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Factors associated with young adults' reported intention of willingness to participate in clinical research

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FACTORS ASSOCIATED WITH YOUNG ADULTS' REPORTED INTENTION OF WILLINGNESS TO PARTICIPATE IN CLINICAL RESEARCH

by

Debra Sue Brandt

An Abstract

Of a thesis submitted in partial fulfillment
of the requirements for the
Doctor of Philosophy degree in Nursing
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Thesis Supervisors: Professor Ann Marie McCarthy
Professor Janet William

ABSTRACT

Although the public understands that participation in clinical research is necessary to advance the knowledge and skills of medical science, the rates of participation have been demonstrated to be trending downwards. Inadequate participation rates can have dramatic scientific and economic effects that ultimately affect the advancement of science. The attitudes and reasons for participation and non-participation in clinical research have been examined by a multitude of researchers. However, willingness to participate research is typically focused on a narrow range of populations, that is those diagnosed with an illness or disease and minority populations. The purpose of this study is to examine the demographic and knowledge factors which influence community-dwelling young adults' attitudes, as the future generation of clinical research volunteers, towards willingness to participate in clinical research. Knowing which factors are associated with young adults' attitudes and intention of willingness to participate will be of benefit to those who conduct research by identifying and rectifying barriers to participation.

Quantitative data, in the form of a one-time questionnaire administered by a paper and pencil instrument, were collected from a purposive sample of Grade 12 (seniors) students recruited from Iowa public high schools. My findings suggest that knowledge, acquired both by formal education and informal education, was associated with behavioral beliefs and attitudes about clinical research in this sample of students as a precursor to being willing to participate in clinical research. Fewer demographic factors, such as gender, race/ethnicity, or socioeconomic status, were associated with the behavioral beliefs and attitudes measures. This is excellent news to those who conduct research as *informational factors may be changed*. Aiming interventions at informing young adults about clinical research process and procedures may be of benefit to attitude formation with hopes to impact future

enrollment in clinical research. Media, as a method of informal education, may be of use as a way to provide information.

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CERTIFICATE OF APPROVAL

PH.D. THESIS

This is to certify that the Ph.D. thesis of

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has been approved by the Examining Committee for the thesis requirement for the Doctor of Philosophy degree in Nursing at the May 2013 graduation.

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Ann Marie McCarthy, Thesis Supervisor

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I dedicate this work to my husband, Bill.
I could not have done this without your unconditional and unrelenting love, encouragement, and support. Churchill may have said it, but you live it every day.
I love you now and forever.
-d.
P.S. You are *still* my sunshine.

Never, ever, ever, ever, ever, ever, ever give up.
Never give up. Never give up. Never give up.

Winston Churchill, Speech to Harrow School, October 29, 1941

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"I can no other answer make, but, thanks, and thanks." William Shakespeare.

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Lastly, a very special thank-you to Renee Pessin. How long have we been friends? We've worked together, raised kids together, and laughed and cried together. Thank you for always being there for me and my family despite the many miles between us.

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Study data were collected and managed using REDCap electronic data capture tools hosted at the Institute for Clinical and Translational Science, University of Iowa University of Iowa REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies, providing: 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources.

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LIST OF ABBREVIATIONS

AAMC	American Association of Medical Colleges
AIDS	Acquired immune deficiency syndrome
CDC	Center for Disease Control
CFR	Code of Federal Regulations
CGM	Consumer Generated Media
CINAHL	Cumulative Index to Nursing and Allied Health Literature
CISCRP	Center for Information and Study on Research Participation
CTCG	Clinical Trials Cooperative Groups
ESRD	End stage renal disease
HIV	Human immunodeficiency virus
HIVVT	Human immunodeficiency virus vaccine trials
IDE	Iowa Department of Education
IRB	Institutional Review Board
NIH	National Institutes of Health
NRA	The National Research Act
SES	Socioeconomic Status
TPB	Theory of Planned Behavior
US	United States
UI IRB	University of Iowa Institutional Review Boards
WTP	Willingness to participate

CHAPTER I

INTRODUCTION

Overview

The scientific community accepts that clinical research is essential for the advancement of medical knowledge (Steinke, 2004). The importance of clinical research is also acknowledged by the general public as the majority of people surveyed by CenterWatch agree that the advancement of medical science depends upon clinical research and support the role of humans as research participants (CISCRP, 2012). Despite these understanding of the importance of clinical research, historically, researchers have experienced a multitude of problems in recruiting volunteers to participate in clinical research studies (Carter, Sonne & Brady, 2005). Overall clinical research participation rates have decreased in the past thirty years and are expected to continue to decline in the coming years (Galea & Tracy, 2007; Rogers, Murtaugh, Edwards & Slattery, 2004).

Many argue that participation in clinical research is a moral obligation (Harris, 2005; Rhodes, 2008; Schaefer, Emanuel & Wertheimer, 2009). Their argument, simply put, is if we all benefit from the results of clinical research (e.g. better antibiotics, increasing success in organ transplantation, etc.) then we should do our part in advancing knowledge through participation. Unfortunately, it has been reported that less than three percent of eligible participants volunteer for studies and less than five percent of studies achieve their desired number of participants within a 2 year timeframe (Gross, 2006; Gul and Ali, 2009; Hunninghake, Darby & Probstfield, 1987).

It is crucial for clinical researchers to be able to recruit an adequate number of study participants (Gul and Ali, 2009; Lovato, Hill, Hertert, Hunninghake & Probstfield, 1997). Clinical research conducted with *inadequate* participation rates can have dramatic scientific

and economic effects that ultimately impact the advancement of science (Carter, Sonne & Brady, 2005; Schroen et al, 2010). For example, participation rates can affect the statistical methods used to determine a difference between the effectiveness of two or more interventions that, in turn, may cause the abandonment of a potentially useful treatment (Rothmeir, Lasley & Shapiro, 2003). Inadequate participation can also prematurely terminate a clinical research study as evidenced by the National Cancer Institutes' Clinical Trials Cooperative Groups (CTCG) who have closed studies due to lack of participation (Schroen et al, 2010). Moreover, approximately two-thirds of *all* publicly funded trials fail to recruit according to their original plan leading to requests for additional monetary support and/or time extensions (Barnard, Dent & Cook, 2010). This lack of participation is costly, both in terms of the stagnation of medical science as well as taxpayer dollars.

The attitudes and reasons for participation and non-participation in clinical research have been examined by a multitude of researchers. However, willingness to participate in research is typically focused on a narrow range of populations, those diagnosed with an illness or disease and minority populations. For example, there have been several studies that examined willingness to participate in people who are diagnosed or at high risk for illnesses, such as human immunodeficiency virus (HIV) or cancer (Advani, et al., 2003; DeFreitas, 2010; Golub et al, 2005; Koniak-Griffin, Nyamathi, Tallen, Gonzalez-Figueroa & Dominick, 2007; Levy et al, 2010; Mathews, Restivo, Raker, Weitzen, & Disilvestro, 2009; Priddy, Cheng, Salazar, & Frew, 2006; Volkmann, Claiborne, & Currier, 2009; White, Koehly, Omogbehin, & McBride, 2010). Minorities, based on race or ethnicity, have also been frequently examined for factors that affect willingness to participate in clinical research (Durant, Legedza, Marcantonio, Freeman, & Landon, 2009; Katz et al, 2009; Priddy et al. 2006; Shavers, Lynch, & Burmeister, 2002; Wendler et al, 2005; White & Hardy, 2010). As

described in the literature review in Chapter 2, one population that has been ignored regarding their views about participation in clinical research is that of community-dwelling young adults who are defined, for the purposes of this research, as being between the ages of 18-20. This is a *critical* population as it includes the potential pool of participants for future prevention and treatment studies. One unique feature of the current generation of young adults examined in this study is their intense exposure to and use of the media. Such exposure has not been examined in terms of its association with the intention of willingness to participate in clinical research.

The Effects of Media

Prensky coined the phrase "digit native" referring to the generations that have spent their entire lives surround by the "toys and tools of the digital age" (2001, p 1). This term includes the examined study population, young adults 18-20 years of age. This generation of young adults spends as much time absorbed in media as sleeping, approximately 7½hours per day each day of the week (Rideout, Foeher & Roberts, 2010). The enormous consumption of media has been called a "public health issue" as it is believed to have affected attitudes and modified behavior with reported deleterious short-term and long-term effects (Beatty, 2006). Studies show that media exposure results in increased likelihood of aggressive and violent behavior (Strenziok et al, 2011), decreased attention and reading skills (Beatty, 2006), increased likelihood of alcohol consumption (Smith & Foxcroft, 2009) and hastened the age of sexual initiation (Collins et al, 2004). On the other hand, media has been used to increase awareness and sway attitudes about important topics such as global warming (Kim, 2011) and to promote behavior change such as the promotion of HIV prevention via social media (Young, 2012).

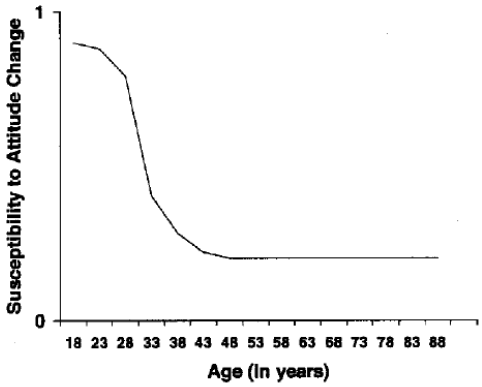
It is unknown if media have affected young adults' attitudes towards willingness to participate in clinical research. In the United States, the media often offer a disparaging view of clinical research and those who conduct it, for example, doctors and researchers. Several generations, including the targeted study population, have grown up with the media depicting Doctor Frankenstein as the quintessential researcher who shirks his responsibility to the public for his own personal gain (Lederer, 2002). Several current media reports of research and researchers may add to young adults' skepticism. A few notable headlines include the Wall Street Journal's *Mistakes in Scientific Studies Surge* (Naik, 2011), the Boston Review's *Big Pharma, Bad Medicine: How Corporate Dollars Corrupt Research and Education* (Angell, 2010) and the New York Times' *University Suspects Fraud by a Researcher Who Studied Red Wine* (Wade, 2012). Popular movies, such as *Rise of the Planet of the Apes* (Chernin, Clark, Jaffa, & Silver, producers, 2011) and *The Constant Gardner* (Abberley et al, producers, 2005), depict research and researchers gone wrong causing an unforeseen chain of deadly consequences. Likewise, popular television shows offer a less than kind image of research and researchers; for example, the drama *Breaking Bad* depicts a researcher using his knowledge for monetary gain by making methamphetamines (Gillen & Johnson, producers 2008). Internet sites, such as the *Improbable Research Collections,* present a frivolous view of researchers such as Dr. Bean's longitudinal self-study of fingernail growth (he concluded that his fingernails grew) and Drs. Witcombe and Meyer's examination of the side effects of sword swallowing (their conclusion was the main side effect is a throat laceration) (n.d.). All in all, any positive images and stories of research in our media may be overshadowed by the large number of negative stories, and consequently impacting young adults' attitudes and beliefs regarding participating in clinical research.

Young Adults' Attitude and Susceptibility to Change

Attitude is defined as "a learned pre-disposition to respond in a consistently favorable or unfavorable manner with respect to a given object" (Fishbein & Ajzen, 1975, p 6). As reflected in the definition, attitudes are learned as the result of past experiences and information available to the individual (Fishbein & Ajzen, 1975). There are different theories about the relationship of age to 'attitude susceptibility', that is the ability to change one's attitude. Three of the major theories regarding attitude formation and susceptibility are depicted by **Figure 1.1.** As demonstrated by the figure, the theories contend that attitude susceptibility fluctuates with age. One point on which the theorists concur is that young adulthood is a time of pronounced attitude formation followed by a decrease in attitude susceptibility (Visser & Krosnick, 1998). In other words, an attitude developed in early adulthood is more difficult to change through the remainder of adulthood. It is also thought that the more favorable the attitude, the more likely it is that an individual will perform the given behavior (Fishbein & Ajzen, 2010). Therefore, it may be theoretically possible to instill a more positive attitude towards participating in clinical research during young adulthood in the hope that this may have some affect in the future if given a chance to partcipate.

The "increasing persistence" theory describes attitude susceptibility as high in early adulthood and gradually decreases through out the rest of the life span.

The "impressionable years" theory describes young adulthood as a period of "plasticity" when core attitudes are formed.



The "life stages" theory can be described as a bimodal curve that is high susceptibility in early adulthood and late adulthood, but low susceptibility in the middle years.

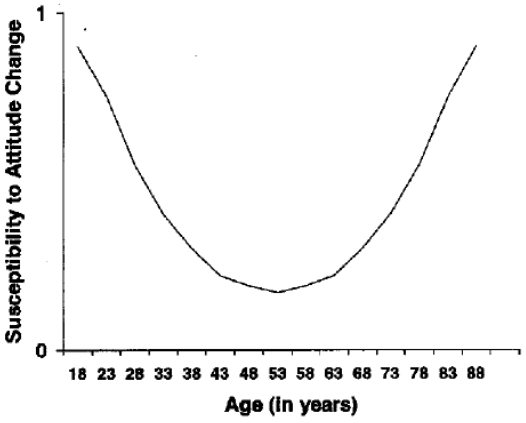


Figure 1.1 Theories of Age in Relation to Attitude Susceptibility

Source: Visser, P.S. & Krosnick, J.A. (1998). Development of attitude strength over the life cycle: Surge and decline. *Journal of Personality and Social Psychology, 75*(6), 1389-1410.

Problem Statement and Significance

In summary, the advancement of medical science is dependent upon human subject participation in clinical research. To the detriment of research, reports indicate that participation rates in clinical research are meager at best and are trending downward (Galea & Tracy, 2007, Gross, 2006, Gul & Ali, 2010). Young adults in our society are and will be needed to volunteer for research now and in the future to continue the advancement of medical knowledge.

Research regarding factors, including unique factors such as media, which may be associated with community-dwelling young adults' attitudes and decisions about whether to participate in research have not been examined to date. The lack of knowledge regarding factors associated with attitudes and beliefs about clinical research may have a negative affect on the ability of those in clinical research to recruit and enroll adequate numbers of study subjects. It is expected that the downward trend of participation in clinical research will continue, and unless it is reversed, inadequate numbers of research participants may negatively impact the pace of scientific discovery. Without robust research, as best described by the Association of American Medicals College (1999), "the impact of revolutionary advances in the biomedical and health sciences on the health of the public will be largely diminished".

This study provided an opportunity to further understand the attitudes and beliefs and the stated intention of willingness of the future generations of potential study participants to participate in clinical research. Improved understanding of the examined study populations' attitudes and beliefs and intention is an important first step in addressing the barriers to participation in clinical research by young adults and to begin the process of impacting future participation.

The Theory of Planned Behavior (TPB) has been put forth in previous studies as the theoretical model for prediction of willingness to participate in clinical research (Giocos, Kagee & Swartz, 2008; Langston et al., 2006). The TPB will be further described in Chapter 2; in brief, the TPB assumes that individuals are rational and make decisions based on information that is available to them (Kuhns & McEwen, 2011). The TPB further states that intention is the critical determinant in performing any behavior: the stronger the intention, the more likely the behavior will be performed. The TPB proposes three conceptually independent determinants of intention: 1) behavioral beliefs and attitude toward behavior; 2) subjective social norms (e.g. concern about family and friends' opinions about the behavior); and 3) perceived behavioral control (e.g. ability and opportunity to perform the behavior). It follows that each of these factors can be influenced by background factors, such as demographic variables or knowledge. Demographic variables may include age, gender, race and ethnicity, or locale (i.e., living in an urban or rural setting) of the person under study. Knowledge can be obtained by formal education or informally (e.g. information obtained through the media). See **Figure 1.2** for a diagram of the TPB.

One of the three determinants of intention, behavioral beliefs and attitudes toward behavior, was the focus of my study. Behavioral beliefs refer to the individual's belief about the consequences of the given behavior (Ajzen, 1991). Attitudes refer "to the degree to which a person has a favorable or unfavorable evaluation or appraisal of the behavior in question" (Ajzen, 1991, p188). Therefore, I included examination of young adults' thoughts about favoring or opposing the use of humans in clinical research as well as background factors that may be associated with those attitudes. Lastly, I examined how behavioral beliefs and attitudes were associated with the stated intention of willingness to participate in three clinical research scenarios.

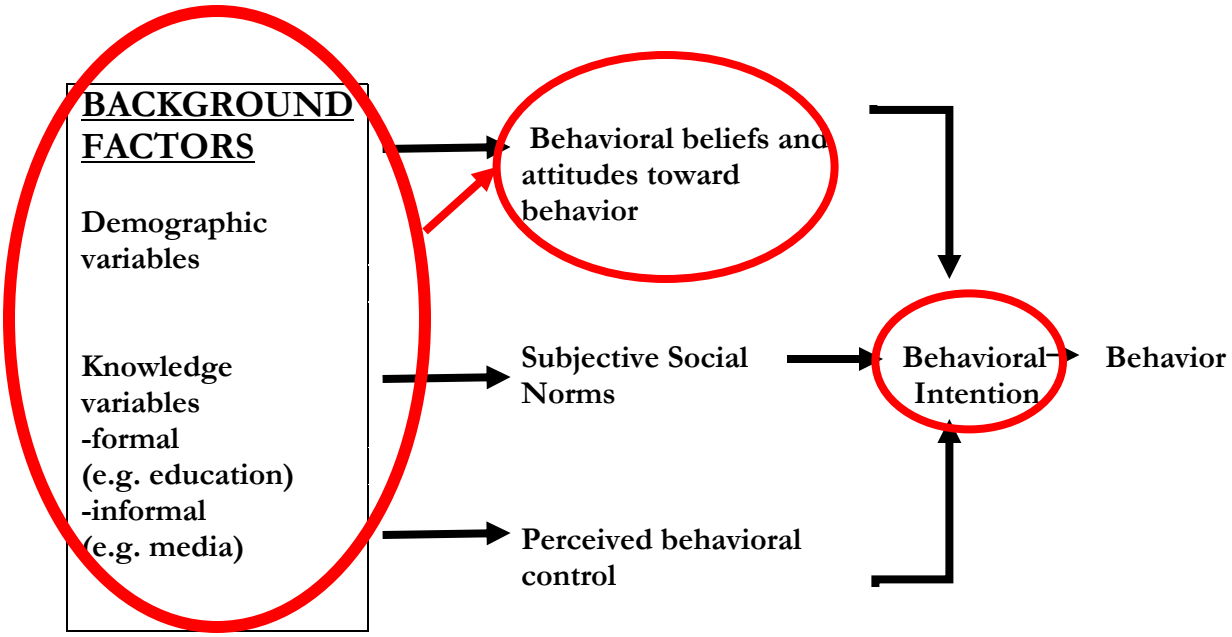


Figure 1.2 Theory of Planned Behavior

Note: Focus of this study is outlined in red.

Purpose

The purpose of this study was to examine the demographic and knowledge factors that are associated with community-dwelling young adults' behavioral beliefs and attitudes towards clinical research as a precursor to the stated intention of willingness to participate in clinical research. I used the TPB as the theoretical model to guide the specific aims of this study.

Specific Aims

The specific aims of this study were to:

Specific aim 1: To describe: (1) the background factors (demographic variables and knowledge, (2) beliefs and attitudes towards participating in clinical research, and (3) the

stated intention of willingness to participate in clinical research in community-dwelling young adults, ages 18-20.

Specific aim 2: To describe the associations among background factors and beliefs and attitude towards clinical research in community-dwelling young adults, ages 18-20.

Hypothesis: There will be an association between background factors (demographic and informational factors) and beliefs and attitudes towards clinical research in community-dwelling young adults, ages 18-20.

Specific Aim 3: To describe the association between beliefs and attitudes towards willingness to participate and the reported intention of participating in clinical research in community-dwelling young adults, ages 18-20.

Hypothesis: There will be an association between beliefs and attitude towards willingness to participate and stated willingness to participate in clinical research in community-dwelling young adults, ages 18-20.

Definition of Terms

The following definitions encompass the main concepts of this study.

Young adults-Per Iowa Legislature, Code 600A.2 (1977): "'*Adult*' means a person who is married or eighteen years of age or older". For the purposes of this study the term 'young adult' will include those who are ages 18-20.

Behavioral beliefs/Attitude/Intention- As previously reported the Theory of Planned Behavior (TPB), the theoretical model for this study, puts forth three independent determinants of intention to perform the behavior under examination: 1) behavioral beliefs and attitude toward the behavior and, 2) subjective social norms, and 3) perceived behavioral control (Ajzen, 1991). This exploratory study focused on one determinant of intention, that is, behavioral beliefs and attitude toward the behavior. Therefore, the TPB definitions of the

following terms were used to examine the beliefs and attitudes toward willingness to participate in clinical research:

- Behavioral beliefs refer to the individual's viewpoint about the consequences of the behavior (Ajzen, 1991). This concept is based on the subjective probability that the behavior will produce a given outcome. For this study, I examined individuals' perceived benefits of clinical research and the perceived physical risks of participating in clinical research.
- Attitude is the degree of positive or negative evaluation of the behavior (Ajzen, 1991). For this study, I examined individuals' thoughts regarding favoring or opposing the use of human beings in clinical research.
- Intention is the indication of an individual's readiness to perform the behavior under examination and is assumed to be an immediate antecedent of the behavior (Ajzen, 1991). Additionally, the stronger the intention of performing a given behavior, the greater the likelihood that the behavior will be performed (Albarracin, Johnson, Fishbein, & Muellerleile, 2001). For this study, the intention of willingness to participate in clinical research was examined using three hypothetical scenarios that offer differing levels of benefit and risk.

Clinical research: This study used the definition of 'clinical research' based on the American Medical Colleges Task Force on Clinical Research. The task force defined clinical research as:

> A component of medical and health research intended to produce knowledge essential for understanding human disease, preventing and treating illness, and promoting health (AAMC, 1999, p6).

This broad definition of clinical research includes a wide spectrum of studies that can involve interactions with human beings or populations, either diagnosed with an illness or

healthy volunteers. This definition would also include evaluating diagnostic clinical materials or evaluation of data. Areas of clinical research can include, among others, those that seek to improve our understanding of disease mechanisms, increase clinical knowledge (detection, diagnosis, and natural history of disease), or evaluate therapeutic interventions; these can include clinical trial, prevention and health promotion, behavioral research, health services research, epidemiology, and community-based and managed care-based research (AAMC, 1999).

Media- A broad definition of media is used. Media can consist of network television and cable programs, movies, the internet, advertisement, news, talk shows or other new media. This includes Consumer Generated Media (CGM), defined here as media created by the end-users that are publically available (Kaplan & Haenlein, 2010).

Summary

Participation in clinical research is needed to advance the knowledge and skills of medical science. Although the public understands the importance of clinical research, participation rates have been trending downwards. Inadequate participation rates can have dramatic scientific and economic effects that ultimately affect the advancement of science. Although research has been conducted regarding factors that affect attitudes and willingness to participate in clinical research, community-dwelling young adults have been excluded from these analyses. I examined the associations between background factors and behavioral beliefs and attitudes towards clinical research in community-dwelling young adults, ages 18-20. Additionally I analyzed the associations between behavioral beliefs and attitudes and the stated intention of willingness to participate in clinical research. Improved knowledge about which factors are associated with young adults' attitudes and willingness to

participate in research will be of benefit to those who conduct research by enabling identification and then rectification of barriers to participation.

In the next Chapter, I discuss the history and ethical consideration for human subjects research. This includes examination of the literature related to the key elements of this study, that is what currently known about adults and their willingness to participate in clinical research. I also describe the conceptual framework that guided the study. Lastly, there is a discussion to relate the literature review to the conceptual framework. In Chapter three, I describe the methodology including study design, inclusion criteria, recruitment strategies, and data management. Statistical analysis is also described. Chapter four will present the analyses. Lastly, Chapter five will present the conclusion of my research including the limitations, need for future research and practical implications.

