (Donelan et al., 2009).

Available data indicated that even with the remarkable processes and regulations, potential research participants regularly lack understanding of the information disclosed during the informed consent process (Floury & Emmanuel, 2004). In a study of informed consent in cancer trials, only 30% of participants in a cross-section of oncology research understood that the treatment assigned to them was proven to be the principal treatment for their condition (Joffe, Cook, Clearly, Clark, & Weeks, 2001b). A study of B-blocker drugs to prolong the lives of patients with myocardial infarction history indicated 44% of research participants interviewed did not know the study required a randomization process (Sorrel, 1991). These studies demonstrate how important the disclosure of the information is to the participants.

A retrospective study on interventions to improve research participants' understanding of information released during the informed consent process concluded limited success (Flory & Emmanuel, 2004). The efforts to improve understanding using multimedia did not provide positive outcomes of participation of understanding of procedures. The study demonstrated that conducting informed consent interviews face-to-face with an educated facilitator appears to be more effective (Flory & Emmanuel, 2004). The trials compared the understanding of research participants who participated in informed consent processes. The reviews of the trials showed participants with higher education and reading level skills had a significantly higher understanding. The

preliminary results of this study identified the difference of understanding between knowledge, education, and no education. In addition, reading levels made a difference in understanding.

An empirical study by the Department of Molecular and Clinical Medicine Division of Pediatrics of the University of Linkoping, Sweden explored the perception of information received in a longitudinal screening for Type I diabetes in children (Stolt, Helgesson, Liss, Svensson, & Ludvigsson, 2005). The study used a randomized selection in which 293 of the mothers selected completed an anonymous questionnaire. The results indicated a difference between the reported satisfactions with understanding of the information provided and the lack of knowledge on some of the objectives and methods of the research screening. This study emphasized the importance of an increased understanding of ethical issues in child research studies. The study showed how the information provided in the informed consent should be analyzed and designed for clear understanding of research participants and their caregivers.

According to ethical standards, the process of informed consent is important to maintaining screening and intervention (Stolt et al., 2005). Informed consent must be obtained appropriately, observing the safeguards and confidentiality of participants and using clear communication for understanding in order for participants to make informed decisions. Unclear communication channels during the communication processes among research participants have revealed difficulties regarding comprehension of the clinical trials processes, increasing possibilities for potential risks (Stolt et al., 2005).

A qualitative study performed in Mali, West Africa, developed to identify deficits in comprehension during consent processes, showed diverse indications of unclear

understanding. The community of Mali was invited to participate in a malaria vaccine trial. After the informed consent was obtained from participants, a nine-item questionnaire was performed to gather their perceptions of the information relevant to the signed consent (Krosin, Klitzman, Levin, Cheng, & Ranney, 2006). Results indicated participants had difficulty-comprehending sections of the informed consent, such as the option to withdraw, possible side effects, and the purpose of the investigation. Results demonstrated participants could not identify the potential for risks related to receiving the therapy over receiving the therapy for their condition; receiving the treatment outweighed any concerns. This study illustrates the potential for miscomprehension in the informed consent process.

Informed consent proves to be an important instrument in the research process (Joffe et al., 2001a, b; Lee, 2010). The instrument identifies the ethical values, confidentiality, and understanding of the clinical trials process among research participants. Communication barriers may promote risks to participants and statistical problems if participants present adverse events or drop out of the studies because of misunderstanding at early stages of the study.

The participation, safety, and compliance of participants during the research process will depend on the recruitment methods (Bachenheimer, 2004). The recruitment process will enhance compliance, retention, and diminishment of medical errors. Building effective parameters of communication between research teams and participants builds productive relationships with clear understanding of clinical trials' goals and procedures. Clear channels of communication enhance participants' opportunities to make informed decisions, increase participation, and promote awareness for education

and research. Clear communication, reduces delays and costs in the development of drugs and medical errors (Bachenheimer, 2004).

A pilot study conducted in Australia identified barriers in nursing partnerships as well as strategies to overcome the presented barriers (Keatinge et al., 2002). The study analyzed 199 registered nurses and 36 consumers. Participants identified communication as the principal problem to nurse-consumer partnership. The analysis of the data found that the nurses' perceptions of partnership with consumers were diverse (Keatinge et al., 2002). This Australian pilot study demonstrated how communication barriers could affect the patient-provider relationship. The participants of the pilot study identified cultural differences, literacy, time, clarity, education, culture, and mismatch of communication/language between providers and patients as barriers of effective methods of clear communication (Keatinge et al., 2002). According to Keatinge et al. (2002), maintaining clear communication to increase the effectiveness of partnerships among providers and health care consumers was important.

Diverse recruitment is important to research for the statistical analysis of goals. Clinical trials are open to different ethnicity and cultures, which brings certain problems to the clinical trials process. Communication between team members and possible participants can be affected when a difference in language exists. A quantitative study examined the communication given by health providers when comparing Spanish-speaking participants and English-speaking participants (Morales, Cunningham, Brown, Liu, & Hays, 1999). This quantitative randomized study implemented a survey instrument to analyze patient care from an independent association of physicians in the western side of the United States. The survey asked questions about health status,

satisfaction, and use of health services during the past 12 months. Each participant obtained the survey in both Spanish and English. The quantitative, randomized study concluded that Spanish participants were significantly more dissatisfied with the provider's communication than English speakers (Morales et al., 1999).

According to Morales et al. (1990), Spanish-speaking patients are at increase of risk and poor quality of care due to language differences in contrast to English-speaking participants (Todd, Samaroo, & Hoffman, 1993). Results of a research study comparing satisfaction in health care services among Spanish and English-speaking patients demonstrated dissatisfaction of Spanish-speaking patients who were assisted by interpreters during clinical processes (Baker, D., Parker, Williams, Coats, & Pitkin, 1996). A study of 48 outpatient medical services demonstrated that participants whose primary language was English were more satisfied than Spanish-speaking participants with the care obtained (Morales et al., 1999).

Part of the Joint Commission National Patient Safety Goals is to enhance the effectiveness of communication among providers and patients (Hall, 2008). Effective communication improves patient safety and meets The Joint Commission accreditation goals. The development of safety goals are applied to every parameter of an organization's care to comply with the safety of its patients (Hall, 2008). Clinical trials are composed of established communication parameters required for the best outcomes of the studies. Clinical trials commence with the establishment of communication between research teams and participants (Brown, Bylund, Siminoff, & Slovin, 2010).

Principal investigators and research participants' interactions. The success of clinical trials is determined by the recruitment process, compliance, and retention of participants. Building good recruitment activities is the first step to maintaining good clinical practices. The process of participant recruitment and retention requires a linear process of communication patterns with the study participants. Good recruitment practices establish a culture of effective communication between participants and physicians as investigators. Good recruitment processes empower future participants to make informed decisions about participation in research activities. Improved communication through recruitment processes support ethical behaviors and decision-making related to potential conflicts during the interactions. Participant interaction is critical, and as part of the informed consent process, interaction should be an ongoing and interactive process beyond the form (Brezis et al., 2008). The interaction between research participants and investigators should be continuous and include disclosures and prolonged communication of study information, dialogue, and assessment of outcomes during the study. The purpose is to establish open and comprehensible communication during the interaction to maintain compliance, recruitment numbers, and safety of the patients.

The Veterans Affairs (VA) promoted a brochure to educate and invite veterans to participate in research (Tsan & Brooks, 2013; U.S. Department of Veteran Affairs, 2014). The Secretary of Health introduced the brochure in 2002 with Spanish and English versions. The brochure stated the interaction of research participants and investigators must be a continuous dialog as a tool to promote the parameters of the informed consent. Researchers from the Institute of Medicine included the brochure in their report as a tool

to encourage research participants to maintain clear communication with investigators. Clear communication parameters between providers and research participants are encouraged by The Joint Commission and Good Clinical Practices accreditation standards to avoid medical unexpected situations that may jeopardize research outcomes and place participants at risk of adverse situations.

Providers conflict as principal investigators in the decision making of participants. One important aspect and potential conflict during research occurs when the provider is the principal investigator assigned to the clinical trial. Providers' double role of treatment influence the research participants in decision making (Snethen, Broome, Knafl, Deatrick, & Angst, 2006). The lack of understanding and education of participants in research studies to differentiate when the provider is acting as a primary medical doctor or investigator influences patients' decision making regarding research participation. Providers are the mediators between patient health care and the decisions patients must make in the treatment process, creating a possible conflict with regard to the provider's influence on the patient's decision to participate in research or use standard of care treatments. Patients with a lack of medical expertise rely on providers' input to decide their treatment status. The influence of physician recommendations may go against the decision of patients' preferred treatments (Gurmankin, Baron, Hershey, & Ubel, 2002). A lack of education and different socio-cultural views place physicians as authority figures with knowledge (Gurmankin et al., 2002). Clinical trials in which the providers are the principal investigators can influence the patients' decision to participate because of the authority and expertise represented by the doctor (Snethen et al., 2006). Decision making regarding whether or not to participate in a study requires an

understanding of methods and circumstances involved in the studies (Parada, Kawa, Salazar, Mazon, & Fliesser, 2006). Part of the exchange of communication can be affected if the patients' providers are the principal investigator because trust in the providers' authority and knowledge could outweigh any concerns of the participant.

Studies have shown shared decision making as the preferred method for providers and patients to approach treatment decisions (Perloff, Bonder, Ray, Ray, & Siminoff, 2006). The idea of shared decision making when choosing between treatments involves the presentation of facts and discussions between providers and patients to determine a final assessment to determine between standard of care and research (Say & Thompson, 2003). Problems arise when communication parameters are not clearly explained to participants by the provider, especially when provider and patients belong to a different culture and ethnicity (Perloff et al., 2006). The goal of the provider is to answer questions and obtain information to minimize patients' misunderstandings and misinterpretations of the risks and benefits of treatments and to avoid the imposing treatment preferences of the provider on the patient. When individuals lack health information, individuals rely on the providers as authorities with the tools to cure (St. Amant & McClung, 2004). This authority figure view in research presents a misconception in which future participants trust the provider to decide about their research participation. The representation of providers as authority figures and communication barriers at the time of the informed consent process is wreaked to confronting medical errors and adverse events during the research process. The literature suggests shared decision making as a standard of care is not achieved. The cross-cultural

interaction of patient-provider during presentation and continued follow up of the research can be affected.

Communication

Removing barriers of communication provides autonomy to the participant to make an informed and understandable decision. Clear communication establishes collaboration and trust. For communication to be effective during informed consent procedures the channels used to transfer the message must support the value and voices of research participants. This means investigators must identify the resources and barriers affecting communication (Young, A. & Flower, 2002; Young, A. & Rodriguez, 2006). The ethical concept of self-determination of participants to partake in clinical trials requires the removal of barriers (Beauchamp & Childress, 2008).

Communication is the tool with which providers and patients establish a medical connection to identify symptoms with treatments (Perloff et al., 2006). Institutional differences make communication difficult between providers and patients. Sociocultural factors play a significant role in communication, as the United States has become culturally diverse enhancing values of intergeneration processes. Doctor-patient communication can be affected by socioeconomic norms, sociopolitical concepts, education, trust, and training (Ashton et al., 2003). Communication and medical understanding are influenced by an individual's belief and views regarding religion, economy, and ethnicity (Sternberg, Grigorenko, & Kidd, 2005).

Primary Language of Participants

Clinical trials are developed in multinational and multicultural environments in which participants differ from the primary language of the principal investigators (Kao et

al., 2004). Culture plays an important role in understanding the processes and the development of communication parameters. Language and cultural differences among participants and investigators require educated staff to compensate for the barriers of communication. The federal funding organizations require participation of multicultural populations for health research (Kao et al., 2010). Multicultural populations include Limited English Proficiency (LEP) individuals (Kao et al., 2010). The IRB requires investigators to provide an informed consent process logistically and clearly in the primary language of the participant. These processes are increasing the potential cost associated with the translation of documents by certified individuals. The verification of how interpreters are educated in medical expertise relies on certifications and the trust of the provider. The documents and interpreted conversations are imperative to the understanding of participants. Nonaddressed misunderstanding could compromise research results, integrity of the study, and result in medical errors (Stober, 2003).

Communication barriers are problems highly studied in the United States because of the increase in cases during the past years (Chandrika & Schmaltz, 2007). Inadequate communication may result in tragic errors and consequences. The following case represents an example of this problem. The case reported by the Massachusetts Medical Society indicated that a 12-year-old Latino male arrived at a Boston emergency department with dizziness and headache (Flores, 2006). The patient, with limited proficiency in English and his mother who was monolingual in Spanish, served as his own translator; the hospital did not provide medical interpretation. The mother described the symptoms presented to the patient and the patient translated for his mother. The physician interpreted the Spanish word used by the mother for dizziness, *mareado*, to be

amarillo, the Spanish word for yellow. The inappropriate interpretation of the physician caused in an error in the diagnosis (Flores, 2006). The case study presented a high risk of misunderstanding and inappropriate care due to a lack of a certified interpreter and communication barriers.

Another case of inadequate communication had a tragic consequence. Misinterpretation of a word delayed the care of a patient causing quadriplegia and death (Flores, Abreu, Schwartz, & Hill, 2000). In this case, the Spanish word *intoxicado* was used to describe the patient's symptoms to the paramedics who arrived at the location; the paramedics were nonSpanish-speaking and understood the word to mean that the patient was intoxicated. The intended meaning of *intoxicado* was to describe the symptom as *nauseated* (Flores, 2006). This patient was treated for drug overdose for 36 hours and after reevaluation, the patient was diagnosed with intracerebellar hematoma with brain-stem compression and subdural hematoma secondary to a ruptured artery (Collins, Sather, 2002). The patient later died as a consequence of the wrong diagnosis.

According to the Census Bureau (2008), 20% of the U.S. residents speak a language other than English and 44% have limited English proficiency. With these numbers, medical facilities are not providing adequate medical interpretation to patients. According to a study of emergency departments admissions, 46% of registered cases involving patients with limited English skills lack interpreters (Baker, S., 1998). Only 23% of teaching facilities in the United States provide training to health care workers to work with interpreters, and the education is optional (Flores, 2006).

Use of interpreters. The representation of interpreters is paramount in the patient-provider relationship. The education and training of interpreters and translators

during the communication process will determine the efficacy and effectiveness of the relationship. The communication process occurs during standard of care visits or the informed consent process for research purposes. Misinterpretation can lead to adverse medical situations (Flores, Barton-Laws, Mayo et al., 2003). Many organizations use family members, friends, untrained personnel, and strangers to interpret clinical encounters. Those interpreters are more likely to commit errors, which can result in direct adverse clinical consequences (Flores, 2005; Flores, Barton-Laws, Mayo et al., 2003). Researchers have found that physicians, especially residents, rarely use professional interpreters, trusting their own insufficient language proficiency (Zheng, Patel, Hryniewicz, & Katz, 2006). These individuals use colleagues or avoid communication with patients with limited English skills (Burbano, Federico, & Hampers, 2003).

To gather a clearer perspective of training practices and problems in health care for LEP patients, the American Medical Association (2006) developed a multivariate logistic regression analysis of national resident physicians in 2004. The multivariate analysis survey contained several questions: (a) did physicians receive training and instructions on medical and hospital procedures, (b) did LEP patients have the right to have professional interpreters, (c) were there dangers in using non-educated interpreters, and (d) other related topics of interpretation. The sample studied consisted of 3,453 eligible residents at 149 hospitals in 563 programs (Ebomoyi, 2006). The Massachusetts General Hospital IRB approved the study. Sixty percent (2047) of the eligible population answered the survey. Of those who responded, 77% of the residents stated they used professional interpreters, 84% used adult family members and friends of the patient as ad

hoc interpreters, and 22% used children as interpreters (Ebomoyi, 2006). More than 50% admitted having cross-cultural problems because of the difficulty in accessing interpreters, lack of time, and lack of written materials in other languages (Zheng et al., 2006).