CHAPTER II

REVIEW OF THE LITERATURE

Overview

I begin with a brief review of the development of the ethics principles and guidelines of human subjects research. Germaine to this study, I emphasize the origin of the concept of voluntariness as a precursor to participation in clinical research. A systematic literature review follows regarding what is currently known about the factors that influence young adults' willingness to participate in clinical research. As seen by the dearth of results from the initial computer search, young adults within the general population have been largely neglected in the research about motivation to participate in clinical research. This being the case, the literature search was expanded to include studies on motivation of adults of all ages to participate in clinical research. Based on results of the literature review, the Theory of Planned Behavior (TPB), used as the conceptual framework for the empirical inquiry, provides theoretical support for the methodology, data collection and analysis.

Development of Voluntariness as an Ethical Principle

The evolution of the ethical principles and guidelines related to human subject protection has been called a process of "reaction" (Marshall, 2002). Case in point, the Nuremberg Code of 1947 is often cited as the first ethical guidelines for the use of human subjects for medical research (Levine, 1995). The Code was written post World War II as a reaction to the Doctors Trial in which sixteen German physicians and administrators were found guilty for crimes against humanity, primarily for the use prisoners of war in heinous experiments under the guise of advancement of science (United States Holocaust Memorial Museum, n.d.). The directives set forth in the Nuremberg Code are considered foundational for protection of the dignity and rights of human medical experimentation (Vollmann &

Winau, 1996). Pertinent to this research project, the first directive of the Nuremburg Code begins "The voluntary consent of the human subject is absolutely essential" (United States Department of Health and Human Services [US DHHS], 1979). Disappointingly, the Nuremberg Code garnered little attention in the United States popular press and therefore had little effect on medical researchers (Faden et al., 1996). Even among the US researchers who were aware of the Code, few perceived personal implications and continued to use their unaware and non-consented patients for their experiments (Faden et al., 1996). However, in the early 1950's, a small faction of researchers became genuinely and profoundly concerned with issues surrounding the use of humans for experimentation. Discussions and writings ensued to address the ethical treatment of humans in medical experimentation and to call for the application of the Nuremberg Code to all medical research. However, this was met with resistence by researchers who thwarted any attempts to establish professional guidelines or legislation to ensure human subject protection (Faden et al., 1996).

It was not until the early 1960's when two highly publicized events raised awareness among the general public about the treatment of human participants in clinical research. These events included the Public Health Service syphilis study, often referred to as the "Tuskegee Experiment" that used non-consented and unaware black men for an investigation of the natural course of syphilis (Katz, 1992). The other event was Dr. Henry Beecher's article regarding 22 experiments using humans exposed to a variety of ethical problems, including coerced participation (Beecher, 1966). As a result of this publicity, a chain reaction began. The public became more vocal about the need to establish regulations regarding the use of human subjects in research studies. This, in turn, led to US government involvement, Senate investigations, and the introduction of a bill called the National Research Act (NRA). The NRA was signed into law on July 12, 1974 by then-President

Richard Nixon and established the National Commission for the Protection of human subjects of Biomedical and Behavioral Research (Childress, Meslin & Shapiro, 2005).

The National Commission, consisting of a variety of researchers, ethicists, and governmental representatives, was charged to "identify the ethical principles which should underlie the conduct of biomedical and behavioral research with human subjects and develop guidelines that should be followed in such research" (Childress et al., 2005, p 3). As identified by the National Commission, the ethical issue raised by research using human subjects rests on the notion of how to balance the rights of the study participants with the interests of the society (Jonas, 1969). Bioethicists maintained that the use of humans in medical research can be justified when it seeks knowledge that will benefit the whole of society providing the research is done with full protection of the participants' rights and dignity (Emanuel, Crouch, Arras, Moreno, & Grady,. 2003, p 151). A key concept to the protection of the participants' rights and dignity is the notion of *voluntary* participation.

The National Commission presented its final work, *Ethical Principles and Guidelines for Research Involving Human Subjects* that was dubbed *The Belmont Report.* The Belmont Report put forth three *primae facie* principles for the protection of human subjects in research, namely respect for persons, beneficence and justice. The right of potential study participants to decide whether or not to participate in clinical research is described by the Belmont Report as application of the respect for persons principle and is stated as "respect for persons demands that subjects enter into the research voluntarily and with adequate information" (DHEW, 1979). The Belmont Report was codified in the Code of Federal Regulations (CFR) Title 45 (public welfare), Part 46 (protection of human subjects) in the early 1980's (Childress et al., 2005). 45CFR46 mandates that the informed consent contain "a statement that participation is voluntary, refusal to participate will involve no penalty or

loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled" (DHHS, 2010). By decreeing that voluntariness in clinical research is solely determined by the potential participant, rights and dignity can be maintained.

Voluntariness and Willingness to Participate

Refusal rates for participation in clinical research have been reported to be as high as 84% and some believe that this is an indication that potential research participants understand the concept of voluntariness, i.e., that they do not have to participate (Nelson & Merz, 2002). Low rates of participation have been documented in various types of clinical research, such as cancer trials, neurological research, and pulmonary research (Burke, Brown, et al., 2011; Cooke et al., 2010; Murthy, Krumholz & Gross, 2004). Investigators have cited a wide variety of factors that effect willingness to participate, such as demographic factors (i.e., race, ethnicity, gender and age) (Burke, Brown, Lisabeth, Sanchez, & Morgenstern, 2011; Cooke, et al., 2010; Murthy et al., 2004) as well as other types of factors, such as fear of researchers or being uncomfortable with the research process (Mills et al., 2006). As part of my investigation, I conducted a systematic review of the literature and to provide a critical critique of this research.

Literature Review

This systematic literature review focused on willingness to participate in clinical research and factors that are known to influence decisions regarding whether or not to participate. The initial question was, "What factors affect willingness of young adults to participate in clinical research?" PubMed (sponsored by the US National Library of Medicine) and the Cumulative Index to Nursing and Allied Health Literature (CINAHL) were used to identify relevant citations. As "clinical research" is not listed as a a MeSH term,

two MeSH terms, "biomedical research as a topic" and "clinical trials as a topic", were conjoined with the Boolean operator 'or' to include a broad range of human experimentation. The MeSH term, "patient participation" was added with the key words "willingness to participate." PubMed limitations were activated to restrict the search to "young adults" (defined by PubMed to be between the ages of 18-24) as this approximates the ages of interest for this study. Conversely, CINAHL did not allow the narrowing of the adult age range, necessitating 'hand' sorting of the citations found in CINAHL. Additional limitations activated included articles written in English and published within the past 10 years. The search of PubMed and CINAHL, after excluding duplicates, produced 28 citations. Titles and abstracts were screened to find those articles relevant to the topic of willingness to participate in clinical research, narrowing the search results to twenty articles.

Lastly, full text articles were reviewed for study populations drawn from the United States (US), in consideration of Fishbein and Ajzen's Theory of Planned Behavior (TPB) as the conceptual framework for this study. The TPB postulates that background factors, such as information gained via knowledge or media influence future behavior, and it follows that such information and media would most likely be unique to the US. It is beyond the scope of this study to examine young adults outside of the U.S.; therefore citations using populations outside of the US were excluded. With these qualifiers, seven articles met criteria for review. Articles were then reviewed for age ranges of participants and those whose mean ages ranges or reported standard deviations did not include participants 18-20 were excluded. The result was a *single article*. See **Table 2.1** for a schematic diagram of this literature search.

The objective of this single study was to examine the interest and the factors that affect willingness of homeless adolescents to participate in future HIV Vaccine Trials

(HIVVT) (Koniak-Griffin et al., 2007). Koniak-Griffin and colleagues used semi-structured interviews with a focus group of 20 homeless young adults recruited from drop-in shelters in Hollywood, California (2007). The sample was predominantly male (75%) with a mean age of 20.45 years (SD$\pm$1.45). The group was reported as "racially diverse" including African Americans (35%), White (25%), other (25%) and Hispanic (5%) (p 690). The majority of participants reported having HIV risky behavior, including unprotected sex with multiple partners (90%) and males having unprotected sex with other males (60%) (p 690). The interviews were content analyzed by a two-member independent panel. Data were sorted into emerging themes, then re-examined and combined into themes. Initial interview questions focused on attitudes and feelings about participation in HIV vaccine trials (HIVVT). A desire to help others was the most common reason given by adolescents who indicated they would be willing to participate in future HIVVTs. On the other hand, participants reported distrust of researchers and their motives for conducting the study as a factor that made them unwilling to consider participation in future HIVVTs. Limitations of the study included the small sample size and underrepresentation of females, thereby limiting generalizability of the results. Despite the limitations, the authors concluded that understanding the perspectives of potential HIVVT participants would enable future researchers to "tailor protocols to their individual needs and cultural values and, thereby, potentially enhance willingness to participate in HIVVTs" (p 696). Although the authors do not elaborate if, or how, protocol tailoring was employed.

This study provided knowledge regarding attitudes and willingness to participate in HIVVTs of young adults who engaged in risky behavior and would enable future researchers to design protocols specific to the study population, with emphasis on targeted recruitment, to bolster future enrollment in HIVVTs. Its results suggest that improved understanding of

factors that impact willingness to participate in clinical research can be used to increase participation in future research; therefore it is of vital importance to improve our in research of attitudes and beliefs of young adults regarding willingness to participate. The population of this study, however, was a circumscribed group of young adults at high risk for HIV and is not generalizable to healthy young adults living in a community setting, thus leaving a gap in the literature. The dearth of information regarding community-dwelling young adults emphasizes the need for this study to begin to fill that gap by examining the demographic and knowledge factors that are associated with beliefs and attitudes towards clinical research in community-dwelling young adults. In turn, it is important to examine how beliefs and attitudes are associated with the reported intent of willingness to participate in clinical research.

Expanding the Literature Search

Due to a lack of relevant citations on young adults, the literature search was broadened to provide an overview of literature that encompasses adults of any age, focusing on factors that are known to influence decisions regarding whether to participate in clinical trials. The new question used for review was "What factors affect willingness to participate in clinical research?" PubMed and CINAHL were again used to identify relevant investigations. Following the same procedure noted above, the MeSH terms "patient participation" and "biomedical research as a topic" or "clinical trials as a topic" were combined with the key words "willingness to participate". Limitations were activated to capture articles written in English within ten years of publication. No limitations were activated for age, so accordingly this search included adults of all ages.

The initial search, after duplicates were excluded, produced 94 citations. Titles and abstracts were screened to find those relevant to the discussion topic of willingness to

participate in clinical trials, narrowing the results to 80 articles. The remaining full text articles were reviewed to eliminate studies whose subject did not include factors that affect willingness to participate in clinical research, for example articles whose subjects were about recruitment techniques that were successful in targeted populations. Additionally, articles were reviewed to eliminate studies conducted in populations outside of the United States and editorials, leaving 29 articles that explored factors that addressed adults' willingness to participate in research (included the previously mentioned article by Koniak-Griffin et al.). See **Table 2.2** for a schematic diagram of the systematic literature review of the expanded question.

Of the 29 articles, most focused on two aspects of willingness to participate in clinical research. One focus was on populations who were diagnosed or at high risk for being diagnosed with an illness or disease, such as HIV, schizophrenia, or cancer (20 of 29 articles). The other focus was the question of whether race or ethnicity plays a role in willingness to participate (6 of 29 articles). Occasionally, both factors were studied (3 of 29 articles). See **Table 2.3** for a compilation of the literature review. Next, I describe factors identified from the literature review that affect willingness to participate in clinical research.

Factors that Influence Decisions to Participate

Age

The reported mean and median age of study participants in the literature search ranged from ages 34 to 73.8 years. Of interest to this investigator, no study in the expanded literature search reported enrollment of a significant number of young adults. The lack of young adults represented in the literature search serves to emphasize the gap in knowledge regarding young adults' willingness to participate in research.

In those studies that looked specifically at age, there were conflicting results of its role as a factor affecting willingness to participate in clinical research. Study designs consisted of interviews or questionnaires that collected demographic information, assessed knowledge and/or attitudes regarding clinical trials or clinical research, and evaluated willingness to participate in hypothetical clinical research. Study participants were generally recruited from populations with a medical diagnosis or at a high risk for a disease. These included participants who were at high risk for Hepatitis C infections, (Levy et al., 2010), diagnosed with cancer (Advani et al., 2003; Lara et al., 2005; Mathews et al., 2009), or renal insufficiency (Israni et al., 2004), or cardiovascular disease (Ding, Powe, Manson, Sherber, & Braunstein., 2007; Peterson, Lytle, Biswas, & Coombs, 2004). Other researchers studied differences in the willingness to participate of minority populations (Priddy, Cheng, Salazar, & Frew, 2006; Shavers, Lynch, & Burmeister,. 2002). One researcher used a comprehensive literature review to examine the factors that effected willingness to participate (Wendler et al., 2005).

Five investigations found that younger study participants reported a higher willingness to participate (Advani et al., 2003; Israni et al., 2004; Levy et al., 2010, Mathews et al., 2009; Shavers et al., 2002;) while two other investigators found older participants more likely to say 'yes' (Ding et al., 2007; Lara et al., 2005). Two other investigations concluded that age was not a factor in predicting willingness to participate (Peterson, et al., 2004; Priddy et al., 2006; Wendler et al., 2005). Note that 'younger' and 'older' are *relative to the ages of the enrolled participants*. For example, studies that reported that 'younger' participants who were more likely to indicate willingness to participate had a reported mean or median ages ranging from 23 to 63 years of age. Given this variability of ages referred to as 'older' or 'younger', it is difficult to come to a conclusion regarding a single age of those most likely to participate.

Race and/or Ethnicity

Race and/or ethnicity were commonly examined as factors affecting willingness to participate in the articles reviewed. Eleven of the 29 studies reported race in their results. (Advani et al., 2003; DeFreitas, 2010; Durant et al., 2009; Golub et al., 2005; Katz et al., 2009; Lara et al., 2005; Lee, Lenert, Weisman, & Kavanaugh, 2005; Peterson et al., 2004; Priddy et al., 2006; Shavers et al., 2002; Wendler et al. 2005). Study designs consisted of interviews or questionnaires to collect demographic information and assess knowledge and/or attitudes regarding clinical trials or clinical research willingness to participate in hypothetical clinical research. Study participants were generally recruited from populations with a medical diagnosis or at high risk for a disease. These included HIV (DeFreitas, 2010; Golub et al., 2005), rheumatoid arthritis (Lee et al. 2005), cancer (Advani et al., 2003; Lara et al., 2005;) or patients scheduled for a cardiac catheterization (Peterson et al., 2004). Three researchers recruited from a community-dwelling population (Durant et al. 2009; Katz et al., 2009; Priddy et al., 2006; Shavers et al. 2002). Lastly, one researcher performed a comprehensive literature review to determine consent rates by race or ethnicity (Wendler et al., 2005).

Interestingly, study findings were in disagreement about the effect of race and/or ethnicity as a factor influencing willingness to participate. Three of the 10 studies mentioning race reported a statistical difference between the willingness of racial groups to participate (Advani et al., 2003; Lara et al., 2005; Lee et al., 2005;), but the remainder of studies reported no statistical difference (DeFreitas, 2010; Durant et al., 2009; Golub et al., 2005; Katz et al., 2009; Peterson et al., 2004; Priddy et al., 2006; Shavers et al., 2002; Wendler et al. 2005). For studies that did report a difference in willingness to participate based on racial and/or ethnic categories, there was disagreement about whether whites were more

likely to be willing to participate compared to minorities. Three of the four studies reported that whites have higher rates of participation (Advani et al. 2003; Lara et al 2005) while one reported African American had higher rates (Lee et al., 2005).

This review of the effect of race or ethnicity demonstrates inconclusive results; thus, the extent to which race or ethnicity affects willingness to participate in clinical research appears remains unknown. Moreover, the study samples used populations generally over the age of 40 years and diagnosed or at high risk for an illness making results of this study difficult to generalize to community-dwelling young adults. Thusly, there remains a void in the literature regarding race or ethnicity as a factor affecting community-dwelling young adults' willingness to participate.

Gender

Gender was reported by some investigators to have an effect on willingness to participate. Four of the 29 studies reported gender in their results (DeFreitas, 2010; Ding et al., 2007; Golub et al., 2005; Peterson et al., 2004). Studies that examined the effect of gender on willingness to participate used populations that were diagnosed with an illness or at high risk for an illness that included HIV (DeFreitas, 2010; Golub et al., 2005) or cardiovascular disorders (Ding et al., 2007; Peterson et al., 2004). Studies employed interviews or questionnaires to examine willingness to participate in hypothetical clinical trials.

Results differed as to which gender was more likely to be a factor in willingness to participate in clinical research. Three studies reported that men were more likely to be willing to participate (DeFreitas, 2010; Ding et al., 2007; Peterson et al., 2004). Conversely, Golub and colleagues, in their examination of intravenous drug users' willingness to participate in HIVVT, reported results based on two data collection points with a portion of

those who had participated in Wave I surveyed again in Wave II (2005). They reported that in the first data collection period, Wave I, willingness to participate was not affected by sex but, in the second collection period, Wave II did demonstrate a significantly higher proportion of women those willing to participate. The authors did not offer their thoughts about why there were gender differences in willingness to participate between Waves.

As with race and ethnicity, there were no community-dwelling young adults represented in the sampled population. As well, I conclude that literature is inconsistent regarding whether gender has an effect on willingness to participate in clinical research. Thus, this study will begin to address the gap in research regarding this population.

Socioeconomic Status

Research has demonstrated that socioeconomic status (SES) is associated with an array of health, cognitive, and socioemotional outcomes in children (Bradley and Corwin, 2002; Williams, 2004). The effect of SES begins prior to birth and continues into adulthood (Bradley & Corwyn, 2002). For example, a higher SES has a positive impact on academic achievement (Williams, 2004).

Researchers have used yearly income as a crude measure of SES (Bradley & Corwyn, 2002; Williams, 2004). Accordingly, Advani *et al.* (2003) and Lara *et al.* (2005) reported income as a factor affecting willingness to participate in study populations derived from oncology patients and their families. These investigators used questionnaires to examine willingness to participate in hypothetical clinical trials and reported that those who reported willingness to participate in clinical research had a higher yearly income (Advani et al. 2003; Lara et al. 2005). For the Advani *et al.* study, the median age was 61 years and approximately 90% of the participants in Lara *et al.* study were 35 years of age or older. Accordingly, it seems unlikely that these study participants were supported by their parents at the time of

the study, making it difficult to generalize these data to young adults that are still living under their parents' roof. I examined whether parental SES status impacts willingness to participate.

Education

Three studies reported the effect of education on willingness to participate in clinical research (Advani et al., 2003; Mathews et al., 2009; Shavers et al., 2002). Drawing from populations affected by cancer (Advani et al., 2003; Mathews et al., 2009) and/or populations with an emphasis on minority populations (Advani et al., 2003: Shavers et al., 2002), these authors consistently reported that those who demonstrated a willingness to participate in research also had a higher level of formal education (measured in years of formal education).

Germaine to my study, reviewed results demonstrated that young adults who plan to attend college are different than those without plans to go to college beyond demographic attributes such as race, gender, or SES (Carpenter & Fleishman, 1987; Egeland, Hunt & Hardt, 1970; Perna, 2011). College-bound young adults also differ in their attitudes about others (Carpenter & Fleishman, 1987; Egeland et al., 1970). For instance, one difference in attitude lies in the degree of ability to consider others' perspectives (Carpenter & Fleishman, 1987). I examined whether this attitude difference also impacted willingness to participate in clinical research.

Health Status

Participants in the reviewed literature also cited past or current health status or the perceived risk of future health issues as a factor affecting willingness to participate in clinical research (Ding, et al., 2007; Israni et al., 2004). Ding *et al.* reported that participants who believed they were at risk for a myocardial infarction were more likely to say they would be

willing to participate in clinical research (2007). Israni *et al.* described that a recent hospitalization (within the past year) increased likelihood of willingness to participate (2004). These investigators used populations who were in a hospital setting at the time of the study and had been previously diagnosed with an illness. I examined a sample community-based population and therefore provided novel information about the impact of past, current or perceived future health status on willingness to participate in clinical research.

Knowledge about Clinical Research

Three investigations measured knowledge about the clinical research process and found a positive effect on willingness to participate rates (Dunlop, Leroy, Logue, Glanz, & Dunlop, 2011; Lara et al 2005; Priddy et al., 2006). These investigators queried participants' knowledge about a variety of topics including the purpose of clinical research and fundamental requirements of the informed consent process. Two focused on such knowledge in minority populations (Dunlop et al., 2011; Priddy et al., 2006) and the third on oncology patients and their families (Lara et al 2005). Of interest, while the investigators reported that knowledge about clinical research was a positive factor; participants were not asked how they had acquired that knowledge.

Somewhat in the same vein, five investigators reported that previous participation in a clinical trial, or having someone close to them who had participated in such a study, was a positive factor associated with willingness to participate in future research (Advani et al., 2003; DeFreitas, 2010; Durant et al., 2009; Holman et al., 2010; Volkmann, Claiborne, & Currier, 2009). Holman and colleagues noted that participants who had previous experience in clinical research had greater knowledge about clinical research (2010), suggesting that knowledge about clinical research can be obtained in a variety of ways. Of note, following

this review, there remained a knowledge gap regarding where young adults acquire their knowledge of clinical research and whether knowledge affects willingness to participate.

In the present study, I assessed knowledge of clinical research and tried to assess *where* the respondents acquired their knowledge about clinical research. The survey included items about formal education (i.e., was clinical research a topic in their high school curriculum?), informal education (i.e., what media programs were observed depicting clinical research or researchers?), and whether they or someone close had participated in clinical research.

Perceived Benefit or Risk

Perceived benefit was reported to have a strong influence on willingness to participate (Advani et al., 2003; Ding et al., 2007; Dunlop et al., 2011; Dunn et al., 2009; Hall et al., 2010; Halpern et al., 2003; Holman et al., 2010; Lee et al., 2005; Volkmann et al., 2009; Zullino et al., 2003). Potential early access to new or publicly unavailable treatments that may offer improved health or free medical care was seen as a personal gain and increased the likeliness of participation in clinical trials. The possibility of medical treatment may have been very significant factor for willingness to participate in clinical research as the population of these studies included those at high risk for illness, such as patients diagnosed with a mental illness (Dunn et al., 2009; Zullino et al., 2003), cancer (Advani et al., 2003; Hall et al., 2010) or a cardiovascular disorder (Ding et al., 2007; Halpern et al., 2003), muscular/joint disorder (Holman et al., 2010; Lee et al., 2005) or patients diagnosed with HIV (Volkman et al., 2009).

As common sense would tell us, many of the same investigators also reported that the potential of risks or side effects of clinical research had a negative affect on participants' willingness to participate in clinical research (Ding et al., 2007; Dunlop et al., 2011; Dunn et

al., 2009; Hall et al., 2010; Halpern et al., 2003; Koniak-Griffin et al., 2007; Lee et al., 2005; Priddy et al., 2006; Volkmann et al., 2009; Zullino et al., 2003). Of these, three studies specifically cited the famous George Bernard Shaw's anti-vivisection phrase "human guinea pig" as a factor affecting willingness to participate (Advani et al., 2003; Mathews et al., 2009; Zullino et al., 2003).

A limitation of these studies that report benefits and risks is that they only asked participants to consider the benefits and risks of participation in a clinical trial, for example, a trial of a medication, instead of the broader concept of clinical research. Therefore, there were no results about whether these participants would be willing to participate in a variety of types of clinical research. The present study offered different scenarios of clinical research (i.e.,studies involving only a blood draw to studies involving testing a new medication) in order to obtain a better understanding of young adults' willingness to participate based on the risk of the study.

Compensation

The effect of compensation for participation was consistently reported as positive factor for willingness to participate in studies. Seven of the 29 studies found that compensation, primarily financial payment, was a positive factor (DeFreitas, 2010; Ding et al., 2007; Dunn et al., 2009; Golub et al., 2005; Halpern et al., 2003; Holman et al., 2010; Priddy et al., 2006). Three of these investigators (DeFreitas, 2010; Golub et al., 2005; Priddy et al., 2006) asked generally about compensation, e.g., "I would do a clinical trial for money" (DeFreitas, 2010; Golub et al., 2005). Holman and colleagues (2010) reported that their participants with lower incomes placed greater emphasis on the importance of payment for willingness to participate.

Two investigators addressed the monetary amount of compensation that is expected by participants based on the perceived level of risk. One investigator examined monetary compensation based on the risks of side effects of medications used in a hypothetical clinical trial, i.e., drug studies (Ding et al. 2007). The other investigator (Dunn et al., 2009) assessed willingness to participate in hypothetical scenarios that had varying levels of clinical research risk based on definitions in the federal regulations. Subjects were asked about perceived level of risk and benefits and then about willingness to participate based on incrementally higher levels of compensation. Both investigators found that participants' willingness to participate correlated with perceived risks and compensation levels, that is participants expected higher compensation if participating in higher risk studies.

As previously mentioned, participants in these studies consisted of patients diagnosed with, or at high risk for, an illness (Ding et al., 2007; Dunn et al., 2009; Golub et al., 2005; Halpern et al., 2003; Holman et al., 2010;) or were focused on a minority population affected by an illness (DeFreitas, 2010; Priddy et al., 2006). Note, of the studies that did report participants incomes, the majority of reported incomes that were generally below the United States poverty level for the year the study was published (Dunn et al., 2009; Golub et al., 2005). It is difficult to generalize these results to young adults who are most likely supported financially by their parents; thus, there remained a gap in our knowledge about whether compensation is seen as important in a population of community dwelling young adults. The present study examined different levels of compensation at escalating levels of perceived clinical research risk.

Altruism/Societal benefit

As opposed to financial compensation as a factor, altruism holds that decisions should be guided by the consideration of other people rather than by self-interest

(Encyclopaedia Britannica, n.d.). Seven investigators cited altruism as a factor that influenced participants' willingness to participate in a research study (Advani et al., 2003; Hall et al., 2010; Halpern et al., 2003; Holman et al., 2010; Lee et al., 2005; Volkmann et al., 2009; White & Hardy, 2010). Additionally, a more general category of "contributing to scientific knowledge" was reported by two investigators as influencing decisions about willingness to participate (Halpern et al., 2003; Zullino et al., 2003). As previously noted, participants in these studies were diagnosed or at high risk for a medical illness, such as cancer (Advani et al., 2003; Hall et al., 2010; White et al., 2010), cardiovascular disease (Hall et al., 2010; Halpern et al., 2003), connective tissue disorder (Holman et al., 2010; Lee et al., 2005), mental illness (Zullino et al., 2003), or HIV (Volkmann et al., 2009) and were only asked about willingness to participate in research related to their diagnosis. This limitation led me to wonder whether what was deemed 'altruism' by these investigators was actually 'collectivism'. Collectivism is described as sacrifice for a group sharing a common culture (Landauer & Rowlands, 2001), and has been studied in groups of patients diagnosed with rheumatoid arthritis (RA) (Devins et al., 2009). The RA group shared attitudes, beliefs, values, and other elements of having their own culture, referred to as a cultural syndrome (Devins et al., 2009). This led to consideration of these responses (in the aforementioned studies) as biased and stressed the need for research in the area of altruism and willingness to participate to be conducted with participants with no predisposition to a cultural syndrome by diagnosis. The present study helped to fill the gap regarding the effect of altruism on willingness to participate, as study participants will be selected from community dwelling young adults and were not likely to have a disease-related cultural syndrome.

Trust in Researchers

The issue of trust in researchers has been of growing interest to investigators over the past two decades (Hall, 2006). The level of trust depends on the participant's judgment of researchers' personality and professionalism (Hall et al., 2006). Trust, or conversely mistrust, of researcher motives was a factor affecting willingness to participate in six studies (Ding et al., 2007; Dunlop et al., 2011; Durant et al., 2011; Lee et al., 2005; Shavers et al., 2002; Volkmann et al., 2009). Of interest, questions regarding trust were primarily directed at the physician providing the participants' health care. In other words, participants were asked if they trusted their health care provider. Hall *et al.* reported that trust in physicians performing non-research medical care may have different characteristics than trust in clinical researchers (2006). For example, the clinical researcher may be seen as having conflicts between the obligation to provide clinical care and promotion of scientific advances. Additionally, to some, clinical research may invoke thoughts about research misconduct, such as the Tuskegee Syphilis Study, or may be influenced by how media portray clinical research or researchers. Therefore, it is not known if the results obtained by these investigators accurately reflect trust in clinical research and/or researchers, indicating a gap in our understanding in this area. The present study specifically addressed trust in clinical researchers.

Impact of Media

The impact of media was rarely addressed among the 29 studies. Only two studies examined the influence of media on willingness to participate. Pentz et al. reported that about half of those surveyed that they initially heard about the clinical trail in the local media (2002). The authors go on to report that the media exposure resulted in a positive first

impression for the majority of people who were willing to participate (60%), however only thirteen percent of the participants reported they thought the media reports were factual. The other study examined the effect of a mass multi-media campaign on willingness to participate and accrual in clinical trials for cancer treatments (Umutyan et al. 2008). The investigators reported media had increased awareness regarding clinical research and increased awareness of a California bill requiring all third-party payers to reimburse the cost of clinical cancer trials-related care. They also noted an increased accrual in these trials following the mass media campaign; however it was unclear whether the increase was the result of the campaign or other variables (Umutyan et al. 2008).

These studies allude to the influence that media can have on willingness to participate in clinical research. However, what young adults currently perceive as depictions of clinical research or researchers is unknown. It is also unknown if young adults base their knowledge about clinical research on television programs that were written for entertainment purposes. It has been long accepted that entertainment media can have a powerful impact on health beliefs of the lay population (Turow, 1996), but it is unknown if media have the same impact on beliefs regarding clinical research. The present study aimed to address that gap in knowledge.

Limitations of the Studies to Date and Strengths of this Study

The aforementioned studies that looked at various factors affecting willingness to participate in clinical research have limitations. First, the majority of these studies enlisted the use of an interview or questionnaire for data collection in which participants had to consent to participate in their respective studies, meaning that overall the subjects may have been more willing to participate in clinical research. Moreover, when investigators queried participants' willingness to participate in clinical research, the clinical research was

hypothetical, in other words, the investigators offered generalized scenarios but did not have an actual study to offer their participants at that time. The decision-making processes may have been different than if it had been an actual clinical research project. Thusly, in actuality the researchers were studying the *intention* of being willing to participate in clinical research.

Another limitation is that participants were largely drawn from specific populations (i.e., disease-based or minority-based), making it difficult to generalize to other populations. Despite these limitations, the reviewed studies provided novel information specific to each of their populations regarding factors affecting willingness to participate in clinical research. An investigator could make good use of the information presented in these studies to adapt study designs to prospectively bolster recruitment and enrollment. My investigation had similar limitations as well, as it employed a survey with hypothetical clinical research scenarios. However, my study involved an appropriate population and setting as per the lack of information currently available regarding factors affecting community dwelling young adults' attitudes and beliefs regarding willingness to participate in clinical research.

Lastly, a limitation of the studies reviewed includes the lack of a conceptual framework to guide empirical inquiry. A conceptual framework provides a "logical structure of meaning that guides the development of the study and enables the researcher to link the findings to the nursing's body of knowledge" (Burns & Grove, 2005). Using a behavioral theory as a conceptual framework enhances understanding of the determinants of behavior and, therefore, may help to change that behavior as well as predict future behavior (Michielsen, Chersich, Temmerman, Dooms, & Van Rossem, 2012). A strength of the present study is its use of the Theory of Planned Behavior as the conceptual framework to organize the numerous factors that affect willingness to participate. This organizational tool

allowed us to consider associations among the variables related to willingness to participate in clinical research.

Conceptual Framework

The Theory of Planned Behavior (TPB), an empirically robust social cognitive theory (Giocos, et al., 2008), is based on the premise that individuals are rational and "assumes a causal chain linking beliefs, formed on the basis of available information, to the person's attitudes, beliefs, and attitudes to intentions, and intentions to behavior" (Fishbein & Ajzen, 1975, p. vi). Beliefs and attitudes can be affected by a variety of background factors, such as unique differences in the individual (e.g., age, race, gender), and informational factors (e.g., knowledge, previous experience, or access to media). The TPB is a strong predictor of human behavior in health-related behaviors and has been used in a variety of research settings. For instance, it has been used in college populations to predict intentions and behaviors of gambling (Thrasher, Andrew & Mahoney, 2011), alcohol consumption (Glassman, Braun, Dodd, Miller & Miller, 2010) and sleep patterns (Knowlden, Sharma & Bernard, 2012).

The TPB has also been used as the theoretical model for studies that have examined willingness to participate in clinical research. In a study of South African adolescents' willingness to participate in HIV vaccine trials, investigators reported variables based on the TPB model significantly improved their ability to predict willingness to participate (79.9% prediction success) (Giocos, et al., 2008).

Coalescence of the Literature Review and Theory of Planned Behavior

This literature review demonstrated that investigators have examined multiple factors in relation to willingness to participate. As reported though, these populations were

primarily disease burdened or minority populations and may not reflect the attitudes of community dwelling young adults. Thus, there was a void in knowledge about factors that affect community dwelling young adults' willingness to participate in clinical research. That said, research must start somewhere and it was reasonable to use the factors that affect specific populations' willingness to participate to see if these factors also affected the population of interest for this study.

Compilation of a list of factors from the literature review resulted in a large number of factors to organize and evaluate for willingness to participate. Background factors such as age, race/ethnicity, gender, socio-economic status, education, health status, and perceived personal and societal benefit influence beliefs and attitudes. Additionally, beliefs and attitudes can be influence by knowledge gained through formal education or informal education via the media. In linear progression, as described by the TPB, beliefs and attitudes are linked to the intention of willingness to participate. As evidenced by **Figure 2.1**, the known factors influencing willingness to participate in research coalesced well with the TPB and supported its use as the theoretical model for this study.

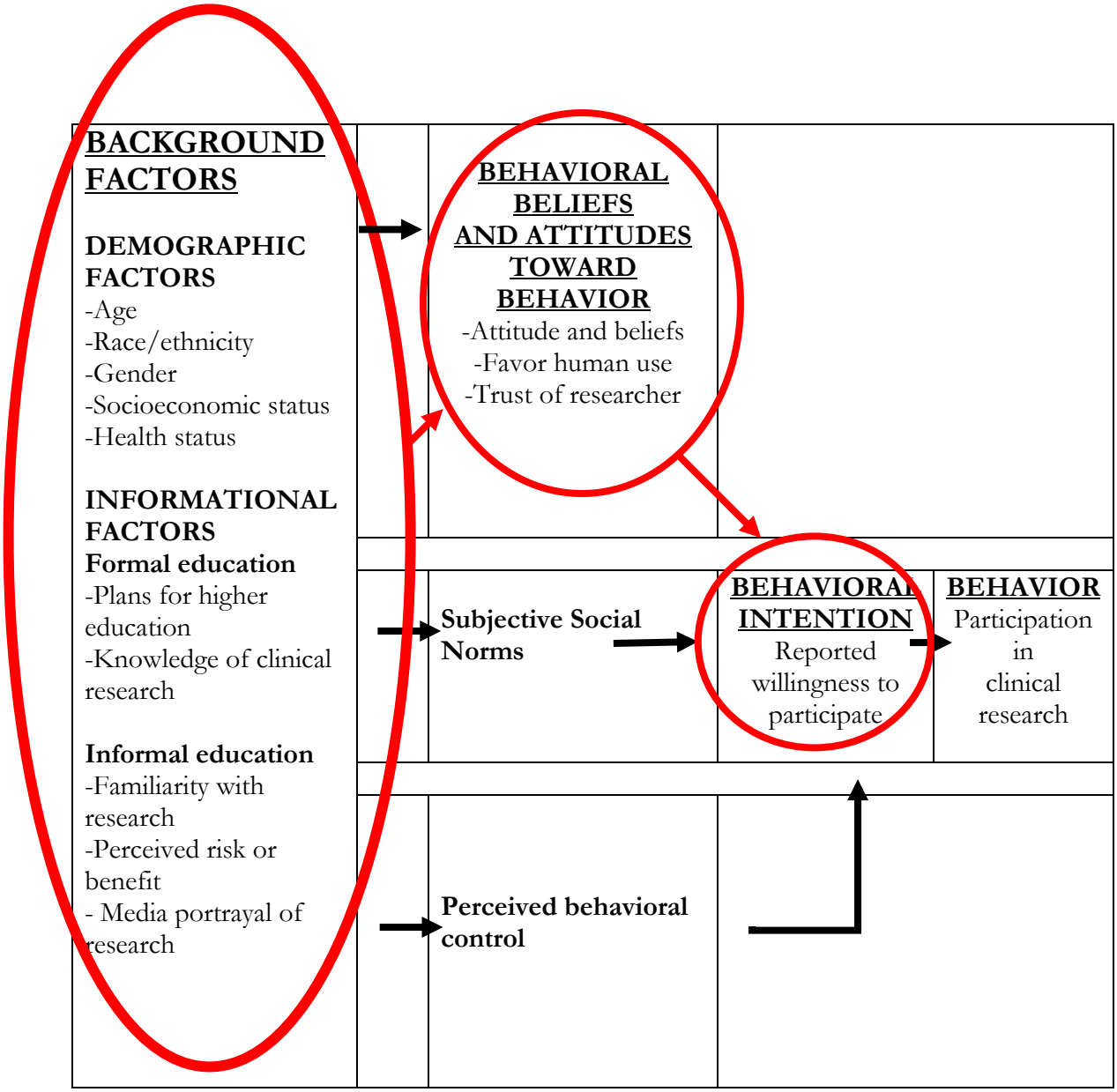


Figure 2.1 Categorization of Factors Identified in the Literature Review into a Model Utilizing the Theory of Planned Behavior.

Note: Focus of this study is outlined in red.

Summary

In this chapter, I explored the evolution of the ethics of the use of human subjects in research and note that it rested on the notion of voluntariness as a linchpin for the protection of rights and dignity of participants. The literature revealed that very little was known about the willingness of community dwelling young adults to participate in research. Expansion of the search to include adults of all ages demonstrated that research about the known factors that influence willingness to participate in clinical research had primarily been conducted with adults at high risk for illness or disease or minority populations. The review supported the use of the Theory of Planned Behavior as a conceptual model. The present study addressed the gap in knowledge regarding identification of associations between background factors and behavioral beliefs and attitudes regarding clinical research, as well as the associations between behavioral beliefs and attitudes and the reported intention of willingness to participate in clinical research. Knowledge gained from the present study may help in the design of interventions that increase future study enrollment of young adults.

Table 2.1 Schematic Diagram of the Systematic Literature Review Resulting from the Question, "What factors affect willingness of young adults to participate in clinical research?"

Records identified utilizing PubMed and CINAHL

Limited to:

- Written in English
- Published in past 10 years
- "Young adult"

28 records screened after duplicates removed

Excluded records based on:

- Subject did not involve willingness to participate in clinical research.
- Editorial

Records excluded=8

20 full text articles assessed for inclusion eligibility

Excluded articles based on:

- Research population outside of the United States
  Records excluded=13

- Mean age of research population greater than 20 years of age
  Records excluded=6

Total records excluded=19

Results: 1 remaining article

Table 2.2 Schematic Diagram of the Systematic Literature Review Resulting from the Question, "What factors affect willingness to participate in clinical research?"

Records identified utilizing PubMed and CINAHL

Limited to:

- Written in English
- Published in past 10 years

94 citations screened after duplicates removed

Excluded records if:

- Subject matter did not involve willingness to participate in clinical research.

Records excluded=14

80 full text articles assessed for eligibility

Excluded articles based on:

- Research population outside of the United States
- Full text review elicited that subject of the article did not include not willingness to participate in clinical research (i.e., recruitment techniques)
- Editorials

Records excluded=49

Results: 29 articles to review for factors affecting willingness to participate.

Table 2.3 Compilation of Literature Review

Citation	Research question	Study populations and reported ages	Factors cited affecting willingness to participate
Advani et al., 2003	Barriers to African-American (AA) Willingness to participate (WTP) in oncology trials	N=270 Oncology patients Median age AA participants-63 yo White participants-61 yo	**Willingness to participate rates:** 40% overall reported willingness 45% among white participants 31% among AA participants **Positive factors identified:** Race (whites > AA) Higher education Higher incomes Younger age Knowing friends/relatives who had participated Belief study benefited people No other treatment options **Negative factors identified:** Belief God controlled cure/death Belief participants are "Guinea pigs"
DeFreitas, 2010	Race/ethnicity differences in WTP in HIV clinical trials.	N=145 Patients at an HIV clinic Primarily ages 40-50 yo.	**Positive factors identified:** Prior clinical trial involvement Understanding the process of clinical trials Monetary reimbursement Gender (men > women) **Negative factors identified:** Depression Fewer number of medications
Ding et al., 2007	Gender differences in WTP in Cardiovascular prevention trials	Patients in Internal Medicine and Cardiovascular clinics Mean age (SD). Men=55.2 ($\pm$15.2) Women=52.8 ($\pm$15.6)	**Positive factors identified:** Gender (men > women) Perceived risk of myocardial infarction Perceived health benefit Older age Current diagnosis Monetary reimbursement **Negative factors identified:** Distrust of medical researchers Perceived risk of harm in RCT Researcher conflict of interest

Table 2.3 continued

Dunlop et al., 2011	Effect of preconsent eduction on African Americans WTP	African Americans Primary Care Clinic outpatients. No age distribution given, however analysis reported 96 participants < 40.	**Willingness to participate rates:** Control group= 27% Intervention group= 43% **Positive factors identified:** Preconsent education about the research process and protections **Negative factors identified:** Mistrust or fear of research/ researcher/ research institution Fear of side effects or unknown effects Privacy concerns No perceived benefit to self or others from participation Structural barriers (work, children) Fear of pain or medical procedures Health insurance concerns
Dunn et al., 2009	WTP in relation to perceived physical risks and benefits among patients diagnosed with schizophrenia.	People diagnosed with schizophrenia or schizoaffective disorder. Middle-aged and older outpatients-ages 40 plus.	**Positive factors identified:** Perceived potential personal benefit **Negative factors identified:** Perceived risk
Durant et al., 2011	Racial differences in WTP in a population previously exposed to clinical research.	N=752 Community dwelling whites and African Americans Mean age =73.8 yo (±9.3).	**Willingness to participate rates:** 53-54% **Positive factors identified:** Prior trial participation **Negative factors identified:** Trust in Primary Care Provider
Golub et al., 2005	Injection Drug Users' (IDU) willingness to participate in HIVVTs	N=1,082 IDUs enrolled in the AIDS Study. Wave I- median age 39.1 Wave II- median age 45.3 yo	**Willingness to participate rates:** Wave I-83% Wave II-86.3% **Positive factors identified:** Gender (female > male) Monetary incentives Non-monetary incentives **Negative factors identified:** Having health insurance

Table 2.3 continued

Hall et al., 2010	Identifying barriers to WTP in prevention trials in people with a high risk of cancer	First degree relatives of person diagnosed with cancer. Median age 49 yo. Range 18-43 yo.	**Willingness to participate rates:** 55% **Positive factors identified:** Information sources Potential benefit to self or others **Negative factors identified:** Perceived potential side effects of study drug
Halpern et al., 2003	Hypertensive patients' WTP in placebo-controlled trials	Hypertensive patients in an outpatient clinic Mean age 59.0 yo (± 11).	**Willingness to participate rates:** 47% **Positive factors identified:** Personal health benefits Helping other patients Contributing to scientific knowledge **Negative factors identified:** Stopping current medications Fear of known side effects
Holman et al., 2010	Factors effecting people diagnosed with fibromyalgia WTP in RCT.	Outpatient clinic. Men- mean age =51 yo (range: 19–80 years. Women mean age= 49 yo (range: 34–64 years).	**Positive factors identified:** Potential for improvement in their own health status Altruism Payment for participation in the study Prior trial experience
Israni et al., 2004	WTP in daily dialysis trials	Chronic hemodialysis patients Mean age= 56 yo (± 15).	**Willingness to participate rates:** 41% **Positive factors identified:** Age (younger > older) Recent hospitalization **Negative factors identified:** Comorbid diagnoses
Katz et al., 2009	The affect of awareness of the Tuskegee Syphilis Study on WTP	N=1,162 Random digit dialing 3 cities. Blacks mean age=47.2 yo Whites mean age=48.4 yo Hispanics=44.3 yo	No statistical difference between whites, AA, and Puerto Rican Hispanic adults in WTP. Awareness of the Tuskegee Syphilis Study did not affect WTP in AA

Table 2.3 continued

Koniak-Griffin et al., 2007	Factors that effect WTP in vaccine trials in homeless 18-24 year olds at high risk for HIV.	Homeless 18-24 year old at drop-in shelters. Mean age =20.45 yo (±1.47).	**Positive factors identified:** A desire to help others Reimbursement **Negative factors identified:** Concern for risk side effects Distrust of researchers' motives
Lara et al., 2005	Factors effecting awareness and WTP in cancer clinical trials	N=1,188 Oncology patients and their families. All ages recruited (range <18 to >75), 51 participants reported to be ages 24 or less (4% of the study population).	**Willingness to participate rates:** 81% **Positive factors identified:** Awareness of research trials Knowledge about research trials Race (Whites > AA) Age (Those between ages 18-24 were less likely to participate. Income (higher > lower)
Lee et al., 2005	Factors effecting people diagnosed with rheumatoid arthritis (RA) WTP in RCTs	RA outpatients. Mean age= 49.5 yo (± 13.2)	**Willingness to participate rates:** White-61%, Hispanics-63% AA-75%, Asians-31% **Positive factors identified:** Race (see above) The possibility of improved health Early access to new therapy The opportunity to help others Free treatments or blood tests. **Negative factors identified:** Feeling "like a guinea pig" Trust in doctors Unknown side effects Potential need to stop current RA therapy
Levy et al., 2010	WTP of young intravenous drug users (IDU) in Hepatitis C virus vaccine trials	IDUs in San Francisco neighborhoods Median (Inter Quartile Range)= 23.7 (21.1–27.2)	**Willingness to participate rates:** 88% **Positive factors identified:** Age (younger > older) **Negative factors identified:** Study length greater than 2 years

Table 2.3 continued

Mathews et al., 2009	Factors that effect WTP of women diagnosed with gynecological cancer in RCTs	Median age=50 (range 15-89). (participants younger than 36 years of age, n=15 (19.0% of participants)	**Willingness to participate rates:** 20% **Positive factors identified:** Age (younger > older) Education (beyond high school > high school) Possession of private insurance **Negative factors identified:** Not wanting to be a "guinea pig"
McQueen, MacCollin, Gusella, & Plotkin, 2008	WTP of people diagnosed with neurofibromatosis 1 (NF1) and their family members	NF1 outpatients and their families. Median age=34.5 yo (no other information given)	**Willingness to participate rates:** 67% Did not find any factors associated with willingness to participate.
Pentz et al., 2002	Media's potential influence on understanding and motivations to participate in a Phase I study.	People diagnosed with cancer and about to enroll in a clinical trial of endostatin. Median age=56 yo (range, 25-79 years)	**Willingness to participate rates:** 80% **Positive factors identified:** Media gave positive first impression to people who were willing to participate, but thought information was likely to be false.
Peterson et al., 2004	WTP in either of 2 cardiac RCTs- medical therapy versus surgical therapy.	N=660 Patients scheduled to undergo cardiac catherization. Mean age=67 years.	**Willingness to participate rates:** 43% willing for medical therapy 32% willing for surgical therapy **Positive factors identified:** Gender (men > women)
Priddy et al., 2006	Examined racial and ethnic differences in knowledge and WTP in HIV vaccine trials.	Community college students in Atlanta. Age not given, but 'college-aged'.	**Willingness to participate rates:** 17% **Positive factors identified:** Compensation Location of clinical trial site Time requirement **Negative factors identified:** Fear of side effect

Table 2.3 continued

Shavers et al., 2002	Racial differences in factors that influence WPT in medical research	N=198 Households in the Detroit area. AA Mean age=41.9 Whites Mean age=50.2 Others Mean age= 48.1	**Willingness to participate rates:** AA males-53% White males-62% AA females-58% White females-88% **Positive factors identified:** Education (high school or more) **Negative factors identified:** Trust in researcher
Umutyan et al., 2008	The effect of a mass media campaign on WTP in cancer clinical trials in Southern California	People diagnosed with cancer in Southern California. Post mass media campaign participants age(%) Age: n(%) <18: 1 (<1%) 18–24: 28 (3%) >25: 847 (95%)	**Willingness to participate rates:** Pre-campaign-51% Post-campaign-53% Unable to determine if mass media campaign effected WTP in a clinical cancer trial or due to other variables.
Volkmann et al., 2009	Factors that contribute to WTP in HIV clinical trials. Effect of an educational intervention to improve WTP.	Outpatients of an HIV clinic. Age not given.	**Willingness to participate rates:** Pre-intervention-92% Post-intervetntion-94% **Positive factors identified:** Personal benefit from participating Greater trust in their provider Benefiting other people **Negative factors identified:** Felt would not receive better care from the study Felt like a "gamble"
Weinfurt et al., 2008	Effect of disclosing financial interest disclosures on WTP.	Panel members who agree to be contacted about research opportunities. Age ranges: 43.3 to 53.7 ($\pm$11.5)	Financial disclosure did not affect WTP.