The study conducted by Zheng et al. (2006) demonstrated providers do not use educated interpreters during language barrier encounters even with the possibility of medical errors during the delivery of care. The probability of using children for interpretation was reported by one fifth of the providers. Researchers required providers to obtain training in patients' legal rights for interpretation. Finally, providers need to know how and when to use interpreters for health care efficiency (Zheng et al., 2006).

Results of the study indicated how important the communication process is during patient-provider interaction. Misunderstandings and misconceptions of words can result in undesirable events. The development and participation of individuals in clinical trials require communication and understanding during the entire process. Professional interpreters can assist investigators; a lack of knowledge of the interpreters can place research studies and patients at risk of adverse events and medical errors.

Conclusion

A thorough review of literature resulted in the discovery of information to support the present study. Communication parameters are important factors in the understanding of the informed consent processes among Limited English Proficiency (LEP) research participants. The development of clinical trials in multinational and multicultural settings and performed in the primary language of the principal investigators (Kao et al., 2010). Participants' cultures play an important role in understanding the communication

parameters during research processes. Because of language and cultural differences among participants and investigators, educated staff are necessary to compensate for the barriers of communication.

Clear communication through the informed consent process is the method whereby patients and investigators exchange information significant to the protocols used in clinical trials (Bustillos, 2009). Clear channels of communication are critical to ensure safety and effective research procedures. The problem is that LEP patients may experience an inability to understand informed consent processes, which could lead to unnecessary errors (Garcia, Barton-Laws et al., 2003).

Summary

Chapter 2 presented a review of the pertinent literature in regard to clinical trials. An important area of focus for the present study is communication between LEP persons and practitioners. Ineffective communication during the informed consent process can result in a misunderstanding of clinical trial processes, risks, benefits, and treatments (Flores, Barton-Laws Mayo et al., 2003).

The focus of the review was on the historical, legal, ethical perspectives and communication theories in relation to their influence on informed consent processes during clinical trials. The majority of studies conducted on communication barriers during informed consent processes suggested medical errors were related to the misunderstanding of clinical trials. The LEP population has reported the existence of communication barriers during clinic visits with health providers (Bustillos, 2009). The same population, by accessing medical services, is likely to be recruited for participation in clinical trials (Wilson et al., 2005). Good Clinical Practice regulations require clinical

trials be conducted in a safe and ethical environment. Accreditation agencies have performed studies exploring the implementation of safe environments and the prevention of adverse events in facilities that provide standard of care. Such studies have demonstrated that communication barriers are a major cause for adverse events in healthcare settings (Hyman, 2006).

Chapter 3 contains a description of the current study's methodology, including a discussion of the research design. The description includes the study's appropriateness of the selected methodology, research questions, and participants' selection process, Chapter 3 detailed steps to obtain study data and triangulation process. This will be followed by a description of geographical location and instrumentation selection, validity, and reliability evaluation. Finally, Chapter 3 includes a description how the data collection and analysis will be executed.

Chapter 3

Method

The purpose of the present qualitative case study was to explore if communication barriers affect the understanding of LEP research participants while participating in the informed consent process during clinical trials. The present qualitative case study conducted at NTRI explored communication barriers LEP clinical trial research participants experienced during the informed consent process. The outcomes of a convenience sample composed of principal investigators (PIs), LEP participants, and interpreters were used. Results of the study might provide leaders of research development and IRBs additional knowledge for future strategic planning of clinical trial practices. Chapter 3 includes the research questions and hypotheses, population, processes of data collection and analysis, and concerns of ethics and confidentiality.

Case Study Approach

The case study method is a research design developed within the field of social science to learn about contemporary, real-life situations (Soy, 1996). Researchers use case studies to emphasize the analysis of events or conditions upon a few or limited individuals within a particular context. While critics may question the value of studying a small number of cases, others believe that bias can so limit the validity of the study that the findings are useless. According to Soy (1996), the case study approach may still offer value if the study is carefully planned.

Research Design

A qualitative approach was essential to the study goal because the aim was to study a contemporary issue occurring within the scientific clinical trials community

(Creswell, 2005). Using the qualitative approach, lived experiences during clinical trial participation data were captured through a semistructured interview in narrative format. The intention of the research was to explore the communication barriers as accurately as possible from the perspective of clinical trial participants. Qualitative research studies are involved in the exploration and analysis of case studies (Creswell, 2005).

Using an exploratory case study design, analysis of experiences, and interpretation of participant responses support understanding of the informed consent process with Limited English Proficiency (LEP) participants. The literature contained information regarding barriers of communication during standard of care procedures, lacking information specifically on clinical trials communication barriers. A pilot study was used to verify flexibility of preliminary questions. A case study attempts to examine contemporary phenomenon as it occurs in real life events and emphasizing experiences not clearly understood (Newman, 2003; Yin, 1981). Case studies use the analytical instead of numeric factors for induction (Newman, 2003). This study considered the context of the experiences of five principal investigators, five interpreters, and nine LEP participants. To provide a description of the research participants during the informed consent process, the systematic application of exploratory case study design was the appropriate method. A systematic approach to case study designs requires a planned sample and adherence to detail data analysis (Creswell, 2005).

Appropriateness of Design

The nature of qualitative studies engages a descriptive approach to data collection and analysis (Creswell, 2005). A Qualitative research analyzed themes, examined words, and presented data based on the views of research participants. The data were obtained

through a face–to-face interviewed using open-ended, semistructured questions. The case study design allowed a context of expressive text from participants' descriptions analyzed for themes (Creswell, 2005). Case studies are beneficial when the objective is to contribute to the knowledge of individual, groups, organizations, social, political, and related phenomena (Yin, 2003). Case studies provide an approach for researchers to investigate complex phenomena. The focus of the study was on research participants' perceptions regarding barriers of communication found during informed consent processes. The information obtained may contain insights into a rationale for procedural modifications in the future of the clinical trials approval process by Institutional Review Boards (IRB). A qualitative research design was appropriate because of the alignment with the perceptual analysis of the events occurring during the informed consent process. The findings may support Creswell's and Jones' (2005) definition of qualitative research uniqueness.

In contrast to qualitative research designs, quantitative methods involve numeric data resulting from large numbers of research participants using questions and statistical analysis as well as objective data interpretations of results (Creswell, 2005). The use of quantitative research was not an alternative because the intent to understand the phenomena of communication barriers during informed consent processes from personal perspectives are not measurable.

A descriptive case study was used for the analysis of the experiences of participants during the informed consent process, which is an enclosed system of events, activities, or interactions between individuals (Creswell, 2005; Stake, 2005). Qualitative research protocols must enhance the accuracy and credibility of the conclusions drawn

from the data (Creswell, 2005). As a process for surveying evidence from diverse data sources and employing varied methods of analysis (Creswell, 2005), triangulation can be used for data collection and analysis, isolating themes and reducing limitations and biases. Stake (2005) indicated studies based on a single source of information are limited and subject to biases.

For the purpose of the present study, data triangulation included the use of three different sample groups: PIs, interpreters, and LEPs, who described their experiences during the informed consent process. Data were extracted from the audiotapes and transcriptions of interviews with study participants. Pilot studies served to increase the accuracy of data collection, ensuring the interview process runs smoothly while refining the interview questions (Creswell, 2005). Pilot study interviews, with one member of each sample group, preceded data collection to evaluate feasibility, clarity of interview questions, duration of interview, and data collection instruments to improve upon the study design.

Pilot testing of the interview questions with three participants took place after receiving approval by the NTRI, local IRB, and the University of Phoenix IRB. The pilot study determined the clarity and appropriateness of the interview questions. The pilot process involved a test of the questions, method of recording information, and revision of the procedures. The pilot test in the current study involved first participant per study group who assessed the interview questions, venue for privacy, and time. The goal of the pilot study was to determine the usefulness and appropriateness of the questions based on the study purpose and to discuss the need of revision. Data from participants involved in the pilot test was not included in the main analysis of the study. Pilot study participants

recommendations were applied to the main study. A descriptive case study was used because the study involved an issue explored through one or more cases within a system (Creswell, 2005). This study analyzed the experiences of research participants during the informed consent process, as part of an enclosed system of events, activities, or interactions between individuals (Stake, 2005)

The study required approval from NTRI IRB before scheduling and conducting any research activity. All research protocols were submitted through the electronic institutional review system prior to review and approval. The IRB approved the study on May 23, 2011, as expedited using a verbal consent (see Appendix A).

The NTRI IRB members reviewed the study for feasibility and good clinical practices. Because the study was not a high-risk investigation, the submission to IRB underwent an expedited review process, as allowed under FDA Rule 45 CFR 46.110 and 21 CFR 56.110. The study was submitted to the IRB as an expedited review because the activities did not presented more than minimal risk to human participants and involved only collection of data through noninvasive procedures. The expedited study fell under categories six and seven of the U.S. DHHS guidelines (2009b). Category six involves collection of data from video, voice, digital or image recordings, made for research purposes (UTSW, 2009). Category seven involves research of individual or group characteristics or behavioral research employing interviews (U.S. DHHS, 2009b; UTSW, 2009).

Population

For the purpose of the current study, the populations chosen were previous clinical trial participants from a NTRI. The NTRI were chosen because the feasibility of

the area for the investigator to conduct face-to faces interviews. The unit of analysis included five principal investigators (PI), eight LEP participants, and four interpreters of different ethnicities and gender at the NTRI. For the study, the researchers planned continuing interviews until data saturation occurred. Data saturation is determined when the researcher identifies through the data collection process that new data will not provide any new information for the themes and categories (Creswell, 2005).

Sample Frame

For the purpose of the current study, the target population was selected using a convenience sampling process of LEP research participants, principal investigators, and interpreters from the Language Access Services departments involved in clinical trials at the NTRI. Convenience sampling is a procedure based on participants' predisposition and accessibility to participate in the study (Creswell, 2005). For the purpose of the study is important to mention the researcher worked as a clinical research coordinator at the research institution. To avoid bias, the investigator did not recruit previous research participants under his clinical trial list. The sample was an accurate representation of the clinical trial population at the NTRI. The number of participants per research group were selected based on the following criteria: (a) employees of the NTRI with at least one clinical trial experience as providers and interpreters, (b) participants of clinical trials at the NTRI with at least one clinical trial experience, and (c) patients with LEP status.

If a participant invited to participate in the study declined participation, the researcher expanded the invitation to the next participant available. The expanded population was still part of the NTRI patient or provider population. The identification of individuals from one organization rather than expanding to other locations was preferable

for the current study because organizations' cultures, climates, and methods of work vary.

Sample

According to Creswell (2005), "a sample population is a subgroup of the target population planned to be studied for generalization about the target population," (p. 146). The sample chosen for the present study shared the same defining characteristics of (a) disorder diagnosis, (b) disorder providers, and (c) disorder interpreters.

PIs, LEP research participants, and interpreters involved in clinical trials at a NTRI comprised the convenience sampling selected for this study. This sample indicated an accurate representation of the clinical trial population at the NTRI. The NTRI is involved in pediatric research with annual grants from the NIH, Center for Disease Control and Prevention, Texas Department of Health, private sponsors, and philanthropists with the purpose of developing clinical trials. Investigators are supported by R01 grants, which comprise the NIH funding for scholars. Although the present case study used a small sample size, results may be appropriate to other departments that practice clinical trials in the same organization (Yin, 2003). The unit of analysis included PIs, LEP participants, and interpreters. A retrospective review of medical records identified previous research participation.

Face-to-face interviews with participants served as the primary sources of data for the study. The interviews with PIs were conducted in English because the primary language of the PI sample was English. Interviews with the interpreters were conducted in English. LEP interviews were conducted in Spanish. Spanish-speaking patients were the target unit for this study.

Principal investigators were identified by using the IRB's investigators database. To serve as an IRB investigator, each PI is required to complete the GCP training to perform clinical trials at the NTRI. The results were placed in an investigator database. Interpreters were identified by using the provider and employee directory of the NTRI. PIs and interpreters were contacted by using letter of invitation through Outlook e-mail, followed by a phone call to discuss the possibilities of participating in the study and scheduling an interview. LEP participants were identified by a retrospective review of the NTRI electronic medical records. Based upon a detailed query of the electronic medical records, names of patients who had participated in previous clinical trials were found. The query identified patients' primary language, clinical trial experience, and contact information. LEPs were contacted by mail using a letter of invitation (see Appendix B) followed by a phone call. Follow-up phone calls took place at a conference room at the NTRI. The room used for the follow-up phone calls provided confidentiality and minimal distractions.

Informed Consent

The Belmont Report by the National Commission for Protection of Human Subjects of Biomedical and Behavioral Research emphasized the protection of human participants (Kaufman & Ramarao, 2005). To work under the ethical guidelines outlined in the Belmont Report, each participant was required to consent to participation in the present research. Providing an informed consent to participants is part of the U.S. DHHS guidelines and research policies at the NTRI. The informed consent form for the study (see Appendix A) contained information on how participants learned about a guarantee of voluntary participation, confidentiality, risks and benefits, and withdrawal. Participants

also learned about the data sought by using a digital recording device to voice record the conversations.

Creswell (2005) indicated that the consenting process is to be conducted before the research and reflect the confidentiality and participants' right to participate in the study. Before each interview, participants received an informed consent form and completed a demographics questionnaire. In the informed consent form, participants received assurance of confidentiality and information pertaining to the purpose of the study, nature, risk, benefits, and confidentiality statements of research participation.

Each participant had ample time to review, ask questions, and read the informed consent before interviews began. The informed consent form included information that participants' information and date would be coded alphanumerically to protect their confidentiality and eliminate risk of identification. Participants were informed that they could withdraw from participation at any time by informing the researcher in writing or verbally without any retribution or reproach. The contact information for the researcher was provided in the introductory letter and the informed consent form.

The process of informed consent formed the substance of the present research study and warrants further discussion. The administrative research leaders at the study site might use outcomes of the study to identify and address barriers of communication during the informed consent process. Researchers use the informed consent process to establish and communicate information about a particular clinical trial. The informed consent form includes the goals of the research, importance of the study, risk and benefits of the study, and volunteers' statements (U.S. Food and Drug, 2009). The informed consent contains the procedures involved in the study, possible side effects of drugs or

treatments, and ample information about the study goals and procedures so participants are fully informed. The informed consent process should provide study participants with the tools to ask comprehension questions and to ask about possible adverse events. Removing communication barriers is imperative for LEP participants to exercise the autonomy of self-determination and ethics regarding research participation (Beuchamp & Childress, 2008).

University of Phoenix Institutional Review Board

The study received approval by the University of Texas Southwester IRB in accordance with the Federal-Wide Assurance and the DHHS that reviews and approves research involving human participants. At the same time, the present study was submitted through the SAS web-Doctoral Dissertation Submission. The original proposal was submitted December 10, 2010, and QRM submission on February 28, 2011, receiving proposal approval May 4, 2011.

Confidentiality

Ethical research guarantees confidentiality to study participants (Creswell, 2005). NTRI and the IRB required assurance of confidentiality for research participants. Complying with informed consent, confidentiality was also paramount for the study to be approved by the UTSW IRB. To protect confidentiality, study participants received an alphanumeric code that included a capital letter at the end: A for LEPs, B for interpreters, and C for PIs. All research information that could identify any aspect of the study participants remained confidential. Access to data is restricted to the investigator directly involved in the present study. Executed consent forms and assigned participant study numbers were stored in a locked file in the researcher's office at the NTRI. Research-

related materials were maintained in a password-protected computer database using assigned participant study numbers as the only identifiers. Information obtained in connection with research that could be identified with a participant will remain confidential and can be disclosed only with the participant's expressed permission.

In accordance with these confidentiality procedures, and as disclosed during the attainment of informed consent, members and staff of the UTSW IRB may review these research records at any time. The purpose of the review would be to ensure both the quality of the information used in the research and compliance with procedures to maintain confidentiality. Participants were informed that records would be destroyed after 3 years of data publication by hiring a professional organization such as Document Destruction Incorporated.