Table 2.3 continued

Wendler et al., 2005	Racial and ethnic minorities' WTP in health research.	A comprehensive literature review based on 20 studies	Race or ethnicity was not a factor in WTP.
White & Hardy, 2010	Palliative care patients and their relatives' attitude research and factors important when considering participation.	A systematic literature review, therefore ages not noted.	**Review of US articles cited** **Positive factors identified:** Benefitting others **Negative factors identified:** Being 'too sick'
White et al., 2010	AA reaction to genetic explanations for disparities in lung cancer incidence rates are associated with WTP in genetic trials	African-Americans diagnosed with lung cancer and their families. Mean age = 43 yo (± 9.3)	**Willingness to participate rates:** Reported as a Likert Scale 4.1 on a scale of 1 (definitely not) to 5 (definitely would) **Positive factors identified:** Beliefs that toxin exposure was an believable explanation for cancer diagnosis
Zullino et al., 2003	WTP in psychiatric trials	Inpatient psychiatric patients Mean age=36.6 yo (±12.7)	**Willingness to participate rates: range 70%-96%** **Positive factors identified:** Benefit future patients Personal benefit of receiving a new treatment **Negative factors identified:** Fear of being a 'guinea pig' Risk of side effects

CHAPTER III

METHODOLOGY

Overview

Here I describe the methodology used for the study, including study design, participant inclusion criteria, measures, recruitment strategies, and statistical considerations.

Study Design

This descriptive cross-sectional study was carried out at high schools across the state of Iowa. Quantitative data in the form of a one-time questionnaire administered by a paper and pencil instrument were collected from research participants.

Participants

A purposive sample of Grade 12 students (seniors) was recruited from Iowa public high schools that granted permission for me to approach their senior class. The Iowa Department of Education's (IDE) *The Annual Condition of Education* reports that Iowa senior class size range from 7 seniors (Diagonal district) to 2,392 seniors (Des Moines Independent district) (2011). The average class senior class size is 116 pupils and the median class senior class size is 160. According to the Iowa Public School PreK-12 Enrollments by race and gender, minority students make up 18.5 percent of the Iowa student body and there are slightly more males than females attending Iowa schools (52%). About one-third of all public students are eligible for free or reduced-priced lunch (38.9%) (IDE, 2011). Reports were not available at the time of writing regarding current Iowa seniors' intention of going to college. Based on data contained in IDE reports from 2009-2010 and 2010-201, report 77% of Iowa seniors intended to attend college.

The focus of this study is on community dwelling young adults. I purposefully decided to include only high school seniors who were 18 years of age or older. Young adults

18 and older are of legal age to make their own decision about whether or not to participate in the study, thus avoiding the need for parental consent according to the University of Iowa IRB guidelines (University of Iowa Human Subjects Office, 2012). This was an important consideration for the study as it had been reported by several investigators that parents' attitudes influence decision-making by their children (Abramovitch, Freedman, Henry, & Van Brunschot, 1995; Broome, 1999; Scherer, 1991). This finding caused concern that using participants who would be required to obtain parental consent may lead to selection bias (seniors who would have participated, but are influenced by their parents not to participate or visa versa) or measurement bias (students whose answers reflect their parents views about clinical research). Hence, the inclusion criterion for this study was young adults, age 18 and above.

Additionally, I purposefully decided to use community-dwelling participants to avoid measurement bias that may have occurred if recruited from a health-related institution (e.g. patients from a hospital or clinic) whose opinions may be influenced by the burden of an illness or their medical care. The senior classes of Iowa high schools were chosen as the venue for the study because of the accessibility of community-dwelling young adults in a congregated site. There were no restrictions in the inclusion criteria based on gender, race, or ethnicity.

Sample size

The study required 566 subjects to achieve adequate statistical power. Sample size calculation was based on the ability to potentially find associations between the dependent variable "willingness to participate" in clinical research and the predictor variables. This calculation assumes that 65% of the population report that they are willing to participate in the survey scenarios, that is 65% of the participants in this research will indicate a

willingness to participate in future clinical research. This figure (65%) was based on a weighted average calculated with studies that reported willingness to participate rates and sample sizes in the articles presented in the Chapter 2 literature review. PASS11 software was used to perform the calculation (Hsieh, Bloch, & Larsen, 1998).

Feasibility and Access to Participants

To determine the feasibility of conducting the study using seniors enrolled in Iowa high schools, a calculation was performed to estimate the number of Iowa seniors who would be 18 years or older and thus eligible to participate. The calculation used the following information:

- According to the Iowa Department of Education, the projected Grade 12 enrollment for the 2011-2012 school year is 36,663 (2011).
- The age for starting kindergarten in Iowa requires that children must be 5 years of age before September 15th (Iowa Legislature, Code section 282.3, 2001).
- The anticipated start date of this project was May 1, 2012.
- Data from the Center for Disease Control (CDC) National Vital Statistics Reports for birth rates per month demonstrated a fairly even distribution of births across the calendar year (2002).

Based on this information, the total population of Iowa seniors who would be 18 years or older at the start of the month of May would be approximately 27,500 students.

To determine if there would be adequate access to potentially eligible seniors to recruit for this study, this investigator used the University of Iowa Cooperating Schools Program's 2011-2012 Iowa Public School Directory to identify all public school districts that had a senior class (2012). I identified 320 Iowa school districts with a senior class served by 304 superintendents (smaller school districts are combined under one superintendent). An

email communication was sent to each superintendent that consisted of a cover letter of introduction to the study, a lay abstract, draft informed consent, and draft survey (see **Appendix A**). Superintendents who were willing to allow access to their high schools provided contact names, usually principals, at each high school. Email communication continued with each named contact person to determine their willingness to allow me to recruit study participants from their senior class. In total, twelve high schools were willing to allow me to approach their senior class for recruitment. Based on reported senior class size from those 12 schools, I estimated 968 seniors would be accessible who were potentially eligible to participate in the study, resulting in an adequate number to participants for completion of this study. To protect confidentiality of study participants, a complete listing of school districts and high schools that allowed this investigator to recruit seniors for the study is available to the dissertation committee upon request, but will not be disclosed in this dissertation.

Measures

A survey was developed for this study, which included factors identified in the literature review that affect attitudes towards the reported intention of willingness to participate in future clinical research. As I found no existing survey that encompassed all of the factors of willingness to participate identified in the literature search, a new survey, entitled *Attitudes and Factors affecting Young Adults' Willingness to Participate in Clinical Research*, was developed. The survey was based in part on components from other investigators' developed and established questionnaires. All investigators were contacted to obtain complete copies of their surveys and for permission to use their survey for this study. All requests were granted, see **Appendix B** for correspondence.

In the development of the new survey, only the components of other investigators' surveys that addressed the specific aims of this study were used to minimize subject burden. Additionally, wording was modified for clarity and consistency in the new survey. For example some investigators use the term "biomedical research" (Al-Jumah et al, 2011), others use "medical studies" (Trauth, Musa, Siminoff, Jewell, & Ricci, 2000) while others use "medical research" (Hall et al, 2006) in their surveys. All terms fit the definition of 'clinical research' as defined for this study (see Chapter 2 and the following paragraph). Therefore, all research was referred to as 'clinical research' in the new survey.

The new survey began with an introduction that served the following purposes: i) reinforced the purpose of the study; ii) defined 'clinical research'; iii) explained to the participant that they may use the option of 'prefer not to answer' for any question they were uncomfortable answering; iv) thanked the potential participant for considering participation and lastly; v) reminded them to return the survey to the specified collection point. The definition for clinical research was based on the American Medical Colleges Task Force on Clinical Research definition that informs the definition for the study, but has been 'translated' to age-appropriate wording for high school seniors.

To facilitate data collection, the new survey included 62 items divided into three sections as informed by the conceptual model for this study, the Theory of Planned Behavior. See **Figure 3.1** for an illustration of the relationship of the survey to the conceptual model. See **Appendix C** for the University of Iowa Institutional Review Boards (UI IRB) approved survey instrument.

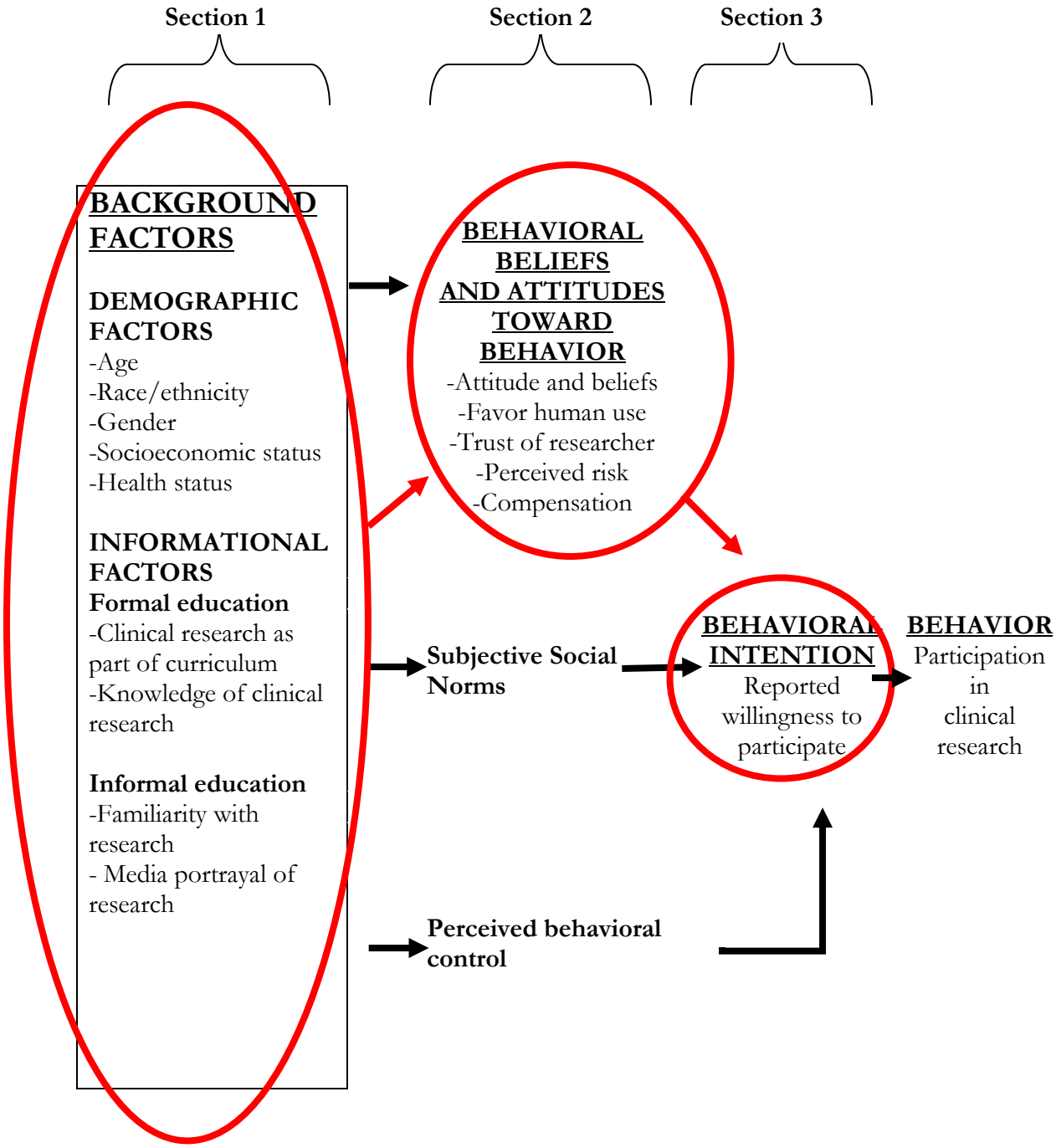


Figure 3.1 Relation of the survey, *Attitudes and Factors affecting Young Adults' Willingness to Participate in Clinical Research* to the Conceptual Model, the Theory of Planned Behavior

Note: Focus of this study is outlined in red.

Background factors

The first section of the questionnaire was comprised of questions that examined demographic and informational factors that may be associated with behavioral beliefs and attitudes regarding clinical research. It began with the demographic factors, including those identified during the literature review as possibly affecting willingness to participate in clinical research.

Demographic factors

Demographic questions consisted of six items answered with closed-ended responses. Options for responses include yes, no, don't know, and prefer not to answer.

- Age. Age was included as a double check of the inclusion criteria. If a participant indicated they are less than 18 years old, their data was not used for analysis.
- Race and ethnicity. The NIH minimum standards for maintaining, collecting and presenting data on race and ethnicity were used for the responses to this question. The standards include five racial categories (American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and White) and two ethnic categories (Hispanic or Latino and Not Hispanic or Latino).
- Gender
- Socioeconomic status (SES). A valid proxy measure of SES used in school age children is participation in the reduced or free lunch program (Ensminger et al, 2000). The National School Lunch Program provides students from families with incomes at or below 130% of the poverty level with free meals. Those with incomes between 130% and 185% of the poverty level are eligible for reduced-price meals (United States Chamber of Commerce, 2012). Respondents were asked, "Are you participating in the free or reduced lunch program?"

- Education. All participants in this study were high school seniors, so it would have been of no value to ascertain level of education. However, as pointed out in the literature review, there remains a knowledge gap as to whether knowledge a future plan of going to college affects willingness to participate; therefore participants were queried to ascertain whether they planned to go to college following graduation from high school.
- Health-related questions included queries regarding perceptions about current health status. Respondents were also asked to indicate if they had been diagnosed with a chronic illness (defined as lasting more than three months) or were hospitalized within the past year. Lastly, respondents were asked if someone close to them, such as a family member or friend, has been afflicted by a chronic illness.

Informational factors

As asserted by the Theory of Planned Behavior, background factors that may affect beliefs and attitude about clinical research include informational factors. Informational factors are comprised of formal and informal methods of acquiring knowledge about clinical research. Therefore, respondents were asked questions to ascertain where they may have acquired their knowledge about clinical research. Additionally, questions also assessed actual knowledge about clinical research. Twenty-one total items were designed to assess informal and formal education, and of these, one item was an open-ended response and the remainder were answered using a Likert scale.

Formal education

Participants were asked whether their high school education included curriculum about clinical research. This question may or may not have accurately reflected students' perceptions of receiving information about clinical research as part of their course work, but

it was used as an indicator of where (high school curriculum versus somewhere else) the participant may have garnered their knowledge. Responses are indicated on a Likert scale of 'strongly agree', 'agree', 'not sure', 'disagree', 'strongly disagree' or 'prefer not to answer'.

Knowledge of clinical research was assessed by seven survey questions that designed to assess knowledge about important components of the rights of study participants in a clinical research study. Of these seven questions, four questions were about various components of the informed consent process that are mandated in the Code of Federal Regulations, 45CFR46 (DHHS, 2010). A Likert scale of 'always true', 'sometimes true', 'never true', or 'I don't know' were the options for participants' responses. The remaining three questions were intended to examine the participant's knowledge about the conduct of clinical research studies, such as the purpose of trials is to evaluate the differences between treatments, and that research starts with a set of questions, and the concept of randomization. Questions for this section were adapted from the *Survey of Perceptions about the Role of Scientific Research in the Field of Health Care* developed by Trauth *et al* (2000). Although the reliability and validity of the instrument has not been reported, it has been used by other investigators to assess knowledge about clinical research, demonstrating its consistency (Burns, Magyarody, Jiang, & Wald, 2011; Garber, Hanusa, Switzer, Mellors, & Arnold, 2007; Kettis-Lindblad, Ring, Viberth, & Hansson, 2006).

Informal education

As suggested by Volkmann *et al*., knowledge of clinical research may also be acquired informally either by previously being enrolled in a prior research project or having a family member enrolled in a research study (2009). Respondents indicated if: they had been asked to participate; they had previously participated in a clinical research project; or, if someone close, such as a family member or friend, had participated in clinical research. Assessment of

familiarity with research consisted of these three items answered with closed-ended responses. Options for responses included 'yes', 'no', 'don't know', and 'prefer not to answer'.

Although previous studies examined how media influence young adult attitudes and beliefs about various issues, such as alcohol use, it is unknown how media may influence beliefs and attitudes about willingness to participate in clinical research. The media were described to participants as network television and cable shows, movies, internet, advertising, news, talk shows or other news media; In order to explore if respondents were aware of clinical research in the media, respondents were asked to name a media program that had seen about clinical research or researchers.

I also included exploratory research on the perception of how the media portrays the trustworthiness of research and researchers, an area that has not previously been examined. Questions that explored this topic were adapted from a validated instrument used to measure trust in medical researchers (Hall et al., 2006). Hall and colleagues' (2006) questionnaire was adapted to examine how the participant perceived media as portraying the trustworthiness of research and researchers. The survey examined how the media represented the following: 1) safety of the study participant; 2) fidelity to the appropriate purposes of conducting research; 3) honesty about the nature and purpose of research; and 4) a global sense of trust in clinical researchers. Responses were in the form of a Likert scale: 'strongly agree', 'agree', 'not sure', 'disagree', 'strongly disagree', and 'prefer not to answer'. Although, the Hall survey was not previously validated for use in this manner, results from these questions provided some insights into how participants perceive the media depiction researchers. (Scoring description of the Hall et al. survey can be found in Section 2.)

Behavioral Beliefs and Attitudes

The second section of the questionnaire was comprised of questions that examine the beliefs and attitudes about research, trust in researchers, and views on compensation. All responses in this section were closed ended.

Measuring Attitudes and Beliefs

Four questions about beliefs and attitudes in research were based on the survey entitled *Public Attitudes Towards Biomedical Research*, designed by Al-Jumah and colleagues (2011) that was used to investigate attitudes regarding biomedical research. Questions included: beliefs about clinical research resulting in cures for disease; perceptions about research conflicting with religion beliefs; and willingness to contribute blood and excess tissue for research. Evidence of validity and reliability were not reported for these questions, however the Al-Jumah *et al.* study reported that "the content validity and feasibility of the questionnaire was ensured through various negotiations with various relevant experts" (2011, p 538). Responses options were a Likert Scale of 'strongly agree', 'agree', 'neutral', 'disagree', or 'strongly disagree'. Negative attitudes statements were scored from 1 (strongly agree) to 5 (strongly disagree) and the reverse as used for positive statements. Total score was divided by the number of items (4) to obtain a mean raw score. A percentage score was obtained by dividing the mean subscale score by the total maximum score (4 question x 5 points = 20 for the total maximum score) and multiplied by 100. Participants with a percentage score less than 60% were considered to have a negative attitude, and conversely a percentage score greater than 60% indicated a positive attitude (Al-Jumah et al., 2011).

Favoring Human Use Score

Additionally, respondents' general attitude toward human use in clinical research was assessed by asking if the participant favors or opposes the use of human beings in research. The response was a Likert Scale ranging from 'strongly favor' to 'strongly oppose'. This question was adapted for use in this survey from Trauth *et al.*'s *Survey of Perceptions about the Role of Scientific Research in the Field of Health Care* (2000).

Measuring Trust in Researchers

Trust is said to be "an attitude of optimism that the goodwill and competence of another will extend to cover the domain of our interaction" (Barnes, 1996, p 4). Respondents' trust in researcher was examined as part of the study. Survey questions to examine trust in clinical researchers were adapted from a validated survey developed by Hall *et al.* (2006). Questions evaluated four components related to trust of the clinical researcher: 1) perceived safety of the study participant, 2) fidelity to the appropriate purposes of conducting research, 3) honesty about the nature and purpose of research, and 4) a global sense of trust in researchers. The original 12-item Hall *et al.* survey has a reported Cronbach's alpha of 0.87. Negative attitudes statements were scored from 1 (strongly agree) to 5 (strongly disagree). The reverse of this system was used for positive statements. The total score was divided by the number of items answered to obtain a mean score.

There are no reports in the literature regarding how young adults view the amount of compensation in relation to the perceived risks of clinical research. The present study used six items to address this subject. These questions were adapted from the *Relationship of Incentives to Risk and Benefit Perceptions and Willingness to Participate in Schizophrenia Research* (Dunn et al., 2009). Based on the Dunn *et al.* survey, three different procedures with varied levels of risks (no more than minimal, minor increase over minimal and more than a minor increase

over minimal risk) as defined by federal regulations were put forth (2009). Participants were queried about their willingness to participate at incremental levels of risk and their expectations of compensation. The issue of compensation was framed as if a person were willing to participate in the described scenario followed by the question, "what do you think would be FAIR compensation"? Responses for compensation questions began with 'no compensation' followed by incremental amounts of compensation, ranging from $5 to $100, for a blood draw scenario, and to $5 to $500, for scenarios that described a biopsy and a drug trial. These levels of compensation were based on the Dunn *et al.* survey (2009). As reported by Dunn and colleagues, "the blood draw compensation values were lower to maintain credibility of compensation values for this minimal risk scenario" (p 732, 2009).

Intention of Willingness to Participate in Clinical Research

The third section of the questionnaire looked at the reported intention of willingness to participate in clinical research was examined using a closed-ended response of 'yes', 'no', or 'don't know/unsure response'. The intention of willingness to participate was based on three different situations: 1) willingness to participate in a clinical research study focused on the participant's health, 2) willingness to participate in a clinical research study focused on the health of someone close, and 3) willingness to participate in a clinical research study that did not impact their health or the health of someone close but added to scientific knowledge.

Expert Panel Review and Pilot Testing

Prior to use in the study, the survey was reviewed by a panel of experts consisting of high school teachers and research personnel for content validity. The expert panel consisted of two high school teachers with combined teaching experience exceeding 40 years. One is a science teacher who is well versed in clinical research. The other members of the panel included a research coordinator and the director of an academic research core facility, all

with expertise in clinical research that included young adult participants and survey construction. The expert panel reviewed the survey for clarity, readability and appropriateness based on anticipated use in a senior class. Their recommendations included content suggestions such as simplification of medical terminology into lay language and design suggestions for the survey such as adding more 'white space'. These suggestions were incorporated into the survey.

Upon UI IRB approval, the survey was pilot tested using a sample of senior students from a local high school to assess readability and clarity. An informed consent document was reviewed with each pilot participant, see **Appendix D**. Recommendations from the students included addition of information stating that the clinical research team can include doctors and nurses as well as other health care professionals and some minor wording changes. Additionally, the following original survey question caused confusion in all pilot participants: "Research on human genetics goes against my religious beliefs" so it was changed it to "Research on humans goes against my religious beliefs". These questionnaires were not used for further analyses. A UI IRB modification was submitted and approved prior to enrolling study participants.