Geographical Location

The present research involved PIs, interpreters, and LEP patients who currently work or had been cared for at the NTRI located in northern Texas. The providers were employees of the UTSW practicing at the NTRI. Interpreters were employees of the NTRI who interpret and translate as part of the Language Access Program. LEP participants were patients with disorders cared for at the NTRI.

Data Collection

Previous researchers have shown that personal, face-to-face interviews promoted clear collection of information and are considered an excellent technique for data collection (Quinn, R., Gutek, & Walsh, 1980). Face-to-face interviews allowed the researcher to spend a sufficient amount of time with participants (Newman, 2003) to allow dialogue between the researcher and participants. The research participants were given permission to direct the dialogue as they wished in order to obtain in-depth information. Audio-recorded interviews were transcribed into narrative written documents. Data involving each study participants' responses were collected from the semistructured interviews, transcribed, and then analyzed using NVivo 9.0.

If a prospective participant agreed to participate but could not participate on the scheduled day, the interview was performed over the phone using an audiotape recording device. One of the problems of conducting a telephone interview is the lack of direct contact with the participant (Creswell, 2005). The lack of a face-to-face interview with the participant may affect the researchers' understanding of the participant's perceptions of the phenomenon under study (Creswell, 2005).

Creswell (2005) stressed the importance of observing the participant's facial expressions during the interview process, which could serve as a catalyst for further probing and soliciting of additional information. Individuals tend to provide shorter answers by phone, and establishing the same rapport as found in face-to-face interviews is more difficult. Because of this assertion, many researchers support the argument that telephone interviews yield less dependable data (Newman, 2003; Quinn, R. et al., 1980).

Preparing and testing equipment prior to interviews with participants is necessary to ensure the equipment functionality

The data consisted of specific lived experiences of the PIs, interpreters, and LEPs during the informed consent process. The goal of the study was to study participants' perceptions of communications barriers during the informed consent. The intimacy and confidentiality of face-to face interviews give participants the confidence and assurance to express and share ideas (Creswell, 2005). A questionnaire (see Appendix C) was used to facilitate an open-ended discussion during the interview process and served as a guide for the development of the interview. Secondary data analyzed for the credibility of the study outcomes included (a) data gathered from the pilot study, (b) records of research field notes, (c) observational notes, (d), retrospective reviews of electronic medical records, (e) and transcription notes.

Data Analysis

The interviews were audiotaped using an electronic recording device. Audio recording interviews allows for review of data transcription for accuracy. The recordings were transferred into a Word document. Details of the conversations were included in each form assigned to participants. The data from the word forms were transferred to NVivo 9 software to analyze the data obtained from the interview process with the research groups. NVivo 9 software was used to facilitate the coding and analysis of the generated data with indexing, searching trends, and theorizing processes to make sense of unstructured information. NVivo 9 was used to merge and link codes within data to find associations between the data for analysis. NVivo9 software assisted the search for themes and patterns concerning the participants' understanding of the informed consent.

By reviewing and analyzing the conversations, the researcher was able to assigned data to themes and identified patterns. The data were analyzed to find associations and trends that emerged from the testing, theorizing, and conceptualizing accomplished through the analysis.

The study used a convenient sample and gathered data from five PIs, four interpreters, and eight LEPs. At the beginning of the interview, participants were asked to answer demographic questions (see Appendix C). Data were collected through in-depth, face-to-face, semistructured interviews, allowing the researcher and the participants in engage in an open dialogue. Initial questions were modified during the process from participants' responses to obtain important reactions from participants. Telephone interviews were possible for LEPs participants who were interested and participated but could not make appointments in person. Telephone interviews did not provide the capability to collect nonverbal data. Interview questions were open-ended to avoid leading participants' responses. The researcher conducted the interviews for PIs at the participants' respective offices. PIs' interviews were performed closed door for confidentiality. Interview with Interpreters were performed in a conference room at the NTRI, LEPs' interviews were conducted over the phone using a conference room with a closed door for privacy and confidentiality.

Validity

Validity pertains to the truthfulness and describes how well results align with reality. The examinations of validities were assessed potential truth aspects, threats, and biases that may jeopardize the study outcomes (Creswell, 2005). The present study elicited the truth by including participants' experiences in their own words in a manner

that enhanced the credibility of the study. According to Creswell (2005), "researchers could obtain meaningful and justifiable inferences from scores about a sample population" (p. 600). The objective of qualitative research is to provide a view of how participants understand the concepts of living through empirical work (Newman, 2003). Researchers have expressed the importance of validity in quantitative studies, while the issue with validity in qualitative research has resulted in controversy (Onwuegbuzie & Leech, 2007).

The analysis of validity in the present study incorporated qualitative information relevant to the study. Data collection methods, analysis, and interpretation are the threats represented in validating the qualitative research process. To strengthen the validity of the research study, a pilot study of the planned semistructured questions was conducted with one participant of each group who did not participate in the formal study. The NTRI IRB reviewed the questionnaire and approved the questions as a valid instrument to gather data. To validate the results, a combination of NVivo 9 software and manual assessments were used to process the data. No changes were made to the questions.

Internal validity. Internal validity is defined as "the truth value, applicability, consistency, neutrality, dependability, and or credibility of interpretations and conclusions within the underlying setting or group" (Onwuegbuzie & Leech, 2007, p. 234). The possible threats to internal validity in this qualitative study were (a) researcher bias, (b) participant reactions, and (c) investigators' credibility. Research bias occurs when the researcher allows personal assumptions to influence the data collection process, analysis, and interpretation. Researcher bias during the data collection process can affect the experiences, in this case perception, of participants (Shark, 2006). Researchers need

to maintain a neutral observational position; limiting the facial expressions and responses to the events occurring during the interview process (Creswell, 2005). Preparing notes of the researcher's observational experience, personal beliefs, and feelings can prevent the conveyance of biases to the study participants (Shark, 2006). Researcher bias occurs when personal assumptions influence the process of data collection, analysis, and interpretation. Internal validity indicates alignment with reality, the triangulation process assisted improving the validity of the study and evolves corroborating information from different data sources.

The design of the study involved placing participants' responses in context by theme and supported internal consistency through the comparison of participants' comments. After each interview, the participant had the time to review the responses. The participants' reviews helped minimize potential threats for internal validity.

Another threat that could cause damage to the outcomes of the study was participants' reactions during the interview process. The participants might have felt uncomfortable in a small room or area with the presence of recording equipment or being interviewed over the phone. Participants could experience the novelty effect described by Onwuegbuzie and Leech (2007) as a response to novel environment stimuli such as observers and tape recorders. Conducting a conversation with the research participants prior to the study allowed the participants' response to novelty stimuli to decrease, which diminished participant reactivity to the interview process.

A last point for validity is PIs' credibility. Principal investigators might have negative reactions to the interview process because they could believe the researcher was evaluating their performance. The conduction of short meetings with PIs before

interviews mitigated this threat to validity. The researcher used these meetings to explain the procedures and aims of the study to the PIs as participants of the study.

External validity. External validity is the ability to generalize results of one study to other settings (Creswell, 2005). To improve external validity, the current case study involved data analysis of occurrences between interpreters, providers, and participants during the informed consent process as part of enrolling patients in a clinical trial. The patients enrolled in this research have Limited English Proficiency (LEP) and needed interpreters during an informed consent process. Other departments in the organization might be able to use the results of this study, as they also are required to employ an interpreter for investigators when enrolling LEP patients. Similar situations increase the current study's external validity because other departments can recognize how results might compare with and be used to improve recruitment strategies.

Reliability

Research is reliable when data are similar or stable during the collection (Creswell, 2005). Reliability is associated with qualitative studies because the concern for credibility depends on the ability and work of the researcher to maintain a stable data collection process (Golafshani, 2003). Quantitative studies rely on the dependability or consistency of processes within research studies. In qualitative studies, reliability is dependent on a defined and descriptive research protocol for data collection allowing the study to be replicated in a different setting or venue. In the present case study, other organizational departments practicing research will be able to follow the protocol procedures and repeat the study. The purpose of the present qualitative case study was to

explore if communication barriers affect the understanding of LEP research participants while participating in the informed consent process during clinical trials.

The current study involved a pilot test to improve reliability of the semistructured interview questions. One participant per study group participated in the pilot study interviews, responding and assessing the questions for clarity and content.

Quantitative studies measure and demonstrate reliability based on empirical evidence with abstract themes (Newman, 2003). Qualitative research studies determine and evaluate empirical details concerning the phenomenon under investigation. The present research studied the communication barriers problem through different cases within the clinical trial system and the informed consent process.

Summary

The aim of the present study was to examine a contemporary issue occurring in clinical trials, a qualitative study was paramount to identify the phenomenon (Creswell, 2005). A convenience sample captured the perception regarding communication barriers during the informed consent process. The case study format places emphasis on the empirical data of research participants to understand their experiences during the informed consent process (Newman, 2003). Chapter 3 contained a discussion of the selected research design, a description of the study population, and a review of the sample. The data were collected through face-to-face semistructured interviews to emphasize the context and descriptions of participants' experiences (Soy, 1996). The chapter included a description of data collection and the instruments used for analysis. The chapter included a description of validity and reliability assessments and how facilitated data collection and analysis. Chapter 4 contains a discussion of the results

based on the participants' descriptions of their experiences during the informed consent process.

Chapter 4

Results

The purpose of the present qualitative case study was to explore if communication barriers affect the understanding of LEP research participants while participating in the informed consent process during clinical trials. Communication barriers present a significant problem in understanding the parameters discussed during informed consent clinical trial processes (Abbe, Simon, Angiolillo, Ruccione, & Kodish, 2006). The case study design allowed a context of expressive text from participants' descriptions that were analyzed for themes (Creswell, 2005). Using open-ended, semistructured questions (see Appendix C), the study focused on research participants' perceptions regarding barriers of communication practices during informed consent processes. By exploring the experiences of three different groups (principal investigators, medical interpreters, and LEP participants) involved in the informed consent process results might assist leaders in the research industry to promote clear communication environments leading to an increase in recruitment, research participation, clear data, and scientific improvements. Communication improvements during the informed consent process are important to conduct safe scientific investigations. Data collection involved the recording and transcription of five PIs', four medical interpreters', and eight LEP participants' responses to a semistructured interview. Chapter 4 includes a presentation of the findings through the (a) recruitment procedures, (b) data collection, and, (c) recurring themes and subthemes. The identification of themes includes major themes and subthemes. Chapter 4 concludes with a summary of findings.

Participants

A convenience sample composed of principal investigators, interpreters, and LEP parents of patients with previous clinical trial experience at an NTRI participated in the study. The sample represented an accurate representation of the clinical trial population at the NTRI. The study used the following criteria regarding the selection of participants: (a) employees of the NTRI with at least one clinical trial experience as PI or as an interpreter, (b) participants of clinical trials at the NTRI with at least one clinical trial experience in the past five years, and (c) patients with LEP status. Table 1 shows the codification system assigned to each group. The codes consisted of a serial number and a capital letter at the end of the number. Letter C for PIs, B for interpreters, and A for LEPs.

Table 1

Participants' Code System

Participant Group	Code
Principal Investigators	#######C
Interpreters	#######B
LEP	#######A

Principal investigators in the current study were medical doctors who (a) worked at the study site, (b) worked as principal investigators in clinical trials, or (c) worked as sub investigators with clinical trial experience. One hundred PIs were approached using e-mails with an attached letter of invitation (see Appendix B) to which only six responded and agreed to the request to participate in this study. Demographics of PIs,

such as age, gender, and specialty, were not collected as requested by the facility and local IRB. All participating PIs worked in the organization for over five years and have overseen two or more clinical trials.

Principal Investigators

As shown on Table 2, the PIs self-reported as Caucasians. Principal investigators' primary language was English. One PI reported German as a second language, one reported a second language of Italian, and one reported to speak Spanish as a second language; four PIs reported poor proficiency in Spanish although they attempted to speak Spanish occasionally. All of the PIs interviewed have a Medical Doctor (MD) degree.

Table 2

PIs Participants Demographic Data

Participant	Ethnicity	First Language	Second Language	Other Languages
(Pilot)03031100C	Caucasian	English	Attempts Spanish	--
062811002C	Caucasian	English	Attempts Spanish	--
0603011003C	Caucasian	English	Italian	--
071111004C	Caucasian	English	Poor Spanish	--
072611005C	Caucasian	English	German	--
072711006C	Caucasian	English	Spanish	Some French

Notification about the interviews to the PI occurred using the local IRB's investigator database. Part of the NTRI requirements is for PIs to complete Good Clinical Practices (GCP) certifications before performing research. GCP test results are placed in the IRBs investigators database with PI contact information. The local IRB's

database includes demographics, contact information, specialty, and positions. An invitation to participants was sent followed by a phone call to discuss the possibilities of participating in the study and scheduling an interview. Of the 100 invitations sent, six PIs responded to the electronic mails with available dates for the interview. The first PI participant was interviewed as part of the pilot text.

Interpreters

There are 35 Interpreters in the language access program at the NTRI. All interpreters from the Language Access Department at the NTRI were invited; five accepted and agreed to participate. As shown on Table 3, the interpreters self-reported as four Hispanics or Latino, and one Caucasian. Four of the interpreters self-reported Spanish as their primary language and English as their second language. One interpreter reported a first language of English and second language of Spanish. Four out of the five interpreters were born in Mexico and one in the United States. One interpreter reported to speak Italian and "a little" Portuguese.

Notification to the interpreters of the study occurred by using the NTRI Outlook employee directory database. The NTRI Outlook divides data by departments and employee work title, making feasible the identification of participants by title and working department. Notification to Interpreters transpired by electronic mail with an attached invitation (see Appendix B) to participate in the study. Contact of interpreters who replied and accepted to participate in the study occurred by phone to schedule a face-to-face interview. The first interpreter participant was interviewed as part of the pilot text.

Table 3

Interpreters Demographic Data for Interpreters

Participant	Ethnicity	First language	Second Language	Other languages
(Pilot)052611001B	Hispanic	Spanish	English	--
060611002B	Hispanic	Spanish	English	--
0606611003B	Hispanic	Spanish	English	--
060911004B	Hispanic	Spanish	English	Portuguese, some Italian
080511005B	Caucasian	English	Spanish	--

Limited English Proficiency (LEP)

Identification of LEP Participants occurred by using querying the NTRI EMR from January 2006 through December 2011. The query provided 377 possible LEP encounters. Validation of the LEP Participants occurred by retrospective review of research encounters using the electronic medical records of the NTRI. A review of the electronic medical record identified the LEPs' ethnicity, primary language, clinical trials participation and contact information. Previous clinical trial participation was confirmed after a review of the medical records, which included searching for a copy of the encounter and a scanned copy of the clinical trial consent form. Twenty LEP Participants were contacted by phone to take part in the research; nine were interviewed. The first LEP participant was interviewed as part of the pilot text. The other 11 LEP participants declined participation because of lack of time or not remembering their participation in a clinical trial. The LEP participants self-reported as Spanish speakers only, not able to read or speak English (see Table 4). All LEP Participants reported Mexico as their country of origin.

Table 4

LEP Participants' Demographic Data for LEP Participants

	Participant	Ethnicity	First language
(Pilot)	11222011001A	Hispanic	Spanish
	1222011005A	Hispanic	Spanish
	11302011006A	Hispanic	Spanish
	2282012007A	Hispanic	Spanish
	02282012008A	Hispanic	Spanish
	02282012009A	Hispanic	Spanish
	02282012010A	Hispanic	Spanish
	02282012011A	Hispanic	Spanish
	112220111004A	Hispanic	Spanish

Two of the LEP Participants reported to have a "*Secundaria"* (secondary) level of education comprising of grades seventh through ninth in the Mexican educational system. Four Participants reported a level of "*Primaria"* (primary) comprising of grades first through sixth in the Mexican educational system. Three Participants reported a level of "*preparatoria"* (high school) *or "bachillerato"* (Bachelor's Degree), consisting of grades tenth through twelfth. LEP Participants were all mothers of patients with clinical trial experience; two fathers approached by first contact referred the call to the patient's mother. None of the participants reported any other languages than Spanish.

Notification to LEP patients occurred by mailing of an invitation letter (see Appendix A) requesting voluntary participation on the study. The invitation letter was sent to 150 LEP patients in Spanish. The invitation letter provided no responses. A phone call to 20 random LEP patients followed the invitation letter two weeks after mailing the invitation letter. Nine LEP patients agreed to participate in the study over the phone at the time of the call. The reasons for not coming to the facility varied: work, had to pick up siblings from school, no clinic appointments in the near future, and lack of transportation. Other meeting places were not suggested because of NTRI privacy rules.

Data Analysis Methods

Personal beliefs and experiences with barriers of communication were extracted from research participants involved during the informed consent process. The analysis of the data occurred through NVivo 9 qualitative software for coding and analysis of themes. NVivo 9 facilitated the storage of words in the transcribed documents and assisted in the organization of the data by participant groups (PI, interpreters, and LEP participants). The software enabled coding; searching for specific words; and, linking data to discover patterns, themes, and construct meaning of participants' responses. NVivo 9 enabled the exploration of the data to make sense of the information collected through reviewing ideas, organizing, and identifying parameters among the transcribed information. Reviews of the transcribed data occurred several times to capture details, ideas, and similarities among the groups before breaking the data into different parts; this occurred by writing memos, notes, and delineating important information. NVivo 9 assisted in the review of procedure by groups and the initial process of exploring the data

as well as facilitated the analysis of each response to categorize the data for themes and subthemes.

After reviewing the data, NVivo 9 abetted the coding process by segmenting and labeling the text to form descriptions and themes in the data using nodes. The NVivo 9 coding process assisted with defining the information, examining, and collapsing the nodes into themes and subthemes. The analysis process occurred by reading the transcribed information stored in NVivo 9, analyzing each conversation, responding to underlying important segments of the dialogue, and coding the segments by placing nodes. The development of themes consisted of answering the research questions and forming an understanding of the data through the description and theme development.

Data Collection

Data collection began after obtaining permission to conduct the study at the NTRI site. The permission came from (a) the Legal Department at the study site (see Appendix D), (b) the institutional review board of University of Phoenix, and (c) the institutional review board at the study site. Following the approvals required, the next step required the identification and communication of the study purpose to possible volunteers. The target samples were three different groups involved in the informed consent process during clinical trial participation. The groups were composed of principal investigators (PI), interpreters, and limited English proficiency parents of patients (LEP).

To develop a convenient sample, nine LEP parents, five interpreters, and six PIs accepted participation in the research study. The first participant contacted at each group participated in the pilot study. The pilot study for the interpreters and PIs took place over a 3-day period in a private office with an audio digital recordings device. LEP parent

interviews took place over the phone in a private office with an audio digital recording system.

The interviews were conducted between November 2011 and February 2012, lasted between 30 to 45 minutes, and consisted of semistructured questions (see Appendix C). Each session opened with a brief explanation of the purpose and interview procedures. The privacy of the rooms allowed the interviews to run smoothly and without distractions. The interviews of the LEP parents took place over the phone in a private office using an audio recording device. The reasons for not coming to the facility for a face-to –face interviewed varied: work, had to pick up siblings from school, and could not schedule Medicaid transportation for no medical arrangements, no appointments in the near future, and lack of transportation. Other meeting places were not suggested because of NTRI privacy rules.

The first step involved welcoming the Participants and acknowledging their voluntary study participation. The study used an IRB-approved, oral informed consent (see Appendix A) to acknowledge participation; the consent described the purpose, rational of the study, procedures, confidentiality, and volunteer participation of the study. The participants had 5 to 7 minutes to ask questions and become comfortable with the interview setting.

Pilot Study

The first participants who responded and agreed to the request took part in the pilot study. The participants included one person from each study group: (a) PI, (b) interpreters, and (c) LEP parents. The pilot study participants consented and completed the study to participate in the pilot study over a 3-day period. The PI and the Interpreter

participants of the pilot study took part in an individual, face-to-face semistructured interview, responding to interview questions that prompted conversation. Audio recordings of the interviews enable the review of the conversation for analysis of the questions.

The LEP Participants who agreed and consented to be part of the pilot study participated in an interview over the phone; a recording device captured the conversation. At the end of the interview, the Participants evaluated the interview process, by discussing the procedure for clarity, discussion content, and pertinent topics of the study purpose. The pilot study allowed participants to make changes to the questions, add possible questions, and provide feedback, comment on the interviews methods and location. The pilot participants were not eligible to participate in the final study.

Pilot Test Data Analysis

The pilot test data indicated the semistructured interview questions prompted conversations regarding (a) communication barriers, (b) challenges in the organization when LEP Participants are a part of research, and, (c) reflection and perception of personal experiences during the informed consent process. The participants agreed the semistructured interview promoted an open discussion and prompted a deep analysis of personal experiences. The participants recommended not changing the dynamic and the wordiness of the semistructured initial questions. The Interpreter participant of the pilot study suggested eliminating abbreviations when interviewing other Interpreters for clarity, as interpreters' trainings do not allow the use of abbreviations during conversations at the NTRI. PI recommended, after finishing the study, presenting the results at the NTRI Grand Rounds and possibly extending the study to the other two

facilities of the medical campus. LEP Participants provided no suggestions and approved the study as presented to them.

Participants involved in the pilot study declared the semistructured questions and the interview process supported the study goals. Pilot study participants agreed the interview process facilitated the exploration of participants' experiences. Assessment of the need to not use abbreviations during the interview process generated the elimination of abbreviations such as, ICF, IRB, LEP, and EMR from the interview.

Interview Process

The interview setting for PIs and Interpreters was an office with a desk located between the researcher and the research participant. The researcher placed the electronic recording device between the researcher and research participant. The setting for the LEP Participant was composed of a private office with a phone that allowed the voice of the participant to be heard through speakers. The consent was reviewed with time for questions and acknowledgment. After the consent was discussed and acknowledged, an alphanumeric code was assigned to the research participant. The alphanumeric code facilitated the identification of the interview with the digital recording device. Demographic information was collected for Interpreters and LEP Participants. No collection of demographics, except primary language, occurred for PIs. Principal education of PIs was assumed as Medical Doctor (MD), as the NTRI requires PIs to have an MD to practice medicine at the facility. Interpreters had interpretation certifications by the NTRI. No Participants who consented called to alter or withdraw from the study. The interviews originated with the standard script (see Appendix C). The first question prompted participants to describe their primary language and experience with clinical

trials in the last 5 years. The second question pertained to their experiences during the informed consent and clinical trial processes.

Principal Investigators Interview Process

The PIs responded with their experiences and began describing organizational challenges in respect to the length, educational level, and legalistic vocabulary comprising the informed consent. PIs discussed the issue of limited access to adequate interpretation and translation of documents for the number of LEP patients at the NTRI and the limited does not compensate the need. The NTRI policy for access to the Language Access Program is for interpreters to assist with the standard of care practices interpretation needs and then research.

The need for certified interpreters is higher during clinical trial procedures because the NTRI considers research second on the tier of importance in relation to interpreters' accessibility and ability to respond to calls. The conversation highlighted the lack of resources, including lack of financial support from research sponsors, to provide adequate translated recruitment materials to potential LEP participants. Some of the statements from PIs inferred the concern with the high cost of translating documents, the high cost of employing an interpreter sometimes not included in the study budget, and the lack of IRB regulations through the informed consent process in regard to language use.

The discussion turned to the possibility of adverse consequences of communication barriers and whether or not PIs believe in communication barriers. Discussion included the informed consent process and the key components of communication barriers during the informed consent process. PIs opened the discussion

and provided a description of how barriers affect LEP patients' understanding of procedures, risk, benefits, and voluntary participation. The conversation included the importance of interpretation and translation in participants' primary language, informed consent forms, procedures, and access to the language proficiency of a patient. The PIs' interviews presented educational and training suggestions regarding the knowledge of Interpreters of clinical trials, adequate certifications, and curriculum development to identify cultural sensitivity in medical schools.

Interpreters Interview Process

After collection of the demographics, the Interpreters' responded with their experiences regarding interpreting the informed consent process during clinical trials. The discussion allowed for identifying the Interpreters' understanding of LEP and knowledge of clinical trials. The Interpreters discussed their position during the informed consent process and the role of interpreting for the research team. Interpreters answered questions regarding barriers of communication. The conversation led to evaluating Interpreters' perception and experiences of communication barriers. The interview procedures allowed for assessing the Interpreters' knowledge regarding IRB and the IRB's functions.

The interpreters answered question regarding perception of communication barriers during the inform consent process. Interpreters exposed ideas regarding the consent of LEP participants to clinical trials when the interpreters had reservations about the patients understanding of the informed consent. The interview uncovered interpreters' challenges to their roles as Interpreters during clinical trials processes and possible recommendations for education and trainings.

LEP Interview Process

Subsequent to the discussion of the research and collection of demographics, LEP participants' interviews began by assessing their perception and experience in clinical trials. The interview process reviewed the purpose of the patient in participating in clinical trials and understanding of the informed consent process. The discussion captured LEP Participants' experiences and understanding of clinical trials and their role as LEP parents of patients invited to participate of a clinical trial. LEP Participants expressed their challenges to understanding clinical personnel, especially when no interpreters are present and/or the ICF documents are presented in English only.

Playing the recorded data privately after the completion of each interview facilitated a review of the individual collected information. PIs had no time after interviews and did not express interest in reviewing the manuscripts. The interpreters asked for a presentation of results during a quarterly meeting in the Language Access Service Department after study completion. Thirty days after the interviews, the researcher mailed a copy of the manuscripts to each LEP participant in Spanish to document the interview process. The manuscripts accompanied the researcher's information and copy of the informed consent form. The researcher received no responses from LEP Participants denying use of the data for this study.

Transcription of the interviews occurred in Microsoft Word documents, based on the review of the audio and written interview text. All participants interviewed with no changes made in the process of discussion. The questions of the semistructured interview served as guidance in the development of the conversation. Each conversation provided

individualistic experiences and perceptions of communication barriers and understanding of the informed consent process.

Interview Results

Categorization of the transcribed data took place by analyzing each conversation and building themes using NVivo 9 software. The system of identifying nodes prompts the reviewer to identify common themes' and subthemes, manually highlighted in the document by coding the text from each interview. The analysis of data content included samples of the participants' quoted text to reveal the experiences and perceptions of research participants during the informed consent process.

The participants' responses to the interview and conversation led to the emergence of themes and subthemes. Each conversation provided an opportunity to explore the perception and experience of participants in the clinical trial process. Interviews promoted an opportunity to explore more themes producing deep discussions beyond the scope of the questions. The conversation led to unexpected themes for all three groups interviewed.

Emerging Themes

The review of each conversation led to the identification of themes in the current study. Four primary nodes emerged from the data, many of the nodes divided into sub-nodes. Analysis of the data coding using the node categories contributed to the formation of themes. The interview coding involved dividing the interviewees into three categories: PIs, interpreters, and LEP Participants. The transfer of the transcribed documents occurred under each category to create three separate folders in NVivo 9.

Five out of five PIs, all four interpreters, and the eight LEPs participants referenced the authority figure theme presented on Table 4. Barriers of communication theme were referenced by five out of five PIs, four out of four interpreters, and eight out of eight LEPs. Cultural sensitivity referenced by four out of five PIs, four out of four interpreters, and none LEPs. Five out of five PIs, three out of four interpreters and none LEPs presented education theme.

Table 5

Emerged Themes and Subthemes

Major Theme	Subtheme 1	Subtheme 2	Subtheme 3
Authority Figure	Presented no other alternatives for treatment by PIs/Providers	--	--
Barriers of Communication	Interpreters emotional involvement	Origin of Language	Body language
Cultural Sensitivity	Religious and superstitious beliefs	--	--
Education	Interpreters level of education	--	--

Theme 1: Authority Figures

The authority figure theme emerged from the data patterns in all data groups. The authority figure theme pertains to the participants' descriptions of the process of signing the informed consent form during the informed consent process. Four out of the four interviewed interpreters described PIs as authority figures to patients. Hundred percent of the PIs stated their position as primary care doctors of the patient working as a researcher was seen as an authority figure for patients. The authority figure perception established a persuasive role. Four of the interpreters and four PIs expressed that many patients could not differentiate between the provider's role during standard of care

practices and investigator role during clinical trials. One hundred percent of the interviewed Interpreters' noted that patients see doctors as the person to cure their child; therefore, anything the doctor suggests is what the patients will do, including enrolling in clinical trials. A sample of the Interpreters' and LEP participants responses outline this below:

Interpreter Participant 052611005B: It is the way the study is presented; if the study was presented as not to have other alternatives of treatment, the patient usually signs the informed consent. No questions asked.

Interpreter Participant 060911004B: Sometimes patients signed the consent because it is the doctor who is telling them. The Hispanics see doctors and hospital personnel, in this case the PIs, as authority figures.

Principal Investigator Participant 063011003C: We have less difficult time recruiting Hispanics. They trust the white coat as an authority figure, meaning they will sign anything you put in front of them.

LEP Participant 02252012007A: I was confused. I was not able to understand what the doctor wanted to do to my child. The doctor showed me some papers and I signed them.

The LEP participants described specific experiences with the PIs presenting the informed consent and the reason to sign, with or without interpretation, but it was their child's primary care doctor presenting the information. To all of the LEP patients, the doctors represent an authority figure regarding the clarity of the communication and understanding of the informed consent; the LEP will sign the consent if it is the provider

who is presenting the consent. One Principal Investigator's statement clearly summarizes this behavior.

Principal Investigator Participant 071111004C: If they are LEP and unsophisticated, they are going to sign anyway because they trust me as a doctor, as a good doctor. They are not going to read a paper they cannot read if the consent is in English, no matter if a translator is present or not.

Subtheme 1: Presented no other alternatives for treatment by PIs. The Interpreters noted that as part of the research group presenting the informed consent to LEP participants, on many occasions, they could present no other alternatives of treatment. This factor limits the options of LEP participants and, in the opinion of the interpreters, other patients who speak English in obtaining complete information to make an informed decision about participating on a clinical trial. Five out of eight LEP participants described how informed consents presented with no other alternatives of treatment. Two of those descriptions follow.

LEP Participant 0228120008A: The doctors explained to me what she (daughter) had, and because I was worried about my child's health, I signed.

LEP Participant 022820120009A: No, she just asked me to sign the papers to put my baby in a study.

Theme 2: Barriers of Communication

The barriers of communication theme appeared across all three investigated groups. Barriers of communication were particularly important for the interpreters group. Interpreters considered barriers of communication a cultural sensitivity problem more than a language issue. A second concern of Interpreters is the fast pace providers interact

face-to-face with the patient. Interpreters expressed an important factor affecting communication is the time constraints on physicians' face-to-face time with patients and the need to advance to the next patient. To facilitate the process, PIs sometimes attempted to use their high school Spanish or ad hoc interpreters to speak with the family during treatments or when presenting research consents. For example, it is not uncommon for an interpreter to find that the informed consent has already been signed upon the interpreter's arrival to the patient's room,

PIs considered barriers of communication a problem across the board regarding patients' recruitment into studies with LEP participants as well as English speakers. The challenges consist of providing clear channels of communication to future research participants with adequate recruitment documents in the primary language of the participant as well as continued accessibility to certified and clinically knowledgeable interpreters. PIs identified the excessive medical terminology involved in the informed consents and the lack of clinically prepared interpreters in specific therapeutic areas as barriers of communication. As for the question of whether or not barriers of communications exist, interpreters and PIs confirmed their belief that communication barriers exist among LEP participants.

LEP participants considered barriers of communication a situational experience in many departments of the NTRI when doctors and other medical personnel do not speak their language. On many occasions, interpreters are not present to assist them with the interpretation and translation of documents. LEP participants expressed during the interview how complicated many of the documents are. LEP participants stated that in many instances, the documents are in English and no one in the clinic or department took

the time to interpret the information. Interpreters stated “Yes” to the question, “Have you signed an informed consent when you did not understand the parameters of the study?" The reason interpreters’ gave for the LEP participants’ signature on the informed consent form is that their main concern is for their child to get cured. Responses from both PIs and LEP participants supported this position.