Procedures

This study was approved by the UI IRB prior to initiation of study procedures.

Recruitment and Informed Consent Process

Recruitment of potential subjects took place at Iowa high schools at which the principal granted the investigator permission to approach high school seniors for study participation. I cooperated with the identified contact person at each high school to determine which of two methods of approaching seniors was the least disruptive to school

activities and minimized burden to teachers and school administrators. Following is a brief description of the two methods:

Recruitment method 1- The informed consent process began with a brief introduction of the study by the investigator to an assembled group of seniors. I then read an UI IRB approved script that described the study purpose and procedures and how to participate in the study. See **Appendix E** for the UI IRB approved script used in these cases. I answered any concerns or questions that the students voiced, then distributed the packets containing the informed consent document and survey. I also notified students who wanted to participate that the completed survey must be returned to the collection point by a designated time after school on that day. The designated time allowed students enough to complete the survey during the day or after the school day if desired.

Recruitment method 2- I set up a research recruitment table in a visible spot, such as near the lunchroom or study hall area, during a time when seniors were expected to be in the building. Schools may have read or posted an UI IRB approved announcement prior to the investigator's arrival that alerted potential participants to my plans to recruit. See **Appendix F** for the UI IRB approved announcement. Those who reported an interest in participating were given a brief description of the study and the packet as described in Method 1. Identical to Method 1, I notified students who wanted to participate that the completed survey must be returned to the collection point by a designated time after school on that day.

All potential participants received an informed consent document prior to completing the survey instrument in accordance with the UI IRB procedure. The informed consent was strategically placed on top of the survey, so that potential participants could not overlook it. The informed consent document contained the elements that are required by the UI IRB; see **Appendix G** for the UI IRB approved informed consent. Potential

participants were informed that completing and handing in the questionnaire was the indication that they have read and agreed to the conditions of the informed consent document. Since this study took place in the school environment, I took special care to avoid participants feeling coerced into completing the survey. As part of the consent process, potential participants were informed that their teachers or administrators would not be told if they elected to participate or not in this survey and that their decision whether to participate would not affect their grades or other school evaluations. Packets were returned, completed or uncompleted, to a central location by a designated time on that day.

Compensation

Participants who complete the questionnaire were compensated with a $10 iTunes® gift card for time and effort involved in their participation in the study. This required students to complete a form with their name and address that was only used by the investigator to mail the iTune® gift cards. To protect confidentiality of the study participants, names and addresses of participants were separated from the surveys upon receipt. Names and addresses were only used for University of Iowa cash handling procedures.

Data Management

The raw data (completed surveys) is kept in the secured office of the investigator. For quality control, data from the surveys were double entered into computer files for analysis. All data is stored in a password-protected computer file in accordance with University of Iowa policies. There are no identifiers on the surveys, meaning that participant names cannot be linked to the survey. Collected data was reviewed during the course of the study and after collection of surveys was complete to identify items that may have been prone to missing responses. No item was noted to be missing more than 5% of the time.

Analysis

Study data were collected and managed using REDCap electronic data capture tools hosted at the Institute for Clinical and Translational Science, University of Iowa (Harris et al, 2009) REDCap (Research Electronic Data Capture). The data analysis was generated using SAS software, Version 9.3. Copyright © 2012 SAS Institute Inc. SAS and all other SAS Institute Inc. product or service names are registered trademarks or trademarks of SAS Institute Inc., Cary, NC, USA.

Parametric tests were used when tests assumptions were met and non-parametric tests were used when data were not normally distributed. Analysis was guided by the specific aims as described in Chapter 2 and restated here for the reader's convenience.

Specific aim 1: To describe the demographic variables, knowledge, attitudes towards participating in clinical research, and willingness to participate in clinical research in community-dwelling young adults, ages 18-20. Univariate analysis was conducted for analysis of all variables related to this aim. Descriptive statistics are presented as means with standard deviations, modes, and medians for continuous variables. Percentages are reported for categorical variables.

Specific aim 2: To describe the associations among background factors and beliefs and attitude towards willingness to participate in clinical research in community-dwelling young adults, ages 18-20. Demographic variables and responses to informational factors and questions pertaining to beliefs and attitudes regarding clinical research were compared using Chi-square tests or Fisher's exact tests depending on sample sizes. In the course of analysis, it was found that some of the data were skewed, therefore a non-parametric test, that makes no assumptions about distribution, was employed. Additionally, in dependent variable scores that were continuous, if scores were skewed then an additional analysis was done with

the scores dichotomized to observe how this might affect the results. The cutoff point was determined by the median; thereby dividing the sample in half. For variables that are ordinal, linear trend testing was conducted using the Cochran-Mantel-Haenszel test for non-zero correlation or the Cochran-Armitage test when one variable was dichotomous. When it was appropriate, categories were collapsed to increase cell size for a more robust analysis. Lastly, an analysis was done with neutral responses removed to determine if the neutral response had an effect on analysis. As this is novel work, p-values less than 0.10 are reported.

Specific Aim 3: To describe the association between beliefs and attitude towards willingness to participate and the reported intention of participating in clinical research in community-dwelling young adults, ages 18-20. Responses to questions pertaining to the intent of willingness to participate in the clinical research scenarios were compared using Chi-square tests or Fisher's exact tests depending on sample sizes. For variables that were ordinal, linear trend testing was performed using the Cochran-Mantel-Haenszel test for non-zero correlation or the Cochran-Armitage test when one variable was dichotomous. The first set of analyses of associations between behavioral beliefs and attitudes and willingness to participate within each scenario were conducted with the three possible responses, 'yes', 'no', and 'don't know/unsure'. The second set of analyses was completed to compare those who stated they were willing to participate to all other responses. This was done as the majority of respondents reported to be willing to participate causing low estimated cell counts. Thereby collapsing 'no' and 'don't know/unsure' increased cell size allowed for more robust analysis. Lastly, analyses were conducted to compare only those who said they were willing to those who unwilling, that is eliminating the responses of 'don't know/unsure'. As this is novel work in this population, p-values less than 0.10 are reported.

CHAPTER IV

RESULTS

Overview

In this chapter, I report on the response rate and include a brief description of participating schools, followed by presentation of study results according to specific aims. For, Specific Aim 1, I describe characteristics of the study participants, that is, community-dwelling young adults, ages 18-20 who are high-school seniors. This includes a description of the background factors (demographic variables and informational factors), behavioral beliefs and attitudes towards participation in clinical research, and reported intention of willingness to participate. For Specific Aim 2, I report associations between respondents' background factors and their behavioral beliefs and attitudes towards willingness to participate. Lastly, for Specific Aim 3, I describe the associations between behavioral beliefs and attitude towards willingness to participate and the respondents' reported intention of participating in clinical research. Individual survey items are referenced in the appropriate result section. Readers are referred to **Appendix C** for the actual survey.

Response Rate and Description of Participating Schools

The University of Iowa Cooperating Schools Program's Public School Directory (2011) identified 304 superintendents serving 320 high schools that contained a senior class. As described in Chapter 3, these superintendents were sent an email communication requesting access to their senior classes for the purposes of conducting the survey. Seventy-eight superintendents responded to the email, a response rate of 25.7% (78 responded/304 superintendents contacted). Of those who responded, 38 superintendents granted permission to recruit seniors within their district for this proposed study and 32 denied this investigator's request. Reasons given by the 32 superintendents for denial of access included

responses such as the students were too busy to participate due to end-of-year school activities, the superintendents did not want to burden their principals or students with an extra activity, or that the research study would not have a direct benefit of participation for their schools or students. Eight superintendents reported they would consider the request, but did not return a follow-up email.

The 38 superintendents that granted permission to approach seniors provided the name of a contact person, typically the high school principal, to arrange a mutually agreed upon date for this investigator to come to their high school. These 38 contact people were emailed with a request to recruit high school seniors for the study. Eighteen of these returned the email with interest in allowing this investigator to recruit seniors to participate in the proposed project. The remainder of the contact people reported they were uninterested in participating or unable to allow their seniors to participate due to the end-of-year school activities or conflicts.

Of the 18 schools that reported they would allow this investigator to recruit high school seniors, ten schools were visited for recruitment, six schools opted not to participate for unknown reasons, and two schools were not visited due to time constraints (the end of the school year). See **Table 4.1** for response rates of Iowa superintendents and high school contact persons.

Data collection occurred at ten high schools over the course of two weeks, May 4 to May 17, 2012. Participating schools were distributed throughout the state of Iowa. Dividing the state into quadrants using Interstate 80 as the north/south divider and Interstate 35 as the east/west divider, the number of schools located in each quadrant was as follows:

- Northeast - five schools
- Southeast - three schools

- Northwest - one school
- Southwest- one school.

The senior classes of participating schools ranged in size from 20 to 300 students. The average senior class size among participating schools was 103 and the median was 76. Reports regarding gender, minority populations and eligibility for free and reduced lunch are provided by the Iowa Department of Education (IDE) for schools as a whole - these figures are not provided for individual grades. The 20011-2012 IDE reports indicated that gender was equally distributed in the participating schools (male=51% and female=49%) and minorities made up 8.9% of the student population. The IDE reported that the percentage of students eligible for free or reduced lunch at the participating schools ranged from 9.0 to 53.9% and the median was 33.7%.

Packets were distributed to senior classes at the schools in one of two methods as described in Chapter 3. In total, 276 packets were distributed and 207 packets were returned for data analysis. **Table 4.2** reports the response rates for each participating high school by study ID including the number of packets distributed at each high school and the number of completed surveys returned to the investigator. Next, results will be presented according to the specific aims of the study.

Specific Aim #1

To describe: (1) the background factors (demographic variables and informational factors), (2) behavioral beliefs and attitudes towards participating in clinical research, and (3) the stated intention of willingness to participate in clinical research in community-dwelling young adults, ages 18-20.

Background factors

This section will begin with a description of the respondents' background factors. This will include demographic factors and informational factors that were identified in the literature review as affecting reported willingness to participate in clinical research. The results for Specific Aim #1 are reported in the following order. Survey questions are repeated within each section to as an aide-memoire for readers.

- Demographic information
- Informational factors
    - Knowledge acquired through formal educational methods
    - Knowledge acquired through informal methods.

Demographic Factors

All respondents reported that they were at least 18 years of age with a small proportion of the sample reported to be 19 years of age (4.3%). Respondents were predominantly White (93.7%) and non-Hispanic (87.4%), but were equally distributed between males (49.8%) and females (50.2%). As a measure of socioeconomic status, 16.9% of the respondents reported that they receive free or reduced rate lunch. The majority of respondents reported plans to go to college following graduation (94.7%).

Information about the population of Iowa high school seniors regarding race, gender, participation in free/reduced lunch program, and intention of going to college was reported in Chapter 3 based on IDE data. The study sample was compared to the population of Iowa high school seniors using a t-test based on these demographics, and is noted as similar to that population according to gender ($P= 0.9446$), but with significantly fewer minorities ($P< 0.0001$), fewer participants in the free or reduced rate lunch program

($P< 0.0001$), and a larger proportion who reported the intention to attend college ($P< 0.0001$).

When asked about their health status, respondents thought they were generally healthy, as they reported their health to be excellent (25.1%), very good (41.0%) or good (29.0%). Furthermore, most respondents denied having an illness that has lasted more than three months (91.3%) or having been hospitalized within the past year (84.5%). Approximately half of the respondents reported that someone close, such as a family member or friend, had been very sick or had an illness that has lasted more than three months (50.2%). See **Table 4.3** for a complete demographic description of the sample.

Informational Factors

Formal Education

Respondents were queried as to whether their school education included presented information about clinical research. Respondents were asked the following:

- The education I received during school included content about clinical research.

Overall respondents thought their education did not include presentation of information about clinical research as the majority of respondents disagreed (46.38%) or strongly disagreed (14.49%) with the statement. A minority reported that they agreed (15.46%) or strongly agreed (1.45%) that their education contained content about clinical research and the remainder were unsure (19.81%). See **Table 4.4** for a complete report of formal education about clinical research.

Knowledge of clinical research was assessed by seven questions as described in Chapter 3. Three questions assessed knowledge regarding the process and procedures of clinical research:

- Clinical research studies determine how well a treatment works.

- Clinical researchers start with a set of research questions they want to answer before starting clinical research studies.
- In a randomized clinical research study, you get to choose the treatment you want.

Four additional items assessed the ability to recognize important components of the informed consent process in a clinical research study as described by the Code of Federal Regulations as follows:

When someone participates in a clinical research study, do you think that they are always, sometimes or never are…

- told that they are participating in a research project.
- told about the possible risks of the clinical research study
- told how they might benefit from the clinical research study
- told they must participate in order to receive medical care.

Answers to the seven survey questions to assess knowledge of clinical research were totaled to produce raw scores. Higher scores indicated accurate knowledge about clinical research, with 24 being the highest possible score. Responses of 'don't know', 'prefer not to answer' and missing responses were assigned a score of zero. Respondents' knowledge raw scores ranged from 5 to 24 (mean, 16.5; median and mode, 18, SD$\pm$ 4.50). These scores indicate that overall respondents were generally knowledgeable about clinical research.

Individual items for this portion of the survey were also reviewed. Respondents largely understood that clinical research determines how well a treatment works (89.78%) as seen from a comparison of 'always true' and 'sometimes true' to 'rarely true' and "never true' and 'don't know' responses. Respondents also understood that researchers start with a set of questions they want to answer before starting a clinical research study (85.03%).

However, ninety percent of the respondents did not reply that study participants are unable to choose their treatment in a randomized study (88.41%).

Questions regarding the informed consent process demonstrated that half of the respondents thought clinical research participants are only sometimes or never told they are participating in a clinical research study (50.73%). Half of the respondents recognized that clinical research participants are always told the risks (54.11%) and how they might benefit (45.41%) from participation in a clinical research study. An equivalent amount recognized that patients are not required to participate in clinical research in order to receive care (50.72%). See **Table 4.5** for a complete report of respondents' knowledge score items.

Informal Education

In order to assess another aspect of gaining familiarity with clinical research respondents were asked if they had ever been asked to participate or had participated in a clinical research project:

- Prior to today, have you ever been asked to participate in a clinical research project?
- Prior to today, have you ever participated in a clinical research project?
- To the best of your knowledge, has someone close to you, such as a family member or friend, ever participated in a clinical research project?

Few of the respondents had been asked to participate in a prior clinical research project (6.2%) and only one respondent reported having participated in a clinical research project prior to this study. A small proportion of the respondents knew of someone close such as a family member or friend, who had previously participated in a clinical research project (8.70%). The remaining responses either denied such knowledge (46.86%) or 'don't know' (44.44%). See **Table 4.6** for complete report of familiarity with clinical research.

Gaining informal education through the media was also assessed in two ways. Respondents were first asked to remember a media production that depicted clinical research or a researcher:

- Please write down the name of a movie or television show or on the internet that you have watched that included a character who was a researcher.

The majority of respondents reported remembering viewing a program that included a character who was a researcher (72.46%). Approximately half of the respondents named a program that they thought included a depiction of research or researcher (54.6%). See **Table 4.7** for results of identification of media programs that contained a character depicting a clinical researcher. As demonstrated by **Table 4.8**, respondents mainly recalled television programs or motion pictures. Most frequently mentioned were the television programs, *House* (n=39) and *Grey's Anatomy* (n=29). See **Table 4.8** for a listing of the names of media presentation that included a character who was a researcher as identified by the respondents.

Second, an adaptation of a statement scale, developed by Hall and colleagues (2006), was used to evaluate respondents' perception of how the media portrays the trustworthiness of clinical research and researchers. As described in Chapter 3, this scale included 12 items as follows:

- The MEDIA portrays doctors who do medical research as caring only about what is best for each patient.
- The MEDIA portrays medical researchers as having no selfish reasons for doing research studies.
- When I watch TV or movies, it makes me think that there are some things about medical research that I cannot trust at all.

- The MEDIA depicts doctors as not doing their medical research study if the doctor thought there was any chance it might harm the person.
- The MEDIA shows medical researchers as not telling people everything they really need to know about being in a research study.
- The MEDIA portrays that the only reason doctors do medical research is to help people.
- The MEDIA portrays that it's safe to be in a medical research study.
- The MEDIA portrays some doctors as doing medical research for selfish reasons.
- The MEDIA portrays doctors as never recommending something that is not the best treatment, just so he or she can study how it works.
- The MEDIA portrays doctors as telling their patients everything they need to know about being in a research study.
- The MEDIA portrays medical researchers as treating people like "guinea pigs."
- The MEDIA makes me feel that I can completely trust doctors who do clinical research.

These statements used a 5-point Likert response scale, with positive attitude statements scored from 5 (strongly agree) to 1 (strongly disagree) while the reverse of this was used for negative statements so that the higher score indicated more trust. As described by the scale developers for analysis, missing data for 'prefer not to answer' (3 respondents) or 'did not answer' (8 respondents) were imputed using the mean score from all other items in the scale. The highest possible score of 60 indicates the highest level of trust.

Respondents' scores for how media depicts the trustworthiness of clinical research and researchers ranged from 17 to 52 (mean, 35.29; median, 36; mode 36; SD$\pm$ 5.89), indicating that respondents thought the media depicted researchers as fairly trustworthy. A review of items on the survey reinforce this perceived trustworthiness; for example approximately half of the respondents thought media depicted doctors who conduct clinical

research as caring only about what is best for each patient (41.06%) and would not do their research if they thought it would harm their patient (31.88%). However, a review of other survey items indicated that one-third of the respondents indicated that media depicted safety for participation in a clinical research study (36.71%). Respondents also believed the media depicted things about research they could not trust at all (61.35%) and half of respondents' perceived media to depict researchers as conducting clinical research for selfish reasons (50.72%). Lastly, one-third believed media depicted researchers as treating people as "guinea pigs" (38.16%). See **Table 4.9** for complete responses regarding media depiction of trustworthiness of the clinical researchers items.

Behavioral Beliefs and Attitudes about Clinical Research

Behavioral beliefs and attitudes were assessed using a variety of measures. First, respondents completed an assessment of attitudes and beliefs about biomedical clinical research. Next, respondents were asked if they favored or opposed the use of human beings in clinical research. Lastly, respondents' trust in clinical researchers was examined.

Measuring Attitudes and Beliefs

Assessment of attitudes and beliefs about biomedical research used a 5-item statement scale that included:

- Clinical research will result in cures for many diseases.
- Research on humans goes against my religious beliefs.
- If I donate blood, for example to the Red Cross, it would be OK with me to use a small part of it (1 tablespoon) for research.
- If I had surgery, I would be willing to allow the use of some of my surgical tissue for clinical research.
- I would allow my name to be put on a registry or list to be contacted for future research.

Following the attitude and belief scoring system described by the scale's developer, positive attitude statements were scored from 5 (strongly agree) to 1 (strongly disagree) while the reverse of this was used for negative statements (Al-Jumah et al., 2011). Adding individual items scores produced a raw score, which was then used to calculate a percentage score. A participant whose percentage score was less than 60% was considered to have a negative attitude; conversely a percentage score greater than 60% was considered a positive attitude (Al-Jumah et al, 2011). The mean of the sample was 74.61% (median and mode, 72%; SD±11.05), indicating that the majority of respondents had a positive attitude regarding clinical research (93.24%).

Individual item scores on beliefs and attitudes questions were also reviewed. The majority of respondents agreed that research will result in many cures (70.04%) and indicated that clinical research was not against their religious beliefs (70.53%). Most respondents were supportive of allowing a small amount of donated blood to be used for clinical research (82.6%), as well as tissue retrieved during surgery (71.98%). However, the majority of respondents were unsure about whether they would allow their name to be put on a registry enabling contact for future research (39.13%). See **Table 4.10** for complete responses for beliefs and attitudes items.

Favoring Human Use Score

Respondents were asked if they favored or opposed the use of human beings for clinical research:

- In general would you say that you favor or oppose the use of human beings for clinical research?

Responses were based on a 5-point Likert scale (5=strongly favor, 4=favor, 3=neutral, 2=oppose, 1=strongly oppose). The majority of respondents indicated 'neutral/ don't

know' (47.83%). However, when 'favor' (40.10%) was combined with 'strongly in favor' (6.28%), the result (46.38%) indicated that approximately half of the respondents were in favor of the use of humans for clinical research. See **Table 4.11** for the complete picture of responses.

Measuring Trust in Clinical Researchers

Trust in medical researchers was examined as a component of attitude. A 12-item statement scale, developed by Hall and colleagues (2006), was used to evaluate respondents' trust in researchers:

- Doctors who do clinical research care only about what is best for each patient.
- Clinical researchers have no selfish reasons for doing research studies.
- There are some things about clinical research that I do not trust at all.
- A doctor would never ask me to be in a clinical research study if the doctor thought there was any chance it might harm me.
- Clinical researchers do not tell people everything they really need to know about being in a research study.
- The only reason doctors do clinical research is to help people.
- It's safe to be in a clinical research study.
- Some doctors do clinical research for selfish reasons.
- A doctor would never recommend something that is not the best treatment, just so he or she can study how it works.
- Doctors tell their patients everything they need to know about being in a research study.
- Clinical researchers treat people like "guinea pigs."
- I completely trust doctors who do clinical research.

Possible responses were ranked on a 5-point Likert scale, where positive attitude statements were scored from 5 (strongly agree) to 1 (strongly disagree) while the reverse of this was used for negative statements so that the higher score indicated more trust, the highest score possible was 60. The range of scores was 12 to 55 (mean, 37.23; median, 37; mode 35; SD ±6.42). The mean score indicated a generally trustful attitude towards clinical researchers.

Review of individual item scores indicated that respondents felt that doctors conduct clinical research to help people (53.14%) and generally agreed that researchers tell their patients everything they need to know about being in a study (42.02%). There were slightly more respondents who disagreed that researchers treat people like 'guinea pigs' (39.13%) than people who agreed (30.42%) or were unsure (29.95%). However, about half of the respondents felt there were some things about research that they could not trust at all (47.33%). See **Table 4.12** for a complete report of the trust in clinical research items.

Of interest to this investigator, the following seven items on this section were answered most frequently as 'not sure'

- It's safe to be in a clinical research study. (n= 96, 46.38%)
- Clinical researchers have no selfish reasons for doing research studies. (n=86, 41.55%)
- Doctors who do clinical research care only about what is best for each patient. (n= 83, 40.10%)
- I completely trust doctors who do clinical research. (n=83, 40.10%)
- Clinical researchers do not tell people everything they really need to know about being in a research study. (n= 82, 39.61%)
- Some doctors do clinical research for selfish reasons. (n=82, 39.61%)
- A doctor would never recommend something that is not the best treatment, just so he or she can study how it works. (n=73, 35.27%)

The Stated Intention of Willingness to Participate Scenarios

Three scenarios were used to ascertain willingness to participate in clinical research. The scenarios had varying levels of risks (no more than minimal, minor increase over minimal and more than a minor increase over minimal risk) as described by the federal regulations.

- Scenario 1 was described as "You are asked to participate in a clinical research study that consisted of taking a small amount of blood out of my arm".

- Scenario 2 was described as "You are asked to participate in a clinical research study that consisted of cutting off a small amount of skin (about the size of a pencil eraser), called a biopsy. This would require an injection (shot) of numbing medicine so that you did not have any pain and two to three sutures (stitches). The biopsy would be on a place where the scar would not be seen, such as you're the top of your hip. There may be mild discomfort or pain for one to two days."

- Scenario 3 was described as "You are asked to participate in a clinical research study that consisted of taking a medication (drug) that will have some side effects from the medicine, such as feeling sick to your stomach (nausea) or throwing up (vomiting)."

For each scenario, respondents were asked their perception of the physical risks associated with the scenario with possible responses on a Likert scale: 'very safe', 'safe', 'neutral', 'risky' or 'very risky'. This question was followed by, "If you were asked today, would you be would you be willing to take part in this clinical research project if:…

- you felt it would benefit your health now or in the future?