LEP Participant 02282012010A: It is hard for me to communicate with them (referring to research team and medical personnel). Every time I go to the hospital, it is hard to understand what they are saying because I do not speak English. I preferred to take my child to his pediatrician because the personnel speak Spanish and the documents are in Spanish.

Principal Investigator Participant 0603311001C: I believe in barriers of communication, and this happens when the interpreter is not there or does not arrive on time. This is when the communication problems come in, because people are trying to take shortcuts.

Principal Investigator Participant 072711006C: I believe barriers of communication can lead to adverse events. Number 1, patients participating in trials think they are going to be cured. If a possible cure is not present or out of the question, I do not offer the trial to the patient; it is too difficult to explore complicated or required several visits to the hospital because the language barriers. I understand not offering the trial to everyone is a violation of the rights of the patient.

Subtheme 1: Interpreter emotional involvement. Four PIs interviewed inferred how interpreters’ emotional involvement with the patient’s family affects the interpretation and communication process. Many therapeutic areas forming part of the

development of clinical trials, such as cardiovascular disease and cancer, are critical to the life of the patients. When PIs placed trust in interpreters to understand and translate the communication and documents clearly, the communication barriers begin if the Interpreter starts crying in front of the family: a negative message is portrayed to the family. The attention is diverted from the care of the patient and the family to the Interpreter breaking the communication.

Subtheme 2: Origin of language. Interpreters stated communication barriers are a complex process of mixed factors. The identification of terms' origins assists in maintaining understanding of communication. One term, statement, or word in one country may not have the same meaning in another country. The communication barrier is still present when language is the same from the speaker to the receiver of the information. Interpreters mentioned the origin of words to be an important factor in establishing communication. The communication barrier increases when one person is not able to identify the origin of the language. Participants' responses supported this subtheme. One example discussed was the word exercise. Translated to Mexican Spanish means "ejercicio" a sport activity. The translation of the word exercise during a research study could mean routine to take study drug or maintained a routine notebook of events.

Interpreter Participant 060611002B: Communication barriers are present all the time. Even though I speak Spanish or English to someone else does not mean the information is getting through clearly. Communication does not have to do with language or grammar; by using one term or another, the origin from Mexican Spanish to

Argentinean Spanish and all the Latin American cultures of Spanish speaking cultures, communication can still be a barrier.

LEP Participant 02282012008A: An interpreter was with the doctor, but I could not understand what the interpreter was saying. The conversation was confusing; our language was not the same.

Principal Investigator Participant 060311001C: I do not think that communication barriers comprise the only factor to the misunderstanding of the informed consent process. I think language, in itself, is a barrier: accents and meanings of words are other barriers.

Subtheme 3: Body language. Principal investigators and interpreters preferred face-to face contact with patients and research teams during the interpretation process. Body language presented an extensive and important augmentation in communication. Principal investigators and Interpreters stated studying the expressions of the patient during the informed consent process could determine if the patient understands the clinical trial procedures explained through the informed consent. Adding a device such as a phone or a computer as other methods of interpretation created more challenges because the body language cannot be seen or read when using a device. The following responses of PIs and interpreters shed light on this issue:

Principal Investigator Participant 062811002C: I absolutely recognized communication barriers are present not just in research but doing normal practices; that is why I so dislike the phone interpretation, because you cannot read body language, because it is difficult to capture the tone of the patient. Patients' expressions body language can tell you if they understand the information you are conveying.

Interpreter Participant 060311003B: You can read so much of the personality and capture ideas of patients understanding during face-to face interpretations. We can capture puzzled faces though the face-to-face interpretation process. The phone and the computer lack so many of the personal elements we, as interpreters, can identify to tell if a person understands the information transmitted.

Theme 3: Cultural Sensitivity

Cultural sensitivity represents the phenomenological connection between LEP and Research team during the informed consent. The transference of information by the PIs to the LEPs during the informed consent does not take into account the possible beliefs, religious, and cultural approaches to science and research from the LEP's place of origin.

Sensitivity to LEP participants' culture during communication is not always present. Cultural sensitivity is particularly important for interpreters whose patient focus extends beyond the understanding of the transfer of information regarding research procedures or standard of care interventions. In the NTRI care and research settings as mentioned by interpreters, challenges are involved in providing a culturally sensitive environment. Interpreters' responses indicated various definitions of cultural sensitivity and how insensitive medical personnel affect the transfer of information. Interpreters expressed that if during the encounter they can identify the cultural background of the patient, such as LEP's place of origin, this can facilitate communication by developing a conversation plan, targeting possible aspects in turn to vocabulary, beliefs systems, and plan approach. The interpreters stated that medical personnel do not allow the interpreters to intervene with the doctors' methods of transmitting information by hospital policies.

The interpreter cannot be in the room with the LEP without the medical provider present. The interpreters stated that identifying the place of origin of the LEP could assist communication by preparing the PI for possible beliefs or specific vocabulary. Cultural sensitivity presented as a collaborative issue in which the provider and the Interpreter lack communication before the presentation of the informed consent to the LEP. Communication before the LEPs presentation of the informed consent between the provider and interpreter would help identify possible issues that could rise during the communication process. These conversations will help present the informed consent in a way that is culturally sensitive to patient needs, as demonstrated in the following responses from Interpreters.

Interpreter Participant 052611002B: The person we are trying to seek for cooperation to participate on a study–if the Doctors'/PIs' nurses do not approach the patients the correct way, and I am talking about with cultural sensitivity, it is not that the patients does not want to participate or understand. It is that the patient is possibly afraid. In many of their countries, research and clinical trials are not practiced, especially for immigrants who come from remote places.

Interpreter Participant 080511005B: The Spanish culture is afraid of someone experimenting with and using them. They lack trust when you mentioned research.

Interpreter Participant 060611002B: Research does not mean the same from here to South America. If you want to cross the communication barrier gap, investigators have to cross the cultural gap. Every person has different beliefs. If investigators and research personnel work in understanding those beliefs, investigators may more capably approach research in a different way.

Interpreter Participant 060611002B: Such as concepts, culture is a big deal. American Health care has its own elements, sometimes, when we are trying to explain, is hard because those elements do not exist in other countries.

Interpreter Participant 0606111003B: Research is not in their everyday life. It is just mentioned in health settings. I do not think they get it–the difference between here and their original countries. Confidentiality can be one of the cultural differences we have. In Colombia, you never see consent. It is cultural. In our countries, very little research is done. Patients are not exposed to research personnel in other countries.

Interpreter Participant 060911004B: Cultures have many superstitions. Some of them wear bracelets and charms around their necks. Some bracelets, like in my culture, they are called "asabaches" [Amulets for good luck and protection from evil made from jet stone]. Understanding these parameters can help investigator in the communication process.

Interpreter Participant 060911004B: Parents are passive; they have all these questions but the mistrust hinder them to not ask questions. Some parents are humble they do not feel comfortable unless someone is speaking in their native language.

The theme of cultural sensitivity developed a subtheme of religious and superstitious beliefs as important factors in the communication barriers during the informed consent process.

Subtheme 1: Religious and superstitious beliefs. The interpreters saw themselves as the first connection between patients, reality of illness, and investigators. The interpreters also understood how important discussion is for research teams to learn patients' decisions, their understanding of medical concepts, and the influence of

religious beliefs on treatments. Based upon the interpreters' responses, identifying patients' cultural beliefs before presenting complicated medical information will assist the investigator in determining the approach to the LEP future participant. These sentiments are expressed through the following statement.

Interpreter Participant 080511005 B: The people of every country have their own belief system, foods, beliefs, and attitudes. So, you just can't say it's the situation. For some people, it's not even the religious belief. As interpreters, we have to breach the gap between one culture and another.

One important aspect perceived by interpreters during the interpretation process is the lack of connection between research teams, including PIs with patients. The patient provider connection is important to determine the medical process needed to continue treatment or establish communication for research purposes. An important connection during the communication process is to learn about the LEP participants' cultural beliefs, including superstitions. Recognizing the prevalence of cultural superstitions may create further motivation for research teams to improve clear channels of communication with LEP participants during the consent process.

The interpreters mentioned PIs harm the process of knowing and exploring the culture of LEP participants because research and care teams are not taking the time to know the LEP patients from a cultural perspective. One interpreter's comments elucidate this subtheme:

Interpreters Participant 060911004B: Some people in Latin American countries believe in the evil eye: "amuletos;" that is why they wear bracelets with certain objects that can stop the evil eye. In the United States, most people do not know what it is or

what the bracelet is for, and if they do know, they do not believe in it. So you have to be sure and explain when you see patients that you explain to the provider the patients' beliefs.

Theme 4: Education

Four out of five PIs and six out of eight LEPs participants described a disconnection in understanding the research language. Even at the simplest level, the language was not basic enough to convey the information during the informed consent process. The LEPs and PIs perceived the complexity of the clinical trials. The complexity of the informed consent and the overloaded medical words in the document do not meet the educational level of LEP participants. Participants pointed to the effect of the level of education of the LEP participant in understanding the clinical trial.

PIs perceived the level of education to be a barrier not only with LEP participants but also for English-speaking participants. Communication barriers are present when the level of education of the patient does not align with the medical terminology or descriptive procedures of the study stipulated in the informed consent. The process becomes complicated during research when precise steps have to be followed for statistical purposes. One important issue expressed by PIs is the difficulty of expressing medical terminology in simple language. The length and high level of words of the informed consent document complicates the informed consent process. The complexity involved in explaining the informed consent increases when the paper form of the informed consent is not in the primary language of the LEP participant. The problem occurs also when a complete translated version of the consent is not available, and when the patient cannot understand the concepts written in the consent. The criterion of

comprehension is perceived as more complicated when the level of education of the LEP is lower than the required eight-grade level by the federal research regulations. The educational level is perceived as a barrier in itself, affecting recruitment processes and compliance.

Interpreters agreed with the PIs' perception that education is paramount to understanding the clinical trial process. Interpreters mentioned the need for constant explanation and continually teaching LEP patients the purpose of research. Providing education during standard of care visits will increase understanding of the facility's clinical trials development. All interpreters stated that offering literature and continuing education regarding research at the NTRI during the standard of care practices would improve communication. Explaining to LEP patients what a clinical trial is, why investigators developed protocols for clinical trials, and clarifying the goals of research before starting the consent process are paramount to increase understanding of the NTRI involvement in trials as a public and teaching facility. The comments from the PIs support the importance of education in understanding informed consent.

Interpreters and PIs described the level of education as a primary factor in understanding the informed concept process. The level of education influences how the communication develops with the research participant. The higher the level of education of the LEP patients, the higher the understanding of interpreters and PIs. All interpreters and all PIs perceive prevalent understanding during the interpretation process is a reflection of the education level of participants. Interpreters and PIs extended the idea of higher level of education: even if the patient is LEP, the patient is able to develop questions in relation to the clinical trial process and demand explanation of the

procedures several times. In contrast with LEP patients with perceived low levels of education, these patients stay silent during the informed consent process, do not formulate questions**,** and their facial expressions are puzzled. Both Interpreters and PIs commented on the effect of education:

Interpreter Participant 080511005B: Even if their language was English with not a higher level of education, I do not think they can understand the process. The level of education of the patient, no matter if Spanish or English, is important in the understanding of the informed consent process.

Interpreter Participant 060611002B: You are talking about elementary or intermediate language; that language is mathematical, complicated for the level of education of our LEP patients. The language is not accurate. I think if you run the consent through patient education, the level of education is a barrier to access.

Interpreter Participant 060611003B: The density of the consent and the level of education of patients make a difference in the understanding of the process.

Interpreter Participant 060911004B: Sometimes with the words of the documents, even though the documents are in Spanish, you think the parents understand. However, some of the verbiage goes beyond their understanding and educational level.

Principal Investigator Participant 060311001C: Understanding depends on their level of education; the language itself is not a barrier for both Spanish and English, and the level of education--it is important to their understanding.

Principal Investigator Participant 062811002C: The education is important in Spanish as well as English speakers. I had a family who moved from Mexico, both parents were professionals. The child was diagnosed in Mexico with a medical

condition. When they moved here, they did not speak a word of English. They refused to talk to anyone without an interpreter. A year later, they both were working and speaking the language. Education is essential for families as well as parents and the population to understand the process.

Principal Investigator Participant 07261005C: The educational level will play an important role in the comprehension of the translated document or conversation.

Principal Investigator Participant 071111004C: I have English-speaking patients who can understand equal or less than a family from El Salvador and the forms offered are in English. But I think Spanish speakers are a different type of patient. I believe that the socioeconomics are as important as the English proficiency. A stupid non-English-speaking patient is a lot different than a highly educated non-English-speaking patient. Then you have the educated and intelligent LEP patient who might grab the concept faster. The problem is the language in which the documents are prepared.

The LEP participants described their perceptions as a participant participating of an informed consent process with a PI or other research personnel presenting the informed consent as part of meeting eligibility criteria for a clinical trial. LEP participants' expressions demonstrated personal views, levels of understanding of the clinical trial, and the informed consent process:

LEP Participant 0228201007A: I do not know what a clinical trial is.

LEP Participant 0228201008A: No, I have never participated of a clinical trial.

LEP Participant 02282012009A: I do not understand what is a clinical trial or the informed consent. I think I have signed some papers but I can remember.

LEP Participant 112220110004A: I remember my child was very sick. I took him to the hospital, and the doctors found a virus, CMB, or something like that. I was taking her to the ear doctor, and they explained to me about the virus and made me sign some forms. I believe the study was done to learn more about the condition that my child had to find new treatments and ways to treat my child and others in the future.

LEP Participant 0228201008A: Sorry, I do not understand the difference between standard of care and research; I just brought my child to the appointments they gave me at the clinic. I do not know what clinical trials are. A doctor approached me with some paperwork and asked me to sign my baby into a study. They wanted my baby to participate of a study in which they were going to use the result for other kids in the future.

For the purpose of the present study, that Participants 0228201009A and 112220110004A were active in a trial at the time of the interview is noted.

Subtheme 1: Interpreters level of education. Interpreters' perceptions varied in recognizing the paradigms involved in clinical trials and others not recognizing the factors and significance of clinical trials. Interpreters experienced a disconnection between the role of clinical trials, parameters involved regarding clinical trials, statements involved in the informed consent form, and regulations. In responding to questions related to the IRB, Interpreters and LEP Participants responded as follows:

Interpreter Participant 052611003B: It is a study that has a different hypothesis and maybe that investigators want to find the truth and validate the hypothesis.

Interpreter Participant 060611002B: Where you use people to determine whether your hypothesis is correct or not.

Interpreter Participant 052611005B: No, I do not know them; I have heard about them. I think they review the rules of the study/look for people who have to be respected during the study.

Interpreter Participant 060611002B: The purpose of an informed consent is for you to know what is going to happen during the study, what the risks are, that participation is voluntary, and they can choose out of it, or if they do not participate, the care will be the same, or if they are going to change it, how they going to change it.

Interpreter Participant 060911004B: My understanding is that patients are chosen at random according to a set of guidelines or what are they trying to research.

Understanding of the Informed Consent

The interview process involves an open discussion and exchange of information. One particular question asked to LEP participants captured an evaluation regarding the experience during the informed consent process. The question was, "How would you rate your experience of the informed consent process: excellent, neutral, or poor?" Five LEPs categorized the informed consent experience as "poor" because the team members were not communicating in their native language or were not able to understand the interpreters. The conversations were fast, and they were afraid to ask questions. The informed consent was not presented in their native language. Two LEPs affirmed that the experience was "good" because the interpreter took time to ask questions for clarity and interpreted the questions to the research team. One LEP considered the informed consent procedures as neutral because the interpreters explained the concepts of the study even after the PI left the room. This LEP stated the informed consent was not in their native language and their major concern was the well-being of their child. The analysis of the question involved determining the level of understanding by placing the experience in simple terms using the Likert scale.