- it would not benefit your health now or in the future but will add to scientific knowledge?

- you felt would not benefit your health but would benefit the health of someone close to you?"

Respondents reported they thought Scenario 1 (blood draw) was very safe (30.43%) or safe (43.96%) and reported they were willing to participate if they thought it would benefit their health (64.73) or the health of someone close to them (70.05%). However, they were less likely to participate if the study did not benefit their health but only contributed to scientific knowledge (40.10%).

Respondents were evenly divided regarding their perceptions of physical risks for Scenario 2 (biopsy). Approximately one-third reported the clinical research to be 'safe' (32.85%), one-third reported 'neutral', and one-third reported 'risky'. Respondents reported they were most likely to participate in Scenario 2 if the clinical research would benefit someone close (60.87%) compared to approximately half of the respondents who reported they would be willing to participate if they felt the clinical research would benefit their health (53.14%). Conversely, half reported they would *not* participate if they participate if the study did not benefit their health but only contributed to scientific knowledge (46.38%).

The majority of respondents indicated they thought Scenario 3 (drug trial) was physically 'risky' (64.74%). Similar to Scenario 2, more respondents indicated they would be willing to participate in Scenario 3 (drug with side effects) if the clinical research benefited someone close (49.28%) rather than themselves (44.44%). On the other hand, the majority would not participate if the clinical research only contributed to scientific knowledge (61.35%). See **Table 4.13** for complete scenario responses.

Compensation

Respondents were asked what they would consider "fair compensation" for participation in each of the three scenarios. Possible responses had incremental amounts of compensation based on the Dunn et al. survey (2009) as described in Chapter 3.

- Sometimes people who participate in clinical research projects are offered compensation, such as money, for their time and effort. If a person was willing to participate in Scenario 1, what do you think would be FAIR compensation?

Approximately eighty percent of the respondent reported they thought participants should be compensated for their time and effort for the blood draw in Scenario 1 (83.09%). Most common amount for compensation was a minimum of $10 (37.68%) followed by $50 (21.26%). Compensation levels increased with Scenario 2 (biopsy), with the majority indicating they thought participants should be compensated for their time and effort (90.82%). Most frequently, respondents replied that $100 (43.96%) is fair compensation. Lastly, respondents largely thought those who participate in Scenario 3 (drug trial) should be compensated for their time and effort (89.86%), and most frequently, they indicated a minimum of $500 as fair compensation (40.10%) for Scenario 3.

Specific Aim #2

To describe the relationship among background factors and beliefs and attitude towards willingness to participate.

The conceptual framework for this study, the Theory of Planned Behavior, asserts that there is a linear progression from background factors to behavioral beliefs and attitudes to the intention of willingness to participate in clinical research to participating in clinical research. See **Figure 4.1** for a diagram of Specific Aim 2 superimposed on a graphic describing the Theory of Planned Behavior.

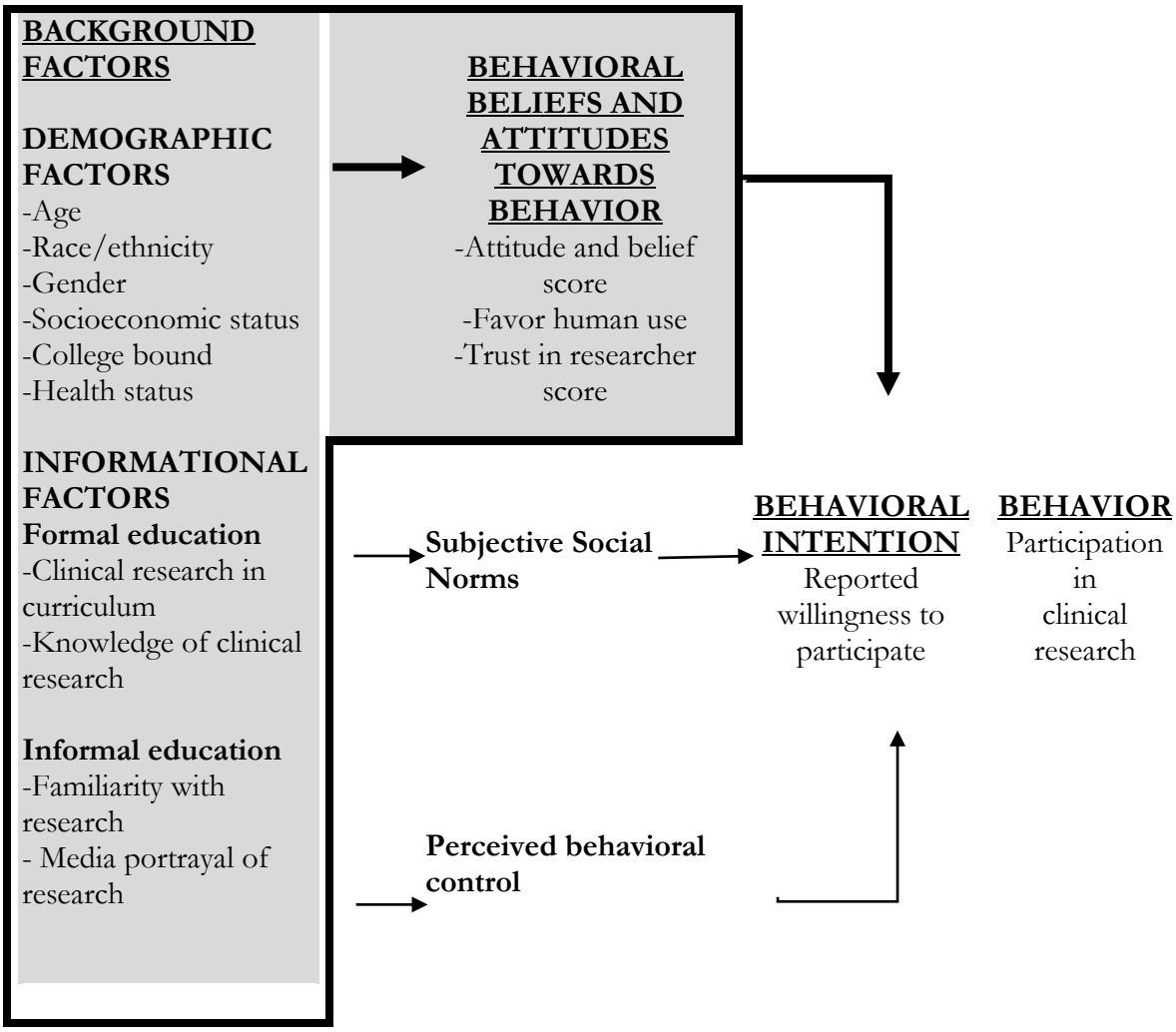


Figure 4.1 Specific Aim 2 shaded on the Theory of Planned Behavior

The results for Specific Aim #2 are reported as follows:

- Background factors (demographic and informational factors) associated with attitudes and beliefs scores
- Background factors (demographic and informational factors) associated with favoring the use of human beings for clinical research
- Background factors (demographic and informational factors) associated with trust in clinical researcher

Background Factors Associated with Attitudes and Beliefs Scores

As reported above, an attitudes and beliefs regarding clinical research score was measured by the responses to seven questions, and the result was a raw score that was converted to a percentage score with a percentage score greater than 60% indicating a positive attitude (Al-Jumah et al, 2011). The majority of respondents had a positive attitude regarding clinical research.

First, analyses for associations were completed with the dependent variable (in this case, the attitude and beliefs score,) as dichotomous, indicating either a positive or negative attitude based on the original authors' description of analysis (Al-Jumah et al., 2011). Background and informational factors examined in the survey were the independent variables. Pearson's chi-square or linear trend testing for categorical datum was employed for statistical analyses, and the null hypothesis was that the attitude and belief score is independent of the background and informational factors. Demographic background factors (race, ethnicity, gender, and health reports) were not found associated with attitude towards or beliefs about clinical research. Socioeconomic status (SES), measured by participation in the free/reduced price lunch program, was weakly associated with the attitude and belief score at the 0.10 significance level. Respondents who reported that they did not receive free or reduced lunch were more likely to have a positive attitude score (P= 0.0980). Background informational factors, either formal or informal, did not appear to be associated with attitudes and beliefs score.

When viewed as a dichotomous outcome (positive or negative), the data were skewed as the majority of respondents had a positive attitude regarding clinical research (93.24%). Linear trend testing can be used, as opposed to Pearson's chi-square test, to better understand the ordinal and skewed nature of the data. Attitude and beliefs scores were

divided into three categories (high, medium, and low attitudes). Categories were identified based on an examination of frequencies as follows, producing a more symmetrical distribution of scores for analysis: low= attitude and belief scores less than or equal to 60%; medium = greater than 60%, but less than 80%; high = equal to or greater than 80%. Using linear trend testing for the trichotomous outcome variable served to increase statistical power from the dichotomous analyses and demonstrated that one background factor and three informational factors are associated with beliefs and attitudes regarding clinical research. Such analysis resulted in elimination of the association between socioeconomic status and attitude and belief scores, but there was a significant association between having been hospitalized within the previous year and having higher scores (P= 0.0201). Regarding informational factors, respondents who agreed that their education included formal learning about clinical research, were associated with higher attitude scores (P= 0.0224). Informal education factors were associated attitude and belief scores as well. Respondents who reported having someone close to them participate in a clinical research study had significantly higher attitude and belief scores (P= 0.0012). Respondents' perception of media trustworthiness of clinical researchers was weakly associated with their attitude and belief scores (P=0.10). Respondents who reported that they thought media portrayed researchers as trustworthy had higher attitude and belief scores (P= 0.0896).

There has been discussion in the literature regarding categorization of data that could be analyzed in a continuous manner. One disadvantage of categorizing continuous data is the loss of information and power as a result of dividing the data at an arbitrary point (Royston, Altman & Suerbrei, 2005). Therefore, attitude and belief scores were analyzed as a continuous outcome variable to provide the most robust analyses. Associations were noted between one demographic variable, that is a prior hospitalization, and attitudes and beliefs

regarding clinical research (*P*= 0.0153). Analyses also demonstrated an association between three informational factors and behavioral beliefs and attitude scores. Having someone who had participated in clinical research (*P*= 0.0002) and perceived media trustworthiness of researchers were strongly associated with attitude and belief scores (*P*< 0.0001). Those with higher knowledge scores had significantly higher attitude scores (*P* <0.0001).

The impact of the 'neutral' response between background factors and attitudes and belief scores was assessed. 'Neutral' responses were eliminated from the data set and the remaining items answered with responses of 'strongly agree', 'agree', 'disagree', and 'strongly disagree' were recalculated. These scores were added then divided by the number of items answered giving a percentage score as performed for original calculation. These scores remained skewed and were therefore divided into a trichotomous outcome variable (scores equal to or less than 60%; scores greater than 60%, but less than or equal to 80%; and scores greater than 80%). There was a continued, though weak (at the 0.10 level of significance), association between hospitalization (*P*=0.0501), those that reported some formal learning about clinical research (*P*=0.0907*)* and higher attitude and belief scores. Familiarity with clinical research gained by having someone close participate in a study was associated with higher attitude and beliefs scores (*P* = 0.0021).

It is noteworthy that the associations between hospitalizations and informal education were consistently demonstrated as significant in all manners of analyses. See **Table 4.14** for a complete report of associations between background and informational factors and attitude and belief scores.

Background and Informational Factors Associated

with Favoring the Use of Human Beings for Clinical Research

Respondents were also asked if they favored or opposed the use of human beings for clinical research using a 5-point Likert scale for response. Approximately half of the respondents were in favor or strongly in favor of the use of humans for clinical research. Analyses for association between background factors and favoring human use in clinical research were conducted with the null hypothesis that favoring the use of human beings for research is independent of background and informational factors.

Data were first analyzed using all five categories of responses, that is, 'strongly favor', 'favor', 'neutral', 'oppose', or 'strongly oppose'. Two demographic factors were associated with a more positive attitude towards use of human beings for clinical research. Male respondents were significantly more in favor of the use of human beings in clinical research (P= 0.0266). Additionally, reported hospitalization within the past year also had a weak association with favoring human use (P= 0.0892). Informational factors associated with a more favorable attitude for human use included knowledge scores, that is the those with higher knowledge scores were significantly more in favor of the use of humans in research (P= 0.0226). Informal education acquired as assessed by awareness of media portraying clinical research was also significantly associated with a more positive attitude regarding human use in clinical research (P= 0.0020).

As noted in Specific Aim #1, the majority of respondents favored the use of human beings for clinical research thereby skewing the data. Data were collapsed to increase cell size and allow for more robust analyses. 'Strongly favor' and 'favor' were combined to make 'favor' and 'oppose' and 'strongly oppose' were combined to make 'oppose'. These new categories were analyzed for associated factors. Gender remained a factor associated with favoring human use indicating males were more favorable towards the use of human beings for clinical research (P= 0.0226). Additionally, using the new categories, a new background

factor was identified as having an association with favoring human use. Those respondents who rated their health lower demonstrated significantly a more favorable attitude regarding human use in clinical research (*P*= 0.0494).

As previously described, half of the respondents reported being 'neutral/don't know' to the question regarding human use (47.83%) in research. Therefore, an analysis was conducted with the 'neutral/don't know' deleted leaving two categories (favor or oppose) with remaining 107 respondents to see the effect of removing the neutrals would have on analyses. The results indicate that there was not an identifiable association between background or informational factors and favoring or opposing the use of human beings for clinical research. See **Table 4.15** for a complete report of background and informational factors associated with favoring the use of human beings in clinical research item.

Background and Informational Factors Associated

with Trust in Clinical Researcher

As previously described, trust in medical researchers was examined by a 12-item statement scale developed by Hall and colleagues (2006). Reponses were indicated on a 5-point Likert scale. As reported earlier in this chapter, respondents' mean score (37.23) indicated a generally trustful attitude towards clinical researchers.

First, analyses were completed with the dependent variable, the trust in clinical researcher score, as a continuous variable. These analyses suggested one background factor, race, as associated with trust in clinical researchers. That is, White, when compared to all other races, was associated with higher trust in clinical researchers (*P*= .0163).

Conversely, several of the informational factors were associated with the trust in researcher scores. Formal information, i.e., those respondents who believed their school curriculum contained learning about clinical researcher demonstrated significantly higher

trust scores (*P*= 0.0143). Additionally, respondents who scored higher on the questions about the process and procedures of clinical research had significantly higher trust in researcher scores (*P*< 0.0001). Likewise, informal education acquired by familiarity with research, gained by having been asked (*P*= 0.0861) or having participated (*P*= 0.0135) or having someone close who had participated (*P*= 0.0661), were associated with higher trust in researcher scores.

Since the continuous score indicated a generally positive attitude towards research, the dependent variable was dichotomized as positive or negative trust to observe how this might affect the results. The cutoff point was determined by the median; thereby approximately half of the sample was positive and half negative. Overall, the results of analyses with a dichotomous dependent variable were consistent with the results of the analyses with the dependent variable as continues. Informational factors continued to be associated with a positive trust score when the outcome variable was dichotomized. Respondents who indicated they thought their education included learning about clinical research (*P*= 0.0289) and correct knowledge regarding the process and procedures of clinical research (*P*= 0.0289) were associated with a positive trust in researcher score. Respondents with the perception that the media portrayed clinical researchers as trustworthy were more likely to have trust in clinical researchers (P< 0.0001). Differences in the analyses included weak association between one background factor and trust in researcher scores at the 0.10 significance level. Respondents who reported they were college-bound also had a positive trust in researcher score (*P*= 0.0901).

To eliminate the effect of respondent neutrality, individual trust in researcher scores were reviewed. In order to be included in this particular analysis, respondents must have rated at least 50% of the items (7 of 12) as positive (Likert score of 4 or 5) or negative

(Likert score of 1 or 2). Of those respondents (n= 138), individual scores were reviewed and respondents were placed into one of two categories based on if the majority of their responses were positive or negative. The results of the linear trend testing demonstrated analyses remained consistent with the analyses, suggesting the neutral responses did not affect the analyses. Respondents who thought their curriculum taught them about clinical research continued to be associated with positive trust in researcher (*P*= 0.0211). Likewise, higher knowledge scores continued to be associated with trust in researchers (*P*= 0.0149).

Specific Aim #3

To describe the association between behavioral beliefs and attitude towards willingness to participate and the reported intention of willingness to participate in clinical research.

The Theory of Planned Behavior contends that the linear progression continues from beliefs and attitudes to the intention of performing a behavior. As such, I examined the associations between behavioral beliefs and attitudes about clinical research and the stated intention of willingness to participate in clinical research. See **Figure 4.2** for a diagram of Specific Aim 3 superimposed on the Theory of Planned Behavior.

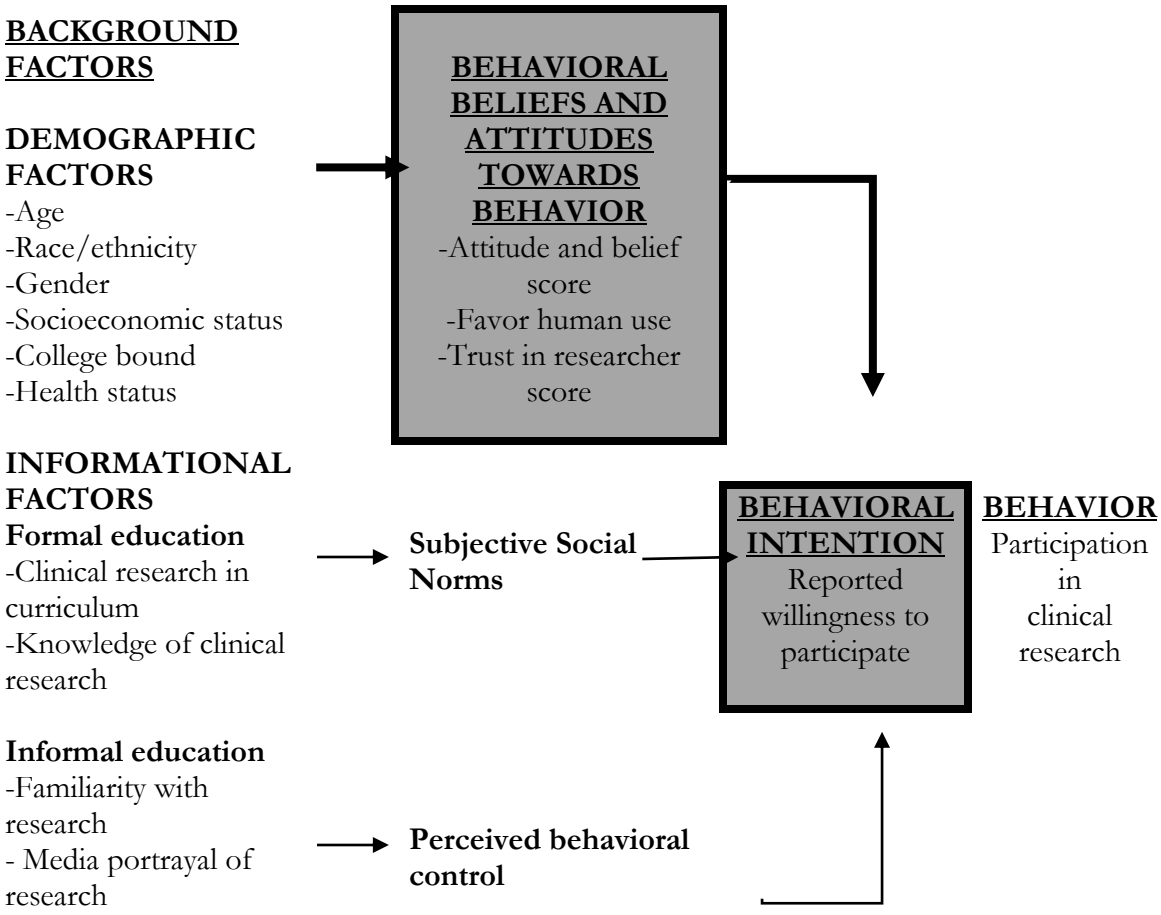


Figure 4.2 Specific Aim 3 shaded on the Theory of Planned Behavior

As described earlier, three scenarios were presented to the respondent, each presenting with increasing physical risk (scenario 1: a blood draw; scenario 2: a cutaneous biopsy involving injection of an anesthetizing medication and sutures; and scenario 3: a pharmaceutical trial with a medication with anticipated side effects of nausea and vomiting). Respondents were asked their willingness to participate in three situations within each scenario: 1) if the research would benefit that individual's health, 2) if the research would not benefit the individual but would benefit the health of someone close to them, and 3) if the research that would not benefit their health but add to scientific knowledge. Responses choices included 'yes', 'no', and 'don't know/unsure'. Linear trend testing was conducted for testing independence between the independent variables, the behavioral beliefs and attitudes, and the dependent variable, the said intention of willingness to participate. The dependent variable, willingness to participate, was manipulated to assess for different effects.

The first set of comparisons involving behavioral beliefs and willingness to participate was conducted with the three possible responses, 'yes', 'no', and 'don't know/unsure'. The second set of analyses was completed to compare those who stated they were willing to participate to all other responses. This was done as the majority of respondents reported to be willing to participate causing low estimated cell counts. Thereby collapsing 'no' and 'don't know/unsure' increased cell size allowed for more robust analysis. Lastly, analyses were conducted to compare only those who said they were willing to those who unwilling, that is eliminating the responses of 'don't know/unsure'.

As described for Specific Aim 2, analyses of the behavioral beliefs and attitudes included various methods of collapsing the data to assess various effects. These data manipulations were also included within this analysis to assess associations in multiple ways.

Behavioral Beliefs and Attitudes Associated with Scenario 1

Benefit the Health of the Respondent

Using the original three possible responses of 'yes', 'no' and 'unsure', linear trend testing demonstrated an association between attitude and belief scores and stated willingness to participate in a clinical research project that consisted of a blood draw. Respondents with positive attitude and belief scores were more likely to indicate they were willing to participate in a clinical research project that consisted of a blood draw that benefited their health ($P< 0.0001$). Respondents who favored human beings use in clinical research also were likely to indicate they were willing to participate in this clinical research project ($P= 0.0450$). Trust in researcher scores were not associated with the intention of willingness to participate in clinical research ($P= 0.5725$).

However, as the majority of respondents indicated they were willing or unsure if they would participate, another analysis was done comparing 'yes' to all other responses ('no' and 'don't know/unsure') ($P< 0.0001$). This increased cell size and allowed for more robust analyses. These analyses demonstrated a significant association in attitude scores ($P< 0.0001$) and favoring human use ($P=0.0499$) and the respondents' reported intention of willingness to participate in this scenario. Analyses of the scenario with the neutrals removed remained overall similar to the analyses with the dichotomous dependent variable indicating the neutrals did not have much of an affect. See Table 4.17 for a complete report of behavioral beliefs and attitudes associated with the intention of willingness to participate in Scenario 1 for a clinical research project that benefited the health of the respondent.

Benefit to Someone Close

A positive attitude and belief score was associated with the intention of willingness to participate if the project did not benefit the health of the respondent but

would benefit the health of someone close (*P*= 0.0005) when analysis was done with a trichotomous dependent variable. As before, for a more robust analysis, the dependent variable was collapsed into two categories. The association between the attitude and belief score remained significant when comparing 'yes' to all other responses ('no' and 'don't know/unsure') (*P*= 0.0002). When neutrals were eliminated, the association continued to remain significant (*P*= 0.0018).

Trust in researchers did not appear to be associated with the intention of willingness to participate in this clinical research scenario. See **Table 4.18** for a complete report of behavioral beliefs and attitudes associated with the intention of willingness to participate in Scenario 1 for a clinical research project that did not benefit the health of the respondent but benefitted the health of someone close.