A second specific question asked to interpreters and PIs was to provide their perception regarding the IRBs' possible regulation of communication of the informed consent process when the patient is LEP. Four interpreters affirmed the IRB should regulate the communication and translation of the informed consent process. Five PIs perceived the IRB should regulate the communication and translation of the informed consent process, an important component in clinical trials development. Both groups

expressed the importance of the documents to be concise and always written in the language of the participant.

Interpreters considered regulation to be necessary because investigators are not using the same parameters to recruit LEP participants; a regulation could be used to determine the steps to facilitate an LEP participant's understanding and recruitment. Both groups considered the informed consent short form an inadequate tool to use to explain a study or provide sufficient information regarding the study procedures to enable a participant to enter into a clinical trial. One PI mentioned the importance of IRB regulation in the informed consent process and expressed concern when sponsors do not provide the monetary resources to translate the documents by a certified entity. The inadequacy limits the resources PIs can use during the consent process.

PIs also noted that the IRB approval process might include a translation of the informed consent form, but the IRB would allow the document without submitting the document for review by an expert. The PIs mentioned an important aspect of Informed Consent Regulation is for the IRB to review the forms translated by expert Spanish translators before obtaining approval. This process is important because the level of Spanish in the informed consent is not accessible to all Spanish speakers, as evidenced by the following statements.

Interpreter Participant 052611003B: The IRB needs to regulate the consent process because I do not think the investigators are doing the same job. Sometimes I find that some investigators spend 5 to 10 minutes and others take, like, 2 hours. Each person [Investigator] is doing something different.

Principal Investigator Participant 060311001C: It is a hard process because many of the Spanish-speaking patients who do not know English can read possibly elementary Spanish. We spend a lot of time and money translating consents and clinical material, and we give the material to them even though they cannot read them in their own language.

A third specific question explored the experiences of Interpreters and PIs during the consent process, indicating if they had recruited and consented a patient into a clinical trial with reservations about the patient's understanding of the parameters discussed during the informed consent. Three PIs acknowledged the recruitment and signature of informed consent to LEP participants who did not understand the parameters of the clinical trial. Five interpreters indicated they assisted in the recruitment of several LEP patients when they had reservations of the participants' understanding of the informed consent and process of clinical trials. Both interpreters and investigators commented on this issue.

Interpreter Participant 052611005B: Yes, I have assisted in the consent process of LEP patients when I had reservations of their understanding of the clinical trials process.

Interpreter Participant 060611002B: Yes, I have, but most of the time when PIs had reservations, then the PI comes back and gives time for the family to process the information. Sometimes the interpreter tells the investigator that the participant did not understand what the PI was saying; so you may try again or comeback later.

Principal Investigator Participant 072711006C: Yes, I do not think they are always clear, but LEPs do not let you know they did not understand. They just accept and sign the paper.

Principal Investigator Participant 060311001C: Yes, I have consented LEP participants that I believe did not capture all the elements of the study.

Summary

Chapter 4 included a presentation of the findings along with a review of (a) demographic information, (b) the process of data collection, and (c) the tools for data analysis, including audio digital recording, transcription, hard copy review, and NVivo 9 software. The semistructured questionnaire prompted the participants to describe their experiences regarding communication barriers with LEP participants during the informed consent process. The participants described (a) the experiences during the informed consent as PIs, (b) the experiences during informed consent as Interpreters, and (c) the experiences as LEP patients participating in an informed consent process. The interview questions were used to elicit the knowledge, challenges, and personal experiences of the three groups relative to the informed consent processes during clinical trials.

During the analysis of the participants' interview responses, themes and subthemes emerged. Analysis began with audio and electronic copies of the transcribed forms using NVivo 9 software to determine the development of nodes. An additional three specific questions for comparative evaluation took place to determine theoretical situations. The process of coding using NVivo 9 software facilitated theme identification for each interview.

The development of themes facilitated a clearer understanding of the participants' experiences integrating modalities in the scope of practice. Using participants' stories to reflect on individuals' experiences during the informed consent process, several experiences and nuances were isolated. Barriers of communication stood out as the primary challenge; other factors explored include accessibility to certified interpreters, authority figures, and cultural sensitivity. Chapter 5 includes a discussion of the (a) results, (b) recommendations for future research, and, (c) recommendations for health care leaders dedicated to clinical trials and the informed consent process.

Chapter 5

Conclusions and Recommendations

The continued development of clinical trials has resulted in efforts to increase patient recruitment. Patients meeting eligible criteria might speak a different language from the research team (Abbe et al., 2006). In the current study, the goal was to explore in-depth the experiences of principal investigators (PIs), interpreters, and LEP research participants regarding communication during the informed consent process. Based upon the information shared and the results presented in Chapter 4, themes and subthemes emerged, forming the foundation for the study's conclusion. Chapter 5 includes the findings bounded by the evidence collected through the interview process: (a) review of the research questions and study purpose, (b) the conclusions (c) the recommendations, and (d) summary of findings.

Conclusions

The purpose of the present qualitative case study was to explore if communication barriers affect the understanding of LEP research participants while participating in the informed consent process during clinical trials. The significance of the study lies in the exploration of communication during the informed consent process with the research participants with LEP. The objective was to improve knowledge, assist in strategic planning of future studies, and develop effective methods of informed consent processes during clinical trials practices. Data collection was conducted by face-to-face interviews, phone interviews, digitally recorded interviews, observation, and a retrospective review of electronic medical records. NVivo 9 computer software assisted in organizing the data for emergent themes.

Research Study Problem and Questions

The general problem was that communication barriers are a significant problem for participants with LEP in understanding the informed consent process during clinical trials practice. The 2010 census indicated 59 million Americans speak a language other than English at home and 25.2 million have limited English proficiency (U.S. Census 2010). This statistical percentage does not include illegal immigrants, who are estimated at 40 million people, accounting for 13.8% of the U.S. population (Justich & Ng, 2005). Among these illegal immigrants, 5.5% are estimated to have LEP (Resnik & Jones, 2006). The current study examined communication barriers during the informed consent process. The following research questions were used to guide the study:

1. What are the communication barriers during the informed consent process among three research groups: PIs, interpreters, and LEP patients?

2. Do interpreters and PIs consider communication barriers during the informed consent process a possible cause for medical error?

3. Do primary language, experience with clinical trials, education, background, culture, and socioeconomic data contribute to communications barriers?

The findings identified in the study are significant and support existing data on communication barriers in medical settings. Four main themes emerged from the analysis of the participants' interviews discussed in Chapter 4. The themes and subthemes include (a) an authority figure with subthemes of no other alternative treatment presented; (b) barriers of communication with subthemes of interpreters' emotional involvement, origin of language, and body language; (c) cultural sensitivity

with subtheme of religious and superstition beliefs; and (d) importance of level of education.

Exploring each theme and subtheme established the association to the literature reviewed in Chapter 2 and the theories structuring the study discussed in Chapter 1. Interpretation of the data provided answers to the research questions. Through language, case studies analyzed the description and experiences of participants to determine important details. The participants provided important data about their experiences and communication during the semistructured interview process.

Each analyzed theme that emerged in the participants' narrative was deconstructed and related to the current literature. Further exploration of transcribed data and recognition of the participants' experiences assisted in determining the intention and meaning of participants' experiences. Categorizing, synthesizing, and reconstructing participants' narrative led to an understanding of the phenomenon occurring during the informed consent process. Study outcomes in relation to the research questions indicated that communication barriers are a problem during the informed consent process when the patient has LEP. Interpreters and PIs conveyed that culture is an important factor in the communication process, and communication barriers can lead to adverse events. PIs maintained that study outcomes are not unique to the informed consent in clinical trials but a major trend in communication between providers and patients during standard medical practices.

Implications of the Findings in Relation to the Literature

The study contributed to the knowledge base of research and clinical trial development leadership by providing strategies to improve the informed consent process

in clinical trials. The conclusion of the current study included the multiple descriptions of the experience of PIs, interpreters, and LEP participants during the informed consent process. The goal of the study was to explore the communication barriers during the informed consent process of clinical trials through the perceptions of the PIs, interpreters, and LEP participants. A second goal involved the way these communication barriers, along with the involvement of the PIs and interpreters, affect the participation of LEP participants in clinical trials.

Theme 1: Authority figures

Patients rely on physicians' visibility to understand personal health factors. The lack of patients' medical knowledge and the influence of physicians in patients' treatments placed physicians as authority figures. In the past, medical authorities were presumed to make medical decisions on behalf of the patients (Parson, 1952; Reedley et al., 2011). With the introduction of policies and governments promoting procedures to a more participatory approach in the decision-making process, patients have become involved in their medical decision making (Reedley et al., 2011; Turner, 2004).

The participatory approach in decision making has not been a firmly established legal and ethical principle when the patients have LEP. The participants acknowledge the physician as authority figures in the decision to participate in clinical trials. The participants acknowledge that the inability of LEP patients to communicate with physicians in their primary language establishes the physician as the decision maker in relation to treatment. In the case of the present study, the physician becomes executor of the agreement to participate in a clinical trial during the informed consent process.

Based upon the previous literature, informed consent is predicated upon the patient's voluntary decision to participate (Wolf et al., 2007). The difference in language between providers and patients is a barrier to the conveyance of consistent, clear, and high quality information on a particular clinical trial in which the patient meets the eligibility criteria. The participants of the present study showed that the ability of the LEP patient to make a decision to participate in clinical trial is based on the physician's communication during the informed consent process. The voluntary decision of the patient to participate is affected by the difficulties in communication resulting from language barriers. Based upon previous literature, the patients' decision to participate in standard of care treatments and clinical trials are influenced by physicians and investigators communication of the treatment (Wolf et al., 2007).

A subtheme that emerged from the theme of authority figures is that no other alternative treatment is presented. This subtheme signified that physicians acting as investigators presented the clinical trial as the only alternative for treatment. Interpreters indicated the importance of the relationship between the provider, acting as an investigator, and the LEP patient during the introduction of the clinical trial in establishing the authority figure main theme. LEP patients confirmed their decision to participate in research was determined by the investigators' method of presenting the information. From the presentation of the information, LEP patients understood no another treatment possible for their child

Theme 2: Barriers of Communication

LEP participants frequently reported experiences with communication barriers. Patients and physicians interaction during the informed consent process affects patients'

decision to participate in a study (Brenner, Brenner, and Horowitz, 2009). The recruitment process of an LEP patient further complicates the discussion. The interaction is a mutual process of communication through the exchange of verbal and nonverbal information during the informed consent process. To transmit the content of the informed consent form effectively, investigators must meet the ethical mandates discussed in Chapter 2 when the participant has LEP. The findings correspond with the literature that LEP patients are less likely to comprehend diagnosis and treatment procedures leading to medical errors in standard of care practices (Schlesinger, 2006). These findings can be applied to the discussion of the informed consent process as demonstrated in the present study by the lack of understanding and adherence to trial procedures by the LEP patients. The use of professional interpreters may decrease the communication barriers and increase compliance (Flores, Abreu, Barone, Bachur, & Lin, 2012; Karliner, Jacobs, & Mutha, 2007). Overcoming communication barriers is a challenge; providing certified interpreters and translators with relevant medical competences reduced the chances of error and miscommunication (Anazawa, Ishikawa and Kiuchi, 2012)

The interpreters' emotional involvement with the patient emerged as a subtheme. Principal investigators described interpreters' emotional involvement as reacting negatively to the situation of the child at the time of the interpretation. A recent study by the Kaiser Foundation supports the findings by indicating that without the ability to establish an open and transparent communication between patient and provider through the use of an interpreter, patients are at risk of decreased access, delayed care, displaced protocol guidelines, and jeopardized study outcomes (2011). Inappropriate or improper

behavior of the interpreter services can increase patient confusion and inflict emotional distress to the patients' health situation. Instead, without the ability to communicate with patients, investigators are at risk of recruiting ineligible patients, decreasing adherence to the study, and increasing the chances for adverse events.

A second subtheme of communication barriers pertained to the challenge Interpreters had in recognizing the origin of language among LEP participants. In the current study, interpreters' recognition of LEP patients' origin of language can minimize communication barriers and assist the investigator in transmitting information. The increased number of foreign language speakers and variations of the same dialect increased the need for expanding the knowledge of the interpreters to the recognition of various dialects. Linguistic barriers can impede interpreters' ability to communicate clear information to investigators (Andrulis, Goodman, & Pryor, 2002). Clear information is needed to identify if patients are eligible to participate in the study. The development of cultural competency skills increases the ability to identify origins of language (Diamond & Jacobs, 2009)

Body language from the participants emerged as a third subtheme of communication barriers. Comments about the methods of interpretation helped explore the challenges by the participants. Negative feelings were tied to the use of language lines and computer programs used for interpretation and communication. Feelings of inadequacy occurred with the lack of face-to-face interpretation. The mandates of the Title VI of 1964 Civil Rights Act have urged organizations to comply with guidelines to provide interpretation needs. The use of commercial technologies for interpretation provides easy-to-use and rapid access of interpreters for different languages, reducing

times and costs associated with face-to-face interpretation (Masland, Lou, and Snowden 2010). The telephonic interpretation services have been found in earlier studies to have a lower satisfaction among providers and patients than face-to-face interpretation. The reduction of visual information through the face-to-face interpretation process follows, along with the results of this study, how technologies reduce the quality of conveying information (Masland, Lou, and Snowden, 2010). In other studies, the use of video interpretation improved quality of care simply by increasing access to professional interpreters due to the time and lack of a certified interpreter (Schenker, Lo, & Fernandez, 2008). The value of face-to-face interpretation appeared as an important factor in detecting patient understanding through body language. The face and the body contribute in conveying the emotional state of patients (Meeren, 2005). Rapid detection of inconsistency in body language is beneficial to interpreters and providers to detect if the LEP patients' body expressions show an underlying confusion or puzzling behavior. Such paralinguistic aids help in determining the understanding of LEP participants.

Theme 3: Cultural Sensitivity

The most frequent challenge for PIs and interpreters was to identify the culture of the patient. Interpreters expressed the effect of the short time with the patient and the investigator during clinic visits makes it impossible to gather enough information to identify the culture and previous experience of the patient. Interpreters and PIs mentioned cultural sensitivity as a factor necessary to integrate communication practices into caregiving. Participants who mentioned cultural sensitivity typically viewed the identification of culture as a challenge that could limit the modalities of communication.

The subtheme of religious and superstitious beliefs emerged from the cultural sensitivity theme.

The Institute of Medicine recommended that cross-cultural education be incorporated into professional training (Institute of Medicine, 2003). Cultural sensitivity interventions have been shown to improve participants' understanding of communication barriers (Diamond & Jacobs, 2010). Previous studies indicated that cultural competency is a crucial part of the communication process (Kodjo, 2009). The difference between the cultural beliefs and values of investigators, interpreters, and LEP participants obstruct the establishment of a communication partnership.

The subtheme of religious and superstitions beliefs occurred in two of the groups (interpreters and PIs) studied under cultural sensitivity. As part of the importance of identified culture, interpreters and PIs indicated the importance of identifying religious and superstitious beliefs during the presentation of clinical trials. The literature presents socio-cultural barriers as well as cultural beliefs to be a common restriction for Hispanics to participate in clinical trials (Wallington, Luta, Noone et al., 2003). Participants regard spiritual health and physical health to be equally important. The use of artifacts, such as rosaries and amulets, by patients are objects that serve as tools for interpreters to identify the culture and beliefs of a patient. The identification of beliefs provides methods to determine the right communication approach. Some studies suggest that patients' outcomes may improve when therapies are integrated with religious beliefs (Curlin, Lawrence, & Meador, 2007). Interpreters implied that the possibility of identifying the patients' religious or superstitious beliefs with regard to treatments establishes how the

communication will be interwoven with these beliefs during the presentation of the informed consent.