No Benefit but Adds to Scientific Knowledge

Respondents with a positive attitude and beliefs score were more likely to express an intention of willingness to participate in clinical research that added to scientific knowledge but did not benefit their health (*P*< 0.0001). Favoring the use of human beings for clinical research was weakly associated with reported willingness to participate in this scenario when neutrals were removed at the .10 level of significance (*P*= 0.0741). Trust in researcher scores were not associated with the intention of willingness to participate in this scenario. See **Table 4.19** for a complete report of behavioral beliefs and attitudes associated with the intention of willingness to participate in Scenario 1 for a clinical research project that did not benefit the health of the respondent but added to scientific knowledge.

Behavioral Belief and Attitudes Associated with Scenario 2

Benefit the Health of the Respondent

A positive attitude and belief score was strongly associated with the intention of willingness to participate in this situation ($P< 0.0001$). All analyses (i.e. the dependent variable as trichotomous, dichotomous, or the neutrals removed) demonstrated this significant association. Favoring human use in clinical research was also associated with reported willingness to participate in clinical research that benefitted the respondent ($P= 0.0011$). See **Table 4.20** for a complete report of behavioral beliefs and attitudes associated with the intention of willingness to participate in Scenario 2 for a clinical research project that benefited the health of the respondent.

Benefit to Someone Close

A positive attitude and belief score was associated with the intention of being willing to participate in this situation ($P= 0.0328$). When neutrals were eliminated from dependent variables for the analysis, a more positive attitude continued was still associated with the intention of being willing to participate ($P= 0.0069$). Respondents who reported that they favored the use of human beings for clinical research were also associated with reporting to be willing to participate in this situation ($P= 0.0045$), however this analysis may be inaccurate due to small cell sizes. When cells were collapsed for a more robust analysis, the associate was insignificant. Interestingly, trust in researcher scores did not appear to be associated with this situation ($P= 0.2961$). See **Table 4.21** for a complete report of behavioral beliefs and attitudes associated with the intention of willingness to participate in Scenario 2 for a clinical research project that did not benefit the health of the respondent but benefitted the health of someone close.

No Benefit but Adds to Scientific Knowledge

Attitude and beliefs scores were found to be associated with the respondents stated willingness to participate (P< 0.0001). Various analyses using two or three categories of willingness to participate consistently demonstrated an association. Likewise, deleting neutral responses also demonstrated that the respondents' attitude and belief scores were associated with their reported willingness to participate (*P*= 0.0166). Respondents who reported they favored the use of human beings for clinical research also reported they were willing to participate in this scenario (*P*= 0.0034), however this analysis may be inaccurate due to small cell sizes. When cells were collapsed for a more robust analysis, the associate was insignificant. See **Table 4.22** for a complete report of behavioral beliefs and attitudes associated with the intention of willingness to participate in Scenario 2 for a clinical research project that did not benefit the health of the respondent but added to scientific knowledge.

Behavioral Belief and Attitudes Associated with Scenario 3

Benefit the Health of the Respondent

Respondents' attitude and belief scores were associated with their reported willingness to participate given these circumstances. Higher scores in trusting clinical researcher were associated with being willing to participate (*P*< 0.0001). Those respondents who favored the use of human beings for clinical research were associated with being more willing to participate in this situation (*P*= 0.0404). Removing the neutral responses from the dependent variable leaving only those who were willing compared to those who were unwilling also demonstrated a positive association between favoring human research and willingness to participate (*P*= 0.0248). Trust in researchers was weakly associated with willingness to participate when 'yes' was compared to all other responses (*P*= 0.0785). See **Table 4.23** for a complete report of behavioral beliefs and attitudes associated with the

intention of willingness to participate in Scenario 3 for a clinical research project that benefited the health of the respondent.

Benefit to Someone Close

The attitude and beliefs score was demonstrated to be associated with respondents' reported willingness to participate (P< 0.0001). This was consistent when the independent and dependent variables were continuous or categorical for analysis as well as when neutrals were deleted. Favoring the use of human beings for clinical research was weakly associated with respondents' willingness to participate in this situation (P= 0.0818), however this analysis may be inaccurate due to small cell sizes. When cells were collapsed for a more robust analysis, the associate was insignificant. This association remained constant when neutral responses were eliminated in the independent variable.

Trust in researcher scores were not associated with the respondents' willingness to participate (P= 0.2566). See **Table 4.24** for a complete report of behavioral beliefs and attitudes associated with the intention of willingness to participate in Scenario 3 for a clinical research project that did not benefit the health of the respondent but benefitted the health of someone close.

No Benefit but Adds to Scientific Knowledge

Respondents' attitude and belief scores were positively associated with their reported willingness to participate (*P*< 0.0001). Likewise, respondents who reported they were in favor of the use of human beings for clinical research were also more likely to report they were willing to participate in this situation (P= 0.592). Trust in researchers was associated with reporting willingness to participate in this situation as those with higher trust in researchers were more likely to be either willing to participate or neutral to participation (P= 0.0127). See **Table 4.25** for a complete report of behavioral beliefs and attitudes associated

with the intention of willingness to participate in Scenario 3 for a clinical research project that did not benefit the health of the respondent but added to scientific knowledge.

Summary

These analyses demonstrated multiple associations among various factors. These associations will be further discussed in Chapter 5.

Table 4.1 Response Rate of Superintendents and High School Contact Persons

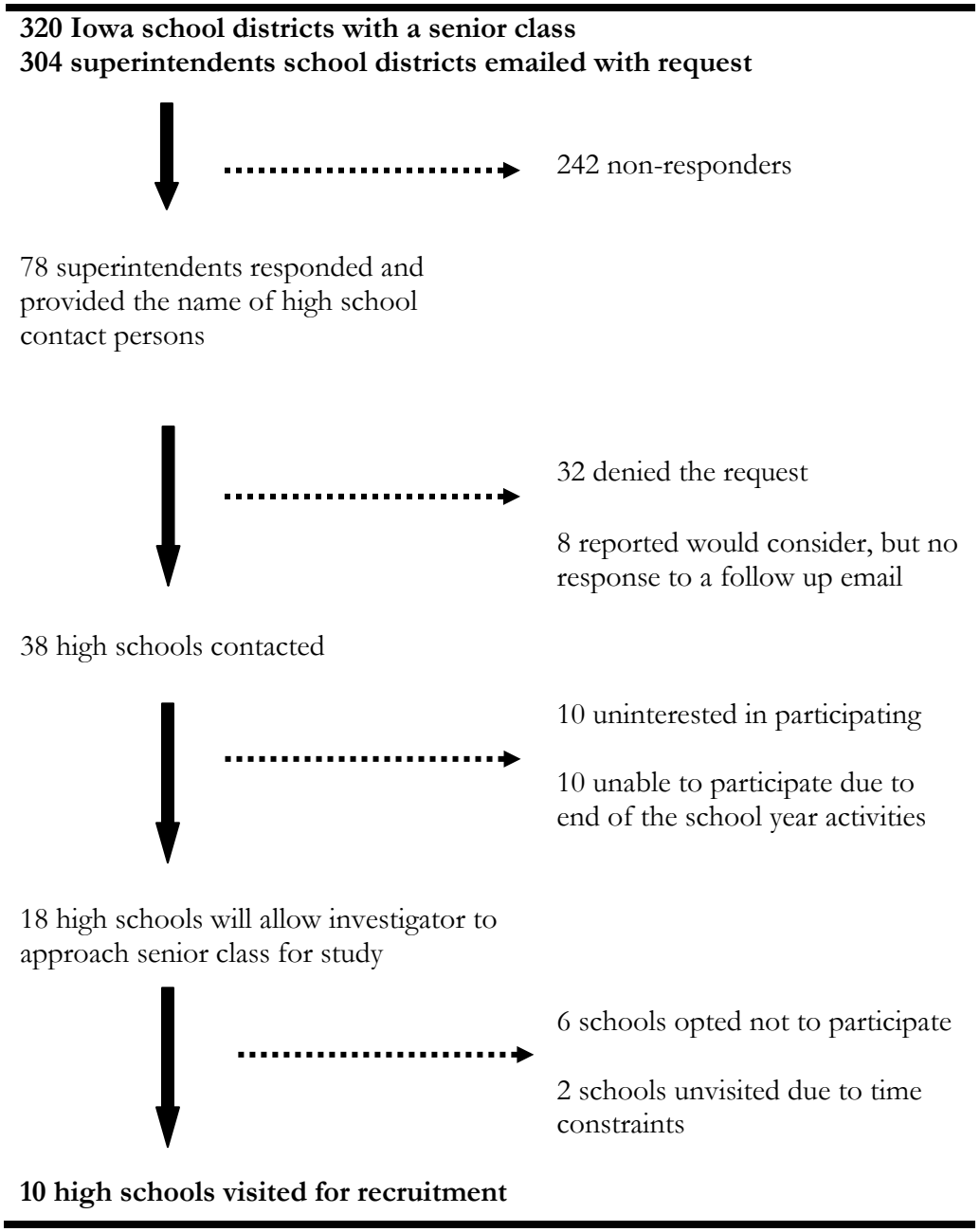


Table 4.2 Response Rate

School Study ID	Packets distributed	Packets returned	Participation rate
504	24	14	58%
507	10	7	70%
508	10	10	100%
509	15	15	100%
510	25	11	44%
511	58	35	60%
514	94	84	89%
515	11	10	91%
516	21	13	62%
517	8	8	100%
TOTAL	**276**	**207**	**75%**

Table 4.3 Study Sample Characteristics

(N=207)	n	(%)
Age		
18 years	199	(95.7)
19 years	8	(4.3)
Race		
American Indian/Alaskan native	1	(0.48)
Asian	3	(1.45)
Black	3	(1.45)
White	194	(93.72)
Other	3	(1.45)
Missing	3	(1.45)
Ethnicity		
Hispanic	5	(2.42)
Not Hispanic	181	(87.44)
Prefer not to answer	11	(5.31)
Missing	10	(4.83)
Gender		
Female	103	(49.76)
Male	104	(50.24)
Participating in free/reduced lunch		
No	156	(75.36)
Yes	35	(16.91)
Refused to answer	15	(7.25)
Missing	1	(0.48)
Health status		
Excellent	52	(25.12)
Very good	85	(41.06)
Good	60	(28.99)
Poor	7	(3.38)
Prefer not to answer	3	(1.45)
Plan to attend college after graduation		
No	2	(1.45)
Yes	196	(94.69)
Unsure	8	(3.86)
Missing	1	(0.48)

Table 4.3 continued

Illness lasting more than 3 months		
No	189	(91.30)
Yes	14	(6.76)
Prefer not to answer	4	(1.93)
Hospitalized within past year		
No	175	(84.54)
Yes	28	(13.53)
Prefer not to answer	4	(1.93)
Illness of someone close		
No	84	(40.58)
Yes	104	(50.24)
Prefer not to answer	6	(9.18)

Table 4.4 Formal Education Regarding Clinical Research

(N=207)	**n**	**(%)**
Strongly agree	3	(1.45)
Agree	32	(15.46)
Not sure	41	(19.81)
Disagree	96	(46.38)
Strongly disagree	30	(14.49)
Prefer not to answer	1	(0.48)
Missing	4	(1.93)

Note: The education I received during school included learning about clinical research

Table 4.5 Knowledge about Clinical Research

(N=207)	n	(%)
Clinical research studies determine how well a treatment works.		
Always true	25	(12.08)
Sometimes true	161	(77.78)
Rarely true	2	(0.97)
Never true	3	(1.45)
Don't know/unsure	15	(7.25)
Missing	1	(0.48)
Clinical researchers start with a set of research questions they want to answer before starting a clinical research studies.		
Always true	77	(37.20)
Sometimes true	99	(47.83)
Rarely true	7	(3.38)
Never true	0	(0.00)
Don't know/unsure	23	(11.11)
Missing	1	(0.48)
In a randomized clinical research study, you get to choose the treatment you want.		
Always true	17	(8.21)
Sometimes true	55	(26.57)
Rarely true	57	(27.54)
Never true	23	(11.11)
Don't know/unsure	54	(26.09)
Missing	1	(0.48)

Table 4.5 continued

Told that they are participating in a research project.		
Always	89	(43.00)
Sometimes	99	(47.83)
Never	6	(2.90)
Don't know/unsure	13	(6.28)
Told about the possible risks of the clinical research study.		
Always	112	(54.11)
Sometimes	62	(29.95)
Never	13	(6.28)
Don't know/unsure	20	(9.66)
Told how they might benefit from the clinical research study.		
Always	94	(45.41)
Sometimes	89	(43.00)
Never	7	(3.38)
Don't know/unsure	17	(8.21)
Told they must participate in order to receive medical care.		
Always	17	(8.21)
Sometimes	40	(19.32)
Never	105	(50.72)
Don't know/unsure	44	(21.26)
Prefer not to answer	1	(0.48)

Note: When someone participates in a clinical research study, do you think that they are always, sometimes or never…

Table 4.6 Familiarity with Research by Participation in Clinical Research

(N=207)	n	(%)
Previously asked to participation		
No	201	(97.10)
Yes	6	(2.90)
Previously participated		
No	205	(99.03)
Yes	1	(0.48)
Missing	1	(0.48)
Someone close participated		
No	97	(46.86)
Yes	18	(8.70)
Don't know/unsure	92	(44.44)

Table 4.7 Media and Clinical Research

(N=207)	**n**	**(%)**
Named	113	(54.60)
Can't recall a program	48	(23.20)
I remember a program, can't recall name	37	(17.90)
Prefer not to answer	8	(3.90)
Missing	1	(0.48)

Note: Please write down the name of a movie or television or on the internet that you have watched that included a character who was a researcher.

Table 4.8 Names of Programs Depicting Clinical Research

Program Named	**Frequency***
House	39
Grey's Anatomy	29
Scrubs	9
Human Centipede	7
Hulk	6
Criminal Minds	4
Bones	3
CSI	3
ER	3
Spiderman	3
Law and Order	2
The Avengers	2
X-Men	2

Note: *Respondents could mention more than one program

The following were each mentioned one time by respondents: 2 Broke Girls Max, Batman, Children's Hospital, Days of Our Lives, Deep Blue Sea, Dexter's Laboratory, Doctors, Dr. Oz, Flowers for Algernon, Fringe, Ghost Busters, I am Legend, Island of Doctor Monroe, Jericho, Mickey Mouse, My Little Pony, My Sister's Keeper, Mystery Diagnosis, NCIS, Pokemon, Nutty Professor, Private Practice, Psych, Push, Rise of the Planet of the Apes, Seven Pounds, Splice, The Big Bang Theory, The Experiment, The Simpson's, Two and Half Men, Who the bleep did I marry, Wit

Table 4.9 Media's Depiction of Trustworthiness of Clinical Researchers

(N=207)	n	(%)
The MEDIA portrays doctors who do medical research as caring only about what is best for each patient.		
Strongly agree	14	(6.76)
Agree	71	(34.30)
Not sure	77	(35.75)
Disagree	39	(18.84)
Strongly disagree	8	(3.86)
Prefer not to answer	1	(0.48)
The MEDIA portrays medical researchers as having no selfish reasons for doing research studies.		
Strongly agree	11	(5.31)
Agree	54	(26.09)
Not sure	74	(35.75)
Disagree	60	(28.99)
Strongly disagree	7	(3.38)
Missing	1	(0.48)
When I watch TV or movies, it makes me think that there are some things about medical research that I can not trust at all.		
Strongly agree	14	(6.76)
Agree	113	(54.59)
Not sure	56	(25.12)
Disagree	24	(11.59)
Strongly disagree	3	(1.45)
Prefer not to answer	1	(0.48)
The MEDIA depicts doctors as not doing their medical research study if the doctor thought there was any chance it might harm the person.		
Strongly agree	8	(3.86)
Agree	58	(28.02)
Not sure	82	(39.62)
Disagree	50	(24.12)
Strongly disagree	8	(3.86)
Missing	1	(0.48)
The MEDIA shows medical researchers as not telling people everything they really need to know about being in a research study.		
Strongly agree	10	(4.83)
Agree	42	(20.29)
Not sure	85	(41.06)
Disagree	66	(31.88)
Strongly disagree	8	(3.86)

Table 4.9 continued

The MEDIA portrays that the only reason doctors do medical research is to help people.		
Strongly agree	8	(3.86)
Agree	66	(31.88)
Not sure	85	(41.06)
Disagree	42	(20.29)
Strongly disagree	5	(2.42)
Missing	1	(0.48)
The MEDIA portrays that it's safe to be in a medical research study.		
Strongly agree	7	(3.38)
Agree	69	(33.33)
Not sure	95	(45.89)
Disagree	31	(14.98)
Strongly disagree	4	(1.93)
Missing	1	(0.48)
The MEDIA portrays some doctors as doing medical research for selfish reasons.		
Strongly agree	10	(4.83)
Agree	95	(45.89)
Not sure	62	(29.95)
Disagree	36	(17.39)
Strongly disagree	3	(1.45)
Prefer not to answer	1	(0.48)
The MEDIA portrays doctors as never recommending something that is not the best treatment, just so he or she can study how it works.		
Strongly agree	11	(5.31)
Agree	62	(29.95)
Not sure	71	(34.30)
Disagree	45	(21.74)
Strongly disagree	2	(0.97)
Missing	1	(0.48)
The MEDIA portrays doctors as telling their patients everything they need to know about being in a research study.		
Strongly agree	4	(1.93)
Agree	59	(28.50)
Not sure	89	(43.00)
Disagree	51	(24.64)
Strongly disagree	3	(1.45)
Missing	1	(0.48)

Table 4.9 continued

The MEDIA portrays medical researchers as treating people like "guinea pigs."		
Strongly agree	10	(4.83)
Agree	69	(33.33)
Not sure	74	(35.75)
Disagree	49	(23.67)
Strongly disagree	4	(1.93)
Missing	1	(0.48)
The MEDIA makes me feel that I can completely trust doctors who do clinical research.		
Strongly agree	5	(2.42)
Agree	33	(15.94)
Not sure	102	(49.28)
Disagree	55	(26.57)
Strongly disagree	11	(5.31)
Missing	1	(0.48)

Table 4.10 Attitudes and Beliefs about Clinical Research

(N=207)	n	(%)
Clinical research will result in cures for many diseases.		
Strongly agree	24	(11.59)
Agree	121	(58.45)
Not sure	56	(27.05)
Disagree	5	(2.42)
Strongly disagree	0	(0)
Prefer not to answer	1	(0.48)
Research on humans goes against my religious beliefs.		
Strongly agree	1	(0.48)
Agree	9	(4.35)
Not sure	47	(22.71)
Disagree	98	(47.34)
Strongly disagree	48	(23.19)
Prefer not to answer	4	(1.93)
If I donate blood, for example to the Red Cross, it would be OK with me to use a small part of it (1 tablespoon) for research.		
Strongly agree	63	(30.43)
Agree	108	(52.17)
Not sure	20	(9.66)
Disagree	12	(5.80)
Strongly disagree	3	(1.45)
Prefer not to answer	1	(0.48)
If I had surgery, I would be willing to allow the use of some of my surgical tissue for clinical research.		
Strongly agree	52	(25.12)
Agree	97	(46.86)
Not sure	40	(19.32)
Disagree	16	(7.73)
Strongly disagree	2	(0.97)
Prefer not to answer	0	(0)
I would allow my name to be put on a registry or list to be contacted for future research.		
Strongly agree	16	(7.73)
Agree	48	(23.19)
Not sure	81	(39.13)
Disagree	44	(21.26)
Strongly disagree	15	(7.25)
Prefer not to answer	2	(0.97)
Missing	1	(0.48)

Table 4.11 Favoring Human Use for Clinical Research

(N=207)	**n**	**(%)**
Strongly favor	13	(6.28)
Favor	83	(40.10)
Neutral/Don't know	99	(47.83)
Oppose	8	(3.86)
Strongly oppose	3	(1.45)
Missing	1	(0.48)

Note: In general would you say that you favor or oppose the use of human beings for clinical research?

Table 4.12 Trust in Clinical Researchers

(N=207)	n	(%)
Doctors who do clinical research care only about what is best for each patient.		
Strongly agree	13	(6.28)
Agree	67	(32.37)
Not sure	83	(40.10)
Disagree	38	(18.36)
Strongly disagree	4	(1.93)
Clinical researchers have no selfish reasons for doing research studies.		
Strongly agree	6	(2.90)
Agree	53	(25.60)
Not sure	86	(41.55)
Disagree	57	(27.54)
Strongly disagree	5	(2.42)
There are some things about clinical research that I do not trust at all.		
Strongly agree	11	(5.31)
Agree	87	(42.03)
Not sure	83	(40.10)
Disagree	23	(11.11)
Strongly disagree	3	(1.45)
A doctor would never ask me to be in a clinical research study if the doctor thought there was any chance it might harm me.		
Strongly agree	25	(12.08)
Agree	81	(39.13)
Not sure	60	(28.99)
Disagree	35	(16.91)
Strongly disagree	4	(1.93)
Prefer not to answer	1	(0.48)
Missing	1	(0.48)
Clinical researchers do not tell people everything they really need to know about being in a research study.		
Strongly agree	7	(3.38)
Agree	66	(31.88)
Not sure	82	(39.61)
Disagree	50	(24.15)
Strongly disagree	2	(0.97)

Table 4.12 continued

The only reason doctors do clinical research is to help people.		
Strongly agree	17	(8.21)
Agree	93	(44.93)
Not sure	51	(24.64)
Disagree	42	(20.29)
Strongly disagree	4	(1.93)
Its safe to be in a clinical research study.		
Strongly agree	9	(4.35)
Agree	77	(37.20)
Not sure	96	(46.38)
Disagree	23	(11.11)
Strongly disagree	2	(0.97)
Some doctors do clinical research for selfish reasons.		
Strongly agree	6	(2.90)
Agree	73	(35.27)
Not sure	82	(39.61)
Disagree	38	(18.36)
Strongly disagree	7	(3.38)
Missing	1	(0.48)
A doctor would never recommend something that is not the best treatment, just so he or she can study how it works.		
Strongly agree	9	(4.35)
Agree	70	(33.82)
Not sure	73	(35.27)
Disagree	51	(24.64)
Strongly disagree	4	(1.93)
Doctors tell their patients everything they need to know about being in a research study.		
Strongly agree	11	(5.31)
Agree	76	(36.71)
Not sure	65	(31.40)
Disagree	51	(24.64)
Strongly disagree	3	(1.45)
Missing	1	(0.48)

Table 4.12 continued

Clinical researchers treat people like "guinea pigs."		
Strongly agree	5	(2.42)
Agree	58	(28.02)
Not sure	62	(29.95)
Disagree	68	(32.85)
Strongly disagree	13	(6.28)
Missing	1	(0.48)
I completely trust doctors who do clinical research.		
Strongly agree	8	(3.86)
Agree	62	(29.95)
Not sure	83	(40.10)
Disagree	44	(21.26)
Strongly disagree	6	(2.90)
Prefer not to answer	3	(1.45)
Missing	1	(0.48)