Theme 4: Educational Level

Participants frequently reported the educational level of the patient interfered with comprehension of the informed consent form (ICF) as a barrier of communication. The complexity of the ICF makes the comprehension difficult, especially in patients with a lower education level. Interpreters found it challenging to interpret the scientific concepts to which PIs referred throughout the document. The PIs' perceptions were determined by the level of education, regardless of a language barrier. The legalistic and detailed document is difficult to comprehend for patients of low educational level with any language of origin. LEP participants found the ICF to be a long document of unlikely comprehension because the documents were not presented in the primary language of the participant. When the LEP participant has a high level of education, PIs and interpreters saw a difference in their ability to play a major role on the communication process: they related more to the interpreter and asked questions until they were satisfied with the answers.

Based upon previous published studies, comprehension and satisfaction with the informed consent during standard of care practices and research were lower among patients with lower educational levels and English as a second language (Breese, Burman, Goldberg, & Weis, 2007; Fink, Prochazka, Henderson et al., 2010). An important part of the informed consent process is the effective communication between the research team and patient about the rights, risk, benefits, and procedures of a specific study. A number of researchers have evaluated the extent of comprehension of patients

during the informed consent process and progression of communication (Bjorn, Rossel, & Holm, 1999; Bresse et al., 2007; Joffe et al., 2001a). These studies by Bjorn, Rossel, Bresse and Joffe had limitations in populations and therapeutic areas; most studies were performed in cancer treatment patients who were English-speaking, non-Hispanic Whites (Pope et al., 2003). This study at the NTRI included a public health clinic teaching facility with a high concentration of immigrants, diverse therapeutic areas, low education levels, and no experience with clinical trials in their country of origin. At the current site in which this study was performed at the NTRI, participants recognized and accepted that the complexity of the document, the scope of practice between standard of care and research, the high concentration of low level of education among the patients, and lack of resources to translate documents influenced communication barriers.

Key findings from previous data included the identification of race, education, and time spent during the consent process as predictors of patient comprehension after the discussion of the informed consent process (Fink et al., 2010). Previous researchers studying health literacy, found that race, age, education level, and ethnicity were delineated factors associated with comprehension (Fink, Prochazka, Henderson et al., 2010; Hekkenberg, Irish, Rotstein et al., 1997; Lavelle-Jones, Byne, Rice, & Cuschieri, 1993). The previous findings, together with the findings of current study observations, supported the position that patients with low or potential language difficulties are likely to have limited understanding of the informed consent process. The process is highly complicated when patients have low levels of education and communication barriers. The participants attributed some success to the understanding of the informed consent when the integration of time and continued support during the screening is provided to

the participants. The study results indicated opportunities for clinical trial leaders who seek to improve communication barriers during the informed consent process. Improvements include integrating communication parameters in the scope of informed consent practice by developing collaboration and education with interpreters, IRBs, PIs, and LEP participants.

Significance of the Findings

Language barrier studies have focused on the standard of care practices with little attempt to show the experiences of PIs, interpreters, and LEP Participants along with their perceptions of communication barriers (Simon, Kodish et al., 2006). According to Simon, Kodish et al. (2006), the effect of communication barriers on the informed consent process during clinical trials is critical to successful research. By exploring the scope, precedents, and perceptions of these three populations involved in the informed consent process during clinical trials, the present study provided research groups with the information to understand the process of informed consent during clinical trials when participants have LEP.

The exploration of LEP experiences during standard of care practices have been studied, providing a unique examination of quality of and access to care when language barriers are present (Flores, Abreu, Barone et al., 2012; Flores, Barton-Laws, Mayo et al., 2003). Diverse ethnic groups continue visiting and accessing health care services at organizations. Many of these organizations promote clinical trials. The recruitment of diverse ethnicities and cultural backgrounds are important to the development of new treatments (Kao et al., 2004). Aligned with the findings of language barriers among the LEP patients during standard of care practices, the study data engendered several concepts affecting the communication of the informed consent process when patients have LEP.

The study resulted in profound descriptions of the experiences of PIs, interpreters, and LEP participants that formed the bases of concepts affecting the clinical trials' informed consent process. The rich data from the three populations in the study

increased the understanding of communication barriers present when the research participant is LEP. The process was in compliance with the Culturally and Linguistically Appropriate Services (CLAS) of the Office of Minority Health. In 2000 and revised in 2013, CLAS officials mandated national standards to ensure people entering the U.S. health care system receive equitable and efficient assistance in a culturally and linguistically appropriate manner. CLAS standards were proposed to correct inequities in the rendering of health services to patients in need, targeting the diversification of cultures and language demographics.

CLAS National Standards were applicable to the present study findings because the standards mandate all researchers associated with federally funded organizations, health care, and care organizations must apply the National Standards to any services and studies. The goal is to eliminate disparities, improve quality services, and meet regulatory and accreditation regulations to the demographic changes in the U.S. health care system. The NTRI receives funds from federal programs such as Medicaid, Medicare, Children's Health Insurance Program, and social security. The current study contributes to the body of literature on language barriers and quality care by filling the knowledge gap about communication barriers experienced by PIs, interpreters, and LEP participants during the informed consent process of clinical trials.

Recommendations

Study results compare with prior literature arguments that communication barriers affect the standard of care practices when patients have LEP (Flores, Abeu, Barone et al., 2012). A relationship exists between the perception of communication barriers among PIs, interpreters, and LEP participants during the clinical trial informed consent process.

Leaders may use the findings as an environmental tool to identify cultural and structural forces affecting how the communication of the informed consent process affects the comprehension and understanding of the clinical trial when the participant has LEP and an interpreter has to be involved in the transfer of information.

Recommendations for Leadership

Informed consent during clinical trials differs from standard of care practices. Understanding the risk, benefits, and voluntary participation in a study means that the Good Clinical Practice regulations were followed and the well-being of the participants were measured against the risks/benefits of the study. The signature of the LEP patient means agreement to a voluntary study in which the purpose, risk, and benefits of the study were explained, considered, and understood. Communication barriers are costly in terms of increasing the chances for adverse events, early withdrawal from trials, incomplete data, and financial losses for sponsors, and ethical recruitment practices (Dixon-Woods et al., 2007). Based upon the results, crucial factors limit clear communication parameters during the informed consent process when the participant has LEP, even after accounting for the language barriers between the PIs and the patients.

Recommendations for Policy

Recommendations for research facilities such as the NTRI and IRBs is to use the study results to develop policies intended to diminish or eliminate communication barriers to understanding informed consent. A corollary recommendation is to appoint an agent of change to address the protocol in the approval process. Another recommendation is for leaders to use the results to separate systematically the allocation of resources in standard of care practices from clinical trials recruitment procedures when

patients have LEP. The results will support the development of standard of procedures when communicating with LEP patients during the presentation of a research study involving interpreters. The standard of procedures can be monitored and revised based on possible changes encountered during the transition and recruitment of LEP in research studies.

Recommendations for Training

Leaders may use the results to develop cultural educational programs empowering PIs and interpreters to increase the scope of knowledge of the nuances involved around communication barriers during informed consent processes. Leaders may also learn the effects of communication barriers on the informed consent process when there are LEP research participants. The inclusion of internal educational and professional resources may support the PIs and interpreters at the working site. Participants acknowledged the need for leaders' support at the study site by providing integration, recognition, and autonomy, and also adding professional development to interpreters' certification in relation to clinical trials development. Participants acknowledged the importance of expanding the integration and development of cultural approaches to reflect the LEP participants' community needs in relation to research participation.

Recommendations for Further Study

The findings support the literature on communication and language barriers in the healthcare system. With the continued growth of the immigrant population, Americans with LEP, and emerging clinical trials, researchers must explore the complex communication barriers and effects of communication barriers on clinical trial outcomes. While ample literature contains information on language barriers in standards of care

practices, an acute shortage of research on communication barriers during the informed consent process in clinical trials continues.

One important finding from the present research was the difference in research between cultures and countries. Participation in clinical trials and informed consent processes in developing countries may not be a commonly advertised practice for alternative treatment. For example, in Mexico, research is commonly practiced in social facilities, a difference from the United States where researchers use diverse facilities such as public teaching hospitals and private research institutions to promote research. Developing countries may have different motivators to take part in clinical trials because the prospective participants may have little or no other alternatives to receive care for their conditions except the care received through clinical trial participation. Identification of the culture of participants goes beyond general competency and requires specific trainings to understand the experiences, values, and motivations of researchers from international communities in previous clinical trials. That knowledge must then be applied in the development of fundamental cultural programs for LEP research participation.

Recommendations for Further Research

Given the important context of leadership and the role PIs, interpreters, and LEP participants play in the development and completion of an accessible informed consent process, further qualitative research is necessary. Researchers might use a larger sample size and participants from diverse organizations to develop parallels to perceived communication barriers in the development of clinical trials. Due to the difficulty in obtaining more information and the lack of flexibility among possible participants, the

emerging themes can be used to develop a survey. The survey could be provided to additional research facilities with ample time for completion. The survey could be used to elicit other perspectives that possibly were not expressed for different reasons, such as fear of lack of confidentiality or repercussions from the facility toward the participants' work during the face-to-face interview. Future researchers would be prudent to develop and include other research team members involved in the informed consent and clinical trials process, such as nurses, study managers, and study coordinators. Including a diverse population will help compare perspectives and experiences with regard to communication barriers to determine similarities or differences from those included in this study.

Limitations of the Study

Qualitative case studies have an inherent number of limitations; studies with the inclusion of triangulation minimize the limitations (Creswell, 2005). The major threat to data validity is interviewer bias: the flexibility and methods of the study often leave room for interviewers' personal influences and bias. To avoid bias in the present study, the interviews were triangulated with documents, notes, and observations (Neuman, 2006).

The credibility of the study was based on participants' honesty, a subjective quality that cannot be absolutely assured. Participants' gender, race, ethnicity, and social and professional status in the organization may have influenced the responses to the interview process. Some participants allocated inadequate time for the interviews, hindering full exploration of their perceptions. In other instances, participants were interrupted during the interview by hospital calls. Many participants accepted the interview and participation of the study by phone instead of face-to-face interviews. The

telephone approach hindered the taking of notes to record body language. The unique experience of the participants of the present study might not represent all methods allocated to other organizations practicing clinical trials. Other organizations might have diverse methods of incorporating interpretation and LEP communication policies.

The findings of the current qualitative study may not be transferable to other healthcare facilities (Neuman, 2006). The study involved a NTRI in the metropolitan area of Dallas with a high concentration of LEP persons from Mexico with Spanish as a first language. The study limited the collection of data in rural settings. The study did not include LEP persons with other primary languages, limiting the data to Spanish-speaking persons from Mexico.

Researcher Reflection and Expertise

Based on the reflective question about whether or not communication barriers affected the informed consent process during clinical trials, the study participants reflected on how communication barriers might affect the informed consent process. The deficiency of resources, such as trained interpreters in specific therapeutic areas, documents written in Spanish, and accessibility to care for LEP patients altered the experience of clinical trials during recruitment procedures. The three groups interviewed perceived communication barriers during the informed consent process and ways in which the process can alter clinical trial experiences if the right resources were allocated. The collected data on experiences and perceptions of participants supported a sense of affirmation and support for the development of their role as a research participant, making the process an educational journey.

Interpretation of the collected data engendered insight and cognitive understanding, allowing the integration of the learning process to gain a perspective of the experiences of research participants. The PIs and interpreters shared a sense of responsibility among the patients, evoking a personal accountability to the quality of care provided to LEP patients. The identified themes are entwined, indicating the need for a more holistic view of communication barriers in the informed consent process necessary to clinical trials. The practical application of these experiences is to share the study outcomes with the NTRI and other professional organizations to enhance LEP participant recruitment methods and create awareness of how communication barriers affect the informed consent process.

Concluding Statement

The study of communication barriers during the informed consent process is an example of a continuing issue studied in response to a neglected ethical standard in the health care system. The results demonstrated that LEP research participants had signed and participated in clinical trials not knowing or understanding the parameters involved. The results showed that a communication gap between leadership, PIs, and interpreters provided an opportunity to improve the assistance provided to LEP patients in understanding their participation in clinical trials with a sound understanding of the purpose, voluntary, risk, and benefits of participating. Unlike previous research performed in standard of care practices, the study did not seek to add statistics or prescribe a change in behavior; instead, the study provided descriptions of the context of experiences of PIs, interpreters, and LEP participants as part of a research team. Each

person interviewed had a unique perspective of the issues and responsibilities with LEP patient involvement.

The study results pointed to agreement on the existence of communication barriers. To ensure the informed consent process during clinical trials is performed clearly and with the ethical principles of good clinical practice when the patient has LEP, PIs and interpreters need to overcome communication barriers as well as cultural barriers. The findings supported the need for more education for patients on clinical trials. Other findings indicated the need for investigators to mentor interpreters as well as apply resources to comply with a high LEP population and the translation of documents in the patient's first language. Another need was continued clinical trial education for patients who visit educational facilities, providing them with interpreters who have a research background. A final need involved the practice of using interpreters when a cultural difference affects the standard of care practices and clinical trials.

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Appendix A

Informed Consent to Participate in Research

UNIVERSITY OF PHOENIX

The University of Texas Southwestern Medical Center at Dallas

Children's Medical Center

CONSENT TO PARTICIPATE IN RESEARCH

Principal Investigator: Roberto Torres, DHAc.

Study Title: COMMUNICATING INFORMED CONSENT WITH LEP PARTICIPANTS DURING CLINICAL TRIALS: A CASE STUDY

Dear Research Participant,

My name is Roberto Torres, and I am a student at the University of Phoenix working on a Doctoral degree in Health Administration. I am conducting a research study entitled *Communication Methods used with Limited English Proficiency (LEP) Research Participants to Acquire Informed Consent During Clinical Trials*. The purpose of the present qualitative case study was to explore if communication barriers affect the understanding of LEP research participants while participating in the informed consent process during clinical trials.

Your participation will involve a semistructured interview with the researcher. This interview will required about 40 minutes of your time. Your participation in this

study is voluntary. If you choose not to participate or to withdraw from the study at any time, you can do so without penalty or loss of benefit to yourself. The results of the research study may be published but your identity will remain confidential and your name will not be disclosed to any outside party.

In this research, there are no foreseeable risks to you. To protect your confidentiality during the study, you will receive an alphanumeric code. All research information that can be identified will remain confidential. Access to data will be restricted to those directly involved in this study.

Although there may be no direct benefit to you, a possible benefit of your participation may lead to a better understanding of the role of communication with LEP during informed consent processes. It is hope that this study may lead to a better understanding of the benefits of communication with LEP during clinical trials participation. Others might benefit in the future from the knowledge gained.

Future clinical trials will benefit from the knowledge gained of this study

As a participant in this study, you should understand the following:

1. You may decline to participate or withdraw from participation at any time without consequences.

2. Your identity will be kept confidential.

3. Roberto Torres, the researcher, has thoroughly explained the parameters of the research study and all of your questions and concerns have been addressed.

4. If the interviews are recorded, you must grant permission for the researcher, Roberto Torres, to digitally record the interview. You understand that the information from the recorded interviews may be transcribed. The researcher will structure a coding process to assure that anonymity of your name is protected.

5. Data will be stored in a secure and locked area. The data will be held for a period of three years, and then destroyed.

6. The research results will be used for publication.

"By signing this form you acknowledge that you understand the nature of the study, the potential risks to you as a participant, and the means by which your identity will be kept confidential. Your signature on this form also indicates that you are 18 years old or older and that you give your permission to voluntarily serve as a participant in the study described."

If you have any questions concerning the research study, please call me at Roberto Torres at 214-[redacted] or e-mail [redacted]@gmail.com

Print name of interviewee_____

Signature of the interviewee _____ Date _____

Signature of the researcher _____ Date _____

Appendix B

Invitation Letter

Date

Dear Provider,

My name is Roberto Torres, clinical research coordinator at Children's Medical Center. Doctor Janna Journeycake is my sponsor for this study. I am a student at the University of Phoenix working on a Doctoral degree in Health Administration. I am conducting a research study entitled *Communicating Informed Consent with LEP Participants During Clinical Trials: A Case Study*.

The purpose of the present qualitative case study was to explore if communication barriers affect the understanding of LEP research participants while participating in the informed consent process during clinical trials. Scientific research is an important part of medical innovation. The recruitment of diverse ethnic groups and cultures in clinical trials provides abundant information to the development of new alternatives of treatment. The importance of maintaining mutually beneficial, clear, and efficient communication during the informed consent process facilitates the research study outcomes. Maintaining clear communication during phases of information exchange during informed consent processes is important to the clinical trials industry because misunderstanding of informed consent processes may jeopardize the outcomes of a clinical trial. This is paramount because misunderstanding of informed consent processes may increase chances for serious adverse events that may require hospitalization, early withdraw from study treatments, incomplete data, and financial losses for sponsors of research as well as present ethical concerns of research participation.

Results of the current study may inform leaders of the medical research industry to promote clear communication environments that will in turn increase research participation, clear data, and scientific improvements.

I would like to invite you to be part of this research study. Your participation will involve a semistructured interview with me. This interview will required about 40 minutes of your time. Your participation in this study is confidential and voluntary. You may choose not to participate or to withdraw from the study at any time; you can do so without consequence or loss of benefit to yourself. The results of the research study may be published but your identity will remain confidential and your name will not be disclosed to any outside party.

In this research, there are no foreseeable risks to you. To protect your confidentiality during the study, you will receive an alphanumeric code.

If you have any questions concerning the research study, please call me at 214-[redacted], 214-[redacted] or e-mail [redacted]

Sincerely,

Roberto Torres

Appendix C

Questions for Interviews

Communication Methods Used With Limited English Proficiency Research Participants To Acquire Informed Consent During Clinical Trials Roberto Torres University of Phoenix School of Advanced Studies	Investigator STUDY Enrollment Form

1. Subject ID: _____	Enrollment Date: ____/____/_____	Consent ☐ Yes ☐ No

1. Date of Birth (mm/dd/yyyy) ____/____/_____
2. Gender: Male…… ☐
   Female….. ☐
3. Ethnic origin: Hispanic/Latino ☐
   Non-Hispanic/Latino ☐
   Not obtained/Unknown ☐
   Refused ☐

4. Race:	Yes	No	Refused	Unknown/Not Obtained
a. American Indian/Alaskan Native	☐ 1	☐ 2	☐ -7	☐ -8

b. Asian	☐ 1	☐ 2	☐ -7	☐ -8
c. Black or African American	☐ 1	☐ 2	☐ -7	☐ -8
d. Native Hawaiian or Pacific Islander	☐ 1	☐ 2	☐ -7	☐ -8
e. White	☐ 1	☐ 2	☐ -7	☐ -8
f. Other _____	☐ 1	☐ 2	☐ -7	☐ -8

Clinical Trial Participation History

5. Clinical Trial Participation ☐ Yes ☐ No How Many trials in the last five years_____

6. Type of Clinical Trial ☐ Randomized ☐ Blinded ☐ no Blinded ☐ double Arm

☐ Other

7. Patients Enrolled in Clinical Trial ☐ outpatient ☐ Inpatient

8. Type of consent experience ☐ Spanish short form ☐ English form ☐ Translated English form

9. Consent was interpreted ☐ Yes ☐ No

10. Principal Investigator, Co-Investigator, Interpreter, Study Team

☐ PI ☐ Co-PI ☐ Int ☐ ST

11. Funding Source for Clinical trials ☐ Private ☐ Government ☐ UK

Which of the following best describes your position?	
❑ Clinician, Private Practice	
❑Clinician, HMO Practice	
❑ Clinician, Non-teaching Hospital	
❑ Medical Director	
❑ Clinician, Teaching Hospital	
❑ Administrator	
❑ Research Coordinator	
❑Nurse	
❑ Educator	

❑ Interpreter ❑ Research Participant ❑Other	
Communication Methods Used With Limited English Proficiency Research Participants To Acquire Informed Consent During Clinical Trials Roberto Torres University of Phoenix School of Advance Studies	STUDY

2. Subject ID: _____		

Questions for Semistructured Interviews: Interpreters Background

- Do you speak a language other than English?
- What is LEP?
- What is a clinical trial?
- What is the purpose of clinical trials?
- Do you have experience interpreting or translating informed consent processes?
- Have you been presented with, interpret, translate or explained an informed consent for a clinical trial?
- What are the procedures to present the informed consent process when the participant is LEP?

Purpose

- What is the purpose of an informed consent?
- What kinds of support would help you through this process?

Adverse Events

- What are adverse events?
- Who has the responsibility for error in clinical trials?
- What are the barriers to identifying, reporting, and analyzing errors during clinical trials?
- Do you believe LEP patients understand the informed consent process?
- Do you think the IRB should regulate the informed consent interpretation and translation process?
- Have you experienced any previous negative experiences within clinical trials?
- Would you characterize patient safety during clinical trials as a system or an individual issue?

Barriers of Communication

- Do you believe in barriers of communication?
- Do you believe barriers of communication can lead to adverse events?
- Do you consider communication barriers a possible cause for medical error?
- Do you consider communication barriers a possible cause for financial concerns for organizations?
- Do you consider communication barriers a possible cause that could jeopardize clinical trials results?

Informed consent Procedures

- Do you believe participants who do not understand the research process jeopardize study procedures and results?
- Do you believe LEP research participants understand the difference between standards of care and research?
- Do you believe LEP research participants understand the difference between treatment, placebo, and randomization?
- Do you believe LEP research participants understand confidentiality?
- Do you believe LEP research participants understand the risks and benefits of clinical trials explained through the consent process?
- How can you certify that the participant understands all the parameters explained in the consent process?
- Do you think that LEP research participants are often unaware of the medical research parameters that are being explained and conducted during the informed consent?
- Do you think the Spanish short form should be considered as an element to determine the understanding of an informed consent?
- Have you interpreted and consented participants on a clinical trial when you had reservations the participant was not clear about the trial objectives and requirements?
- During an informed consent process with a LEP, did you interpret the informed consent for the PI with the participant or did someone assist you? If yes, who?

Communication Methods Used With Limited English Proficiency Research Participants To Acquire Informed Consent During Clinical Trials Roberto Torres University of Phoenix School of Advance Studies	STUDY Enrollment Form

3. Subject ID: _____	Enrollment Date: ____/____/_____	Consent ☐ Yes ☐ No

Training/Education

- Do you have an interest in education, training, and skills development in patient safety during clinical trials?
- What are the specific training/education needs of PIs, Interpreters and research teams related to LEP participation in clinical trials?

1. Date of Birth (mm/dd/yyyy) ____/____/_____

2. Gender: Male…… ☐

   Female….. ☐

3. Ethnic origin: Hispanic/Latino ☐

   Non-Hispanic/Latino ☐

   Not obtained/Unknown ☐

   Refused ☐

4. Race:	Yes	No	Refused	Unknown/Not Obtained
a. American Indian/Alaskan Native	☐ 1	☐ 2	☐ -7	☐ -8
b. Asian	☐ 1	☐ 2	☐ -7	☐ -8
c. Black or African American	☐ 1	☐ 2	☐ -7	☐ -8
d. Native Hawaiian or Pacific Islander	☐ 1	☐ 2	☐ -7	☐ -8
e. White	☐ 1	☐ 2	☐ -7	☐ -8
f. Other _____	☐ 1	☐ 2	☐ -7	☐ -8

_____

Clinical Trial Participation History

5. Clinical Trial Participation ☐ Yes ☐ NO How Many trials in the last five years __

6. Type of Clinical Trial ☐ Randomized ☐ Blinded ☐ not Blinded ☐ double Arm

☐ Other

7. Time Enrolled in Clinical Trial ☐ outpatient ☐ Inpatient

8. Date of Enrollment in Clinical Trial ____/_____ (mm/yyyy)

9. Type of consent signed ☐ Spanish short form ☐ English form ☐ Translated English form

10. Consent was interpreted ☐ Yes ☐ No

11. Medical Insurance ☐ Yes ☐ No

12. Type of Insurance ☐ Private ☐ Government

Which of the following best describes your position? ❑ Clinician, Private Practice ❑Clinician, HMO Practice ❑ Clinician, Non-teaching Hospital ❑ Medical Director ❑ Clinician, Teaching Hospital ❑ Administrator ❑ Research Coordinator ❑Nurse ❑ Educator ❑ Interpreter ❑ Research Participant ❑Other	

Communication Methods Used With Limited English Proficiency Research

Participants To Acquire Informed Consent During Clinical Trials

STUDY

Roberto Torres

University of Phoenix School of Advanced Studies

4. Subject ID: _____		

Questions for Semistructured Interviews: LEP Participants

- Why was the study being done?
- Why was the study considered research?
- Why were you asked to be part of the study?
- Do you know how many people took part in the study?
- What was involved in the study?
- What type of study did you participate in? (Phase I, II, III, IV) Randomization, blinded, open enrollment).
- What is a clinical trial?

Purpose

- What is the purpose of clinical trials?
- What is the informed consent process?
- What is the purpose of the informed consent?
- What is your role during the informed consent process?
- What is the purpose of a research study? Give your participation in a previous research as an example.

Procedures

- What were the procedures of the study?
- Were you assigned to a group? What type of group? (Placebo or Treatment)
- Did your study involve randomization? What is randomization?
- How long did you expected to be in the study?
- Were blood samples drawn during the study? Did you understand why blood samples were drawn?
- How long were the samples stored and where?

- Did the study involve genetic samples?
- What is genetics?

Risk

- What is the meaning of possible risks of the study?
- What is the meaning of confidentiality?

- Did you understand the possible side effects of the study drug and treatment?

Benefits

5. Subject ID: _____	Enrollment Date: ____/____/_____	Consent

- What is the meaning of possible benefits of the study?
- What is voluntary participation?
- What options were available to you if you decided not to participate in the study?
- Did you understand the process of voluntary participation?

Adverse Event

- What is an adverse event?
- What were the risks of the study?
- Did you understand how risks were minimized or prevented through the consent process?
- If you were having problems during the study, what instructions were given to you?
- Were you paid to take part in the study?
- What would happen if you were harmed during the study?

Consent Procedures

- Was the consent process explained to you by an interpreter? If not, by whom?

- Did you understand all the parameters discussed in the informed consent process?
- Do you think the provider/principal investigator clearly explained the study?
- How would you describe the importance and the objectives of a study?
- From 1 to 5, five being the strongest, how would you rate your understanding of the informed consent process?
- Why did you sign the consent?
- Did you receive a copy of the signed consent? Which one Spanish, English or, both?

Communication Methods Used With Limited English Proficiency Research Participants To Acquire Informed Consent During Clinical Trials Roberto Torres University of Phoenix School of Advance Studies	Investigator STUDY Enrollment Form

1. Date of Birth (mm/dd/yyyy) ____/____/_____

2. Gender: Male…… ☐

   Female…... ☐

3. Ethnic origin: Hispanic/Latino ☐

   Non-Hispanic/Latino ☐

   Not obtained/Unknown ☐

   Refused ☐

4. Race:	Yes	No	Refused	Unknown/Not Obtained

a. American Indian/Alaskan Native	☐ 1	☐ 2	☐ -7	☐ -8
b. Asian	☐ 1	☐ 2	☐ -7	☐ -8
c. Black or African American	☐ 1	☐ 2	☐ -7	☐ -8
d. Native Hawaiian or Pacific Islander	☐ 1	☐ 2	☐ -7	☐ -8
e. White	☐ 1	☐ 2	☐ -7	☐ -8
f. Other _____	☐ 1	☐ 2	☐ -7	☐ -8

Clinical Trial Participation History

5. Clinical Trial Participation ☐ Yes ☐ NO How Many trials in the last five years __

6. Type of Clinical Trial ☐ Randomized ☐ Blinded ☐ no Blinded ☐ double Arm

☐ Other

7. Patients Enrolled in Clinical Trial ☐ outpatient ☐ Inpatient

8. Type of consent experience ☐ Spanish short form ☐ English form ☐ Translated English form

9. Consent was interpreted ☐ Yes ☐ No

10. Principal Investigator, Co-Investigator, Interpreter, Study Team

☐ PI ☐ Co-PI ☐ Int ☐ ST

11. Funding Source for Clinical trials ☐ Private ☐ Government ☐ UK

Which of the following best describes your position? ❑ Clinician, Private Practice	

❑Clinician, HMO Practice ❑ Clinician, Non-teaching Hospital ❑ Medical Director ❑ Clinician, Teaching Hospital ❑ Administrator ❑ Research Coordinator ❑Nurse ❑ Educator ❑ Interpreter ❑ Research Participant ❑Other	
Communication Methods Used With Limited English Proficiency Research Participants To Acquire Informed Consent During Clinical Trials Roberto Torres University of Phoenix School of Advanced Studies	STUDY
6. Subject ID: _____	

Questions for Semistructured Interviews: Principal Investigators.

Background

- Do you speak a language other than English?
- What is LEP?
- What is a clinical trial?
- What is the purpose of clinical trials?
- Do you have experience with informed consent processes?
- Have you been presented with and explained an informed consent for a clinical trial?
- What are the procedures to present the informed consent process when the participant is LEP?

Purpose

- What is the purpose of an informed consent?
- What kinds of support would help you through this process?

Adverse Events

- Who has the responsibility for error in clinical trials?
- What are the barriers to identifying, reporting, and analyzing errors during clinical trials?
- Do you believe LEP patients understand the informed consent process?
- Do you think the IRB should regulate the informed consent interpretation and translation process? Have you experienced any previous negative experiences within clinical trials?
- Have participants in your research studies suffered an unexpected event during a clinical trial due to barriers of communication?
- Would you characterize patient safety during clinical trials as a system or an individual issue?

Barriers of Communication

- Do you believe in barriers of communication?
- Do you believe barriers of communication can lead to adverse events?

- Do you consider communication barriers a possible cause for medical error?
- Do you consider communication barriers a possible cause for financial concerns for organizations?
- Do you consider communication barriers a possible cause that could jeopardize clinical trials results?

Informed consent Procedures

- Do you believe participants who do not understand the research process jeopardize study procedures and results?
- Do you believe LEP research participants understand the difference between standards of care and research?
- Do you believe LEP research participants understand the difference between treatment, placebo, and randomization?
- Do you believe LEP research participants understand confidentiality?
- Do you believe LEP research participants understand the risks and benefits of clinical trials explained through the consent process?
- How can you certify that the participant understands all the parameters explained in the consent process?
- Do you think that LEP research participants are often unaware of the medical research parameters that are being explained and conducted during the informed consent?
- Do you think the Spanish short form should be considered as an element to determine the understanding of an informed consent?
- Have you consented participants on a clinical trial when you had reservations the participant was not clear about the trial objectives and requirements?
- During an informed consent process with a LEP, did you discuss the informed consent with the participant or did someone assist you? If yes, who?

Training/Education

- What are the specific training/education needs of PIs and research teams related to LEP participation in clinical trials?

- Do you have an interest in education, training, and skills development in patient safety during clinical trials?

Appendix D

Permission to Use Premises

UNIVERSITY OF PHOENIX

PERMISSION TO USE PREMISES, NAME, AND/OR SUBJECTS

(Facility, Organization, University, Institution, or Association)
Children's Medical Center Dallas

Check any that apply:

☑ I hereby authorize Roberto Torres, student of University of Phoenix, to use the promises (facility identified below) to conduct a study entitled (Communication Methods Used With Limited English Proficiency Research Participants To Acquire Informed Consent During Clinical Trials)

☑ I hereby authorize Roberto Torres, student of University of Phoenix, to recruit subjects for participation in a conduct a study entitled (Communication Methods Used With Limited English Proficiency Research Participants To Acquire Informed Consent During Clinical Trials)

☐ I hereby authorize Roberto Torres, student of University of Phoenix, to use the name of the facility, organization, university, institution, or association identified above when publishing results from the study entitled (Communication Methods Used With Limited English Proficiency Research Participants To Acquire Informed Consent During Clinical Trials)

Signature

09/21/2010
Date

Kathy Spoor, RN, PhD
Name

Director, EBP & Research Department
Title

Address of Facility:

Children's Medical Center Dallas, 1935 Medical District Dr., Dallas, TX 75235

1