Table 4.13 Scenario Responses

	Scenario: (N=207)	**1** (blood)	**2** (biopsy)	**3** (drug)
Physical risk		**n (%)**	**n (%)**	**n (%)**
	Very Safe	91 (43.96)	17 (8.21)	5 (2.42)
	Safe	63 (30.43)	66 (31.88)	21 (10.14)
	Neutral	26 (12.56)	60 (28.99)	47 (22.71)
	Risky	21 (10.14)	51 (24.64)	103 (49.76)
	Very Risky	6 (2.90)	12 (5.80)	31 (14.98)
	Missing	0	1 (0.48)	0
Willingness to participate				
Benefit your health				
	Yes	134 (64.73)	110 (53.14)	92 (44.44)
	No	24 (11.59)	54 (26.09)	71 (34.30)
	Don't know/unsure	48 (23.19)	42 (20.29)	43 (20.77)
	Prefer not to answer	1 (0.48)	1 (0.48)	1 (0.48)
	Missing	0	0	0
No benefit your health, but benefit health of someone close				
	Yes	145 (70.05)	126 (60.87)	102 (49.28)
	No	24 (11.59)	42 (20.29)	60 (28.99)
	Don't know/unsure	36 (17.39)	39 (18.884)	45 (21.74)
	Prefer not to answer	1 (0.48)	0	0
	Missing	1 (0.48)	0	0
Only contribute to scientific knowledge				
	Yes	83 (40.10)	57 (27.54)	34 (16.43)
	No	64 (30.92)	96 (46.38)	127 (61.35)
	Don't know/unsure	57 (27.54)	53 (25.60)	46 (22.22)
	Prefer not to answer	2 (0.97)	1 (0.48)	0
	Missing	1 (0.48)	0	0
Compensation				
	No compensation	21 (10.14)	5 (2.42)	5 (2.42)
	A minimum of $5	16 (7.73)	6 (2.90)	5 (2.42)
	A minimum of $10	78 (37.68)	**	**
	A minimum of $25	**	56 (27.05)	30 (14.49)
	A minimum of $50	44 (21.26)	**	**
	A minimum of $100	34 (16.43)	91 (43.96)	68 (32.85)
	A minimum of $500	**	35 (16.91)	83 (40.10)
	Prefer not to answer	12 (5.80)	12 (5.80)	13 (6.28)
	Missing	2 (0.97)	2 (0.97)	3 (1.45)

Note: ** = not asked

Table4.14 Association of Background and Informational Factors with Attitudes and Beliefs Score

	Responses: Positive/ Negative	Responses: H/M/L†	Continuous	Responses: No neutrals H/M/L†
Background factors	N=207	N=207	N=207	N=207
Race				
All race options	0.7204[5]	0.9128[5]	0.8537[1]	0.7596[5]
White/all other	0.8830[4]	0.8557[4]	0.8925[2]	0.8301[4]
Ethnicity	0.3621[4]	0.7001[4]	0.8277[2]	0.5639[4]
Gender	0.5678[4]	0.9904[4]	0.4834[2]	0.8235[4]
Free/reduced lunch	0.0989[3] *	0.2613[3]	0.4801[2]	0.1180[3]
College bound	0.6299[3]	0.9320[3]	0.8088[2]	0.3956[3]
Reported health status				
5 categories	0.2281[3]	0.6358[3]	0.8070[1]	0.6453[3]
3 categories	0.7402[3]	0.4461[3]	0.6629[1]	0.0791[5]
Chronic illness	0.1187[3]	0.1134[3]	0.4631[2]	0.3528[3]
Hospitalizations (year)	0.6214[3]	0.0201[3] **	0.0153[2] **	0.0501[3] *
Someone close ill	0.1538[3]	0.2627[3]	0.3063[2]	0.2300[3]
Informational factors				
Formal education				
High school curriculum				
All responses	0.6401[3]	0.0224[5] **	0.2565[1]	0.1275[5]
Yes/unknown/no	0.1700[3]	0.2560[3]	0.2911[1]	0.1593[3]
Yes/all others	0.3104[3]	0.1961[3]	0.1163[2]	0.0907[3] *
Knowledge score				
Continuous	0.9032[2]	0.5562[1]	<0.0001[2] **	0.5030[1]
2 categories	0.8423[3]	0.5375[3]	0.4042[2]	0.5342[3]
Informal education				
Familiarity with research				
Previously asked	0.3169[3]	0.1109[3]	0.0083[2] *	0.2647[3]
Previously participated	0.6865[3]	0.1445[3]	0.1215[2]	0.2368[3]
Someone close part	0.2806[3]	0.0012[3] **	0.0002[2] **	0.0021[3] **
Media				
Aware of media portray	0.6390[3]	0.6509[3]	0.4898[2]	0.6585[3]
Perceived media trust	0.7769[2]	0.0896[1] *	<0.0001[2] **	0.3454[1]

Note: Shaded column considered the most robust analysis, see document for discussion.

† H=high attitude scores (>80%); medium attitude scores (>60%, but < 80%); L=low attitude score ≤ 60%.

***P* <0.05, **P* < 0.10 level.

[1] ANOVA, [2] T Test, Cochran-Mantel-Haenszel Statistics: [3] Nonzero correlation, [4] Row means score, [5] General association.

Table 4.15 Association of Background and Informational Factors with Favoring Use of Human Beings for Clinical Research Results

	Response: Strongly favor Favor Neutral Oppose Strongly oppose	**Response: Favor Neutral Oppose**	**Response: Neutrals deleted Favor Oppose**
Background factors	N=207	N=207	N=107
Race			
All race options	0.9087[5]	0.7073[5]	0.7879[5]
White/all other	0.9895[5]	0.8699[5]	0.4403[5]
Ethnicity	0.3125[4]	0.4708[4]	0.5337[4]
Gender	0.0266[4]**	0.0226[4]**	0.7081[4]
Free/reduced lunch	0.3056[3]	0.3056[3]	0.5983[3]
College bound	0.6884[3]	0.8002[3]	0.4403[3]
Reported health status			
5 categories	0.2869[5]	0.2530[5]	0.8734[5]
3 categories	0.2099[5]	0.0494[5] **	0.6927[5]
Chronic illness	0.1785[3]	0.5583[3]	0.9320[3]
Hospitalizations (year)	0.0892[3]*	0.3900[3]	0.5667[3]
Someone close ill	0.8102[3]	0.8684[3]	0.8265[3]
Informational factors			
Formal education			
High school curriculum			
All responses	0.4082[5]	0.0965[5]*	0.8055[5]
Yes/unknown/no	0.5560[3]	0.5052[3]	0.5796[3]
Yes/all others	0.2131[3]	0.2555[3]	0.3907[3]
Knowledge score			
Continuous	0.7324[1]	0.6124[1]	0.7344[2]
2 categories	0.0226[3]**	0.0693[3]*	0.1262[3]
Informal education			
Familiarity with research			
Previously asked	0.0674[3]*	0.0757[3]*	0.4403[3]
Previously participated	0.4151[3]	0.2698[3]	0.7083[3]
Someone close part	0.2098[3]	0.2767[3]	0.8145[3]
Media			
Aware of media portray	0.0020[5]**	0.0062[3]**	0.4255[3]
Perceived media trust	0.5658[1]	0.3325[1]	0.9356[2]

Note: ***P* <0.05, **P* < 0.10 level.

[1] ANOVA, [2] T Test, Cochran-Mantel-Haenszel Statistics: [3] Nonzero correlation, [4] Row means score, [5] General association.

Table 4.16 Association of Background and Informational Factors with Trust in Clinical Researchers Score

	Response: Continuous	Response: 2 categories	Response: Neutrals deleted 2 categories
Background factors	N=207	N=207	N=138
Race			
All race options	0.2374[1]	0.2699[4]	0.2948[4]
White/all other	0.0163[2]**	0.1114[4]	0.0660[4]*
Ethnicity	0.8490[2]	0.7044[4]	0.9365[4]
Gender	0.9440[2]	0.9423[4]	0.8463[4]
Free/reduced lunch	0.3649[2]	0.4025[3]	0.6740[3]
College bound	0.2463[2]	0.0901[3]*	0.8204[3]
Reported health status			
5 categories	0.4276[1]	0.3301[5]	0.1957[5]
3 categories	0.3169[1]	0.3991[5]	0.5238[5]
Chronic illness	0.2595[2]	0.7006[3]	0.9645[3]
Hospitalizations (year)	0.4256[2]	0.5723[3]	0.8800[3]
Someone close ill	0.8802[2]	0.8374[3]	0.9486[3]
Informational factors			
Formal education			
High school curriculum			
All responses	0.0018[1]**	0.0031[3]**	0.0211[3]**
Yes/unknown/no	0.0199[1]**	0.0086[3]*	0.0638[3]*
Yes/all others	0.0143[2]**	0.0336[3]**	0.1810[3]
Knowledge score			
Continuous	<0.0001[2]**	0.2741[2]	0.3711[2]
2 categories	0.0069[2]**	0.0289[3]**	0.0149[3]**
Informal education			
Familiarity with research			
Previously asked	0.0861[2]*	0.1219[3]	0.2349[3]
Previously participated	0.0135[2]**	0.3384[3]	0.3551[3]
Someone close part	0.0661[2]*	0.1988[3]	0.3554[3]
Media			
Aware of media portray	0.5523[2]	0.7897[3]	0.8260[3]
Perceived media trust	0.0027**	<0.0001[2]**	0.1804[2]

Note: Shaded column considered the most robust analysis, see document for discussion.

**P <0.05, *P < 0.10 level.

[1] ANOVA, [2] T Test, Cochran-Mantel-Haenszel Statistics: [3] Nonzero correlation, [4] Row means score, [5] General association.

Table 4.17 Scenario 1 Association Results: Benefits Your Health

	Response: Yes/neutral/no	Response: Yes/all other	Response: Neutrals deleted Yes/no
	(N=206)	(N=206)	(N=158)
Attitude score			
Continuous	<0.0001[1]**	<0.0001[2]**	0.0005[2]**
3 categories	<0.0001[3]**	<0.0001[3]**	0.0150[3]**
2 categories	0.0067[3]**	0.0046[3]**	0.0231[3]*
Neutrals deleted			
3 categories	<0.0001[3]**	<0.0001[3]**	0.0010[3]**
2 categories	0.0023[3]**	0.0020[3]**	0.0085[3]**
Favor human use			
5 categories	0.0880[3]*	0.0926[3]*	0.1583[3]
3 categories	0.0450[3]**	0.0499[3]**	0.0989[3]*
Neutrals deleted			
2 categories	0.3566[3]	0.5183[3]	0.2894[3]
Trust in researchers			
Continuous	0.5725[1]	0.2522[2]	0.4762[2]
2 categories	0.4702[3]	0.7522[3]	0.3085[3]
Neutrals deleted			
2 categories	0.8542[3]	0.7635[3]	0.4767[3]

Note: Scenario 1: You are asked to participate in a clinical research study that consisted of TAKING A SMALL AMOUNT OF BLOOD OUT OF MY ARM.
If you were asked today, would you be willing to take part in this clinical research project if you felt it WOULD BENEFIT YOUR health now or in the future?

Shaded column considered the most robust analysis, see document for discussion.

$^{**}P < 0.05$, $^{*}P < 0.10$ level.

[1] ANOVA, [2] T Test, Cochran-Mantel-Haenszel Statistics: [3] Nonzero correlation, [4] Row means score, [5] General association.

Table 4.18 Scenario 1 Association Results: Benefits the Health of Someone Close

	Response: Yes/neutral/no	Response: Yes/all other	Response: Neutrals deleted Yes/no
	(N=205)	(N=205)	(N=169)
Attitude and belief score			
Continuous	0.0005[1]**	0.0002[2]**	0.0018[2]**
3 categories	0.0150[3]**	0.0049[3]**	0.0144[3]**
2 categories	0.0231[3]**	0.0211[3]**	0.0059[3]**
Neutrals deleted			
3 categories	0.0010[3]**	0.0008[3]**	0.0063[3]**
2 categories	0.0085[3]**	0.0154[3]**	0.0087[3]**
Favor human use			
5 categories	0.1583[3]	0.1940[3]	0.0919[3]*
3 categories	0.0989[3]*	0.1120[3]	0.0788[3]*
Neutrals deleted			
2 categories	0.2894[3]	0.1676[3]	0.0736[3]*
Trust in researchers			
Continuous	0.4762[1]	0.3705[2]	0.7826[2]
2 categories	0.3085[3]	0.4357[3]	0.4707[3]
Neutrals deleted			
2 categories	0.4767[3]	0.8251[3]	0.8321[3]

Note: Scenario 1: You are asked to participate in a clinical research study that consisted of TAKING A SMALL AMOUNT OF BLOOD OUT OF MY ARM.
If you were asked today, would you be willing to take part in a study that you felt WOULD NOT BENEFIT YOUR HEALTH BUT WOULD BENEFIT THE HEALTH OF SOMEONE CLOSE TO YOU?

Shaded column considered the most robust analysis, see document for discussion.

**P <0.05, *P < 0.10 level.

[1] ANOVA, [2] T Test, Cochran-Mantel-Haenszel Statistics: [3] Nonzero correlation, [4] Row means score, [5] General association.

Table 4.19 Scenario 1 Association Results: Adds to Scientific Knowledge

	Response: Yes/neutral/no	Response: Yes/all other	Response: Neutrals deleted Yes/no
	(N=204)	(N=204)	(N=147)
Attitude and belief score			
Continuous	<0.0001[1]**	<0.0001[2]**	<0.0001[2]**
3 categories	0.0012[3]**	<0.0001[3]**	0.0032[3]**
2 categories	0.3825[3]	0.2841[3]	0.3942[3]
Neutrals deleted			
3 categories	0.0006[3]**	<0.0001[3]**	0.0010[3]**
2 categories	0.5013[3]	0.2679[3]	0.5320[3]
Favor human use			
5 categories	0.0662[3]*	0.2545[3]	0.0741[3]*
3 categories	0.0871[3]*	0.3476[3]	0.0884[3]*
Neutrals deleted			
2 categories	0.2806[3]	0.9668[3]	0.2398[3]
Trust in researchers			
Continuous	0.4139[1]	0.2277[2]	0.4894[2]
2 categories	0.7295[3]	0.4452[3]	0.7823[3]
Neutrals deleted			
2 categories	0.9008[3]	0.6825[3]	0.8250[3]

Note: Scenario 1: You are asked to participate in a clinical research study that consisted of TAKING A SMALL AMOUNT OF BLOOD OUT OF MY ARM.
If you were asked today, would you be willing to take part in this clinical research project if it would NOT BENEFIT YOUR HEALTH NOW or in the future but will ADD TO SCIENTIFIC KNOWLEDGE?

Shaded column considered the most robust analysis, see document for discussion.

$^{**}P < 0.05$, $^{*}P < 0.10$ level.

[1] ANOVA, [2] T Test, Cochran-Mantel-Haenszel Statistics: [3] Nonzero correlation, [4] Row means score, [5] General association.

Table 4.20 Scenario 2 Association Results: Benefits Your Health

	Response: Yes/neutral/no	Response: Yes/all other	Response: Neutrals deleted Yes/no
	(N=206)	(N=206)	(N=164)
Attitude and belief score			
Continuous	<0.0001[1]**	<0.0001[2]**	<0.0001[3]**
3 categories	<0.0001[3]**	<0.0001[3]**	<0.0001[3]**
2 categories	0.0005[3]**	0.0003[3]**	0.0004[3]**
Neutrals deleted			
3 categories	<0.0001[3]**	<0.0001[3]**	<0.0001[3]**
2 categories	0.0002[3]**	0.0005[3]**	<0.0001[3]**
Favor human use			
5 categories	0.0023[3]**	0.0018[3]**	0.0048[3]**
3 categories	0.0014[3]**	0.0011[3]**	0.0035[3]**
Neutrals deleted			
2 categories	0.0035[3]**	0.0169[3]**	0.0029[3]**
Trust in researchers			
Continuous	0.1557[1]	0.3510[2]	0.0684[2]*
2 categories	0.0882[3]*	0.9311[3]	0.2681[3]
Neutrals deleted			
2 categories	0.1605[3]	0.6481[3]	0.1610[3]

Note: You are asked to participate in a clinical research study that consisted of CUTTING OFF A SMALL AMOUNT OF SKIN (about the size of a pencil eraser), called a biopsy. This would require an injection (shot) of numbing medicine so that you did not have any pain and two to three sutures (stitches). The biopsy would be on a place where the scar would not be seen, such as you're the top of your hip. There may be mild discomfort or pain for one to two days.
If you were asked today, would you be willing to take part in this clinical research project if you felt it WOULD BENEFIT YOUR health now or in the future?

Shaded column considered the most robust analysis, see document for discussion.

**P* <0.05, **P* < 0.10 level.

[1] ANOVA, [2] T Test, Cochran-Mantel-Haenszel Statistics: [3] Nonzero correlation, [4] Row means score, [5] General association.

Table 4.21 Scenario 2 Association Results: Benefits the Health of Someone Close

	Response: Yes/neutral/no	Response: Yes/all other	Response: Neutrals deleted Yes/no
	(N=207)	(N=207)	(N=168)
Attitude and belief score			
Continuous	0.0037[1]**	0.0328[2]**	0.0069[2]**
3 categories	0.0237[3]**	0.0459[3]**	0.0291[3]**
2 categories	0.2363[3]	0.4989[3]	0.1699[3]
Neutrals deleted			
3 categories	0.0059[3]**	0.0045[3]**	0.0153[3]**
2 categories	0.2345[3]	0.3301[3]	0.2195[3]
Favor human use			
5 categories	0.0532[3]*	0.2318[3]	0.0308[3]**
3 categories	0.0341[3]**	0.2053[3]	0.0157[3]**
Neutrals deleted			
2 categories	0.0190[3]**	0.2164[3]	0.0081[3]**
Trust in researchers			
Continuous	0.2961[1]	0.2420[2]	0.1197[2]
2 categories	0.1050[3]	0.9409[3]	0.1827[3]
Neutrals deleted			
2 categories	0.5910[3]	0.7119[3]	0.8000[3]

Note: You are asked to participate in a clinical research study that consisted of CUTTING OFF A SMALL AMOUNT OF SKIN (about the size of a pencil eraser), called a biopsy. This would require an injection (shot) of numbing medicine so that you did not have any pain and two to three sutures (stitches). The biopsy would be on a place where the scar would not be seen, such as you're the top of your hip. There may be mild discomfort or pain for one to two days.
If you were asked today, would you be willing to take part in a study that you felt WOULD NOT BENEFIT YOUR HEALTH BUT WOULD BENEFIT THE HEALTH OF SOMEONE CLOSE TO YOU?

Shaded column considered the most robust analysis, see document for discussion.

$**P < 0.05$, $*P < 0.10$ level.

[1] ANOVA, [2] T Test, Cochran-Mantel-Haenszel Statistics: [3] Nonzero correlation, [4] Row means score, [5] General association.

Table 4.22 Scenario 2 Association Results: Adds to Scientific Knowledge

	Response: Yes/neutral/no	Response: Yes/all other	Response: Neutrals deleted Yes/no
	(N=206)	(N=206)	(N=143)
Attitude and belief score			
Continuous	<0.0001[1]**	<0.0001[2]**	<0.0001[2]**
3 categories	<0.0001[3]**	<0.0001[3]**	<0.0001[3]**
2 categories	0.0421[3]**	0.0747[3]*	0.0462[3]**
Neutrals deleted			
3 categories	<0.0001[3]**	<0.0001[3]**	<0.0001[3]**
2 categories	0.0121[3]**	0.0388[3]**	0.0166[3]**
Favor human use			
5 categories	0.0008[3]**	0.0034[3]**	0.0016[3]**
3 categories	0.0013[3]**	0.0053[3]**	0.0024[3]**
Neutrals deleted			
2 categories	0.0235[3]**	0.2069[3]	0.0499[3]**
Trust in researchers			
Continuous	0.0369[1]**	0.1423[2]	0.0405[2]**
2 categories	0.0868[3]*	0.3109[3]	0.1183[3]
Neutrals deleted			
2 categories	0.0803[3]*	0.1904[3]	0.0866[3]*

Note: You are asked to participate in a clinical research study that consisted of CUTTING OFF A SMALL AMOUNT OF SKIN (about the size of a pencil eraser), called a biopsy. This would require an injection (shot) of numbing medicine so that you did not have any pain and two to three sutures (stitches). The biopsy would be on a place where the scar would not be seen, such as you're the top of your hip. There may be mild discomfort or pain for one to two days.
If you were asked today, would you be willing to take part in this clinical research project if it would NOT BENEFIT YOUR HEALTH NOW or in the future but will ADD TO SCIENTIFIC KNOWLEDGE?

Shaded column considered the most robust analysis, see document for discussion.

**P* <0.05, **P* < 0.10 level.

[1] ANOVA, [2] T Test, Cochran-Mantel-Haenszel Statistics: [3] Nonzero correlation, [4] Row means score, [5] General association.

Table 4.23 Scenario 3 Association Results: Benefits Your Health

	Response: Yes/neutral/no	Response: Yes/all other	Response: Neutrals deleted Yes/no
	(N=206)	(N=206)	(N=163)
Attitude and belief score			
Continuous	<0.0001[1]**	<0.0001[2]**	<0.0001[2]**
3 categories	0.0002[3]**	0.0002[3]**	0.0004[3]**
2 categories	0.0719[3]*	0.1180[3]	0.0717[3]*
Neutrals deleted			
3 categories	0.0001[3]**	0.0002[3]**	0.0002[3]**
2 categories	0.0728[3]*	0.1032[3]	0.0724[3]*
Favor human use			
5 categories	0.0490[3]**	0.0404[3]**	0.0609[3]**
3 categories	0.0206[3]**	0.0292[3]**	0.0248[3]**
Neutrals deleted			
2 categories	0.1263[3]	0.2944[3]	0.1206[3]
Trust in researchers			
Continuous	0.1546[1]	0.0785[2]*	0.1761[2]
2 categories	0.7476[3]	0.5764[3]	0.7774[3]
Neutrals deleted			
2 categories	0.2228[3]	0.1581[3]	0.2577[3]

Note: You are asked to participate in a clinical research study that consisted of TAKING A MEDICATION (DRUG) that will have some side effects from the medicine, such as feeling sick to your stomach (nausea) or throwing up (vomiting).
If you were asked today, would you be willing to take part in this clinical research project if you felt it WOULD benefit your health now or in the future?

Shaded column considered the most robust analysis, see document for discussion.

$^{**}P < 0.05$, $^{*}P < 0.10$ level.

[1] ANOVA, [2] T Test, Cochran-Mantel-Haenszel Statistics: [3] Nonzero correlation, [4] Row means score, [5] General association.

Table 4.24 Scenario 3 Association Results: Benefits the Health of Someone Close

	Response: Yes/neutral/no	Response: Yes/all other	Response: Neutrals deleted Yes/no
	(N=207)	(N=207)	(N=162)
Attitude and belief score			
Continuous	<0.0001[1]**	<0.0001[2]**	<0.0001[2]**
3 categories	0.0008[3]**	0.0006[3]**	0.0025[3]**
2 categories	0.0393[3]**	0.1887[3]	0.0333[3]**
Neutrals deleted			
3 categories	0.0015[3]**	0.0009[3]**	0.0035[3]**
2 categories	0.0585[3]*	0.1483	0.0537[3]*
Favor human use			
5 categories	0.1319[3]	0.1742[3]	0.1539[3]
3 categories	0.0818[3]*	0.1506[3]	0.0836[3]*
Neutrals deleted			
2 categories	0.2512[3]	0.5404[3]	0.2132[3]
Trust in researchers			
Continuous	0.2566[1]	0.1845[2]	0.4937[2]
2 categories	0.7578[3]	0.9519[3]	0.7774[3]
Neutrals deleted			
2 categories	0.4249[3]	0.3851[3]	0.4612[3]

Note: You are asked to participate in a clinical research study that consisted of TAKING A MEDICATION (DRUG) that will have some side effects from the medicine, such as feeling sick to your stomach (nausea) or throwing up (vomiting).
If you were asked today, would you be willing to take part in a study that you felt would NOT benefit YOUR health but would benefit the health of SOMEONE CLOSE TO YOU?

Shaded column considered the most robust analysis, see document for discussion.

**P* <0.05, **P* < 0.10 level.

[1] ANOVA, [2] T Test, Cochran-Mantel-Haenszel Statistics: [3] Nonzero correlation, [4] Row means score, [5] General association.

Table 4.25 Scenario 3 Association Results: Adds to Scientific Knowledge

	Response: Yes/neutral/no	Response: Yes/all other	Response: Neutrals deleted Yes/no
	(N=207)	(N=207)	(N=161)
Attitude and belief score			
Continuous	<0.0001[1]**	<0.0001[2]**	<0.0001[2]**
3 categories	0.0002[3]**	<0.0001[3]**	<0.0001[3]**
2 categories	0.0359[3]**	0.0424[3]**	0.0339[3]**
Neutrals deleted			
3 categories	0.00108[3]**	0.0008[3]**	0.0005[3]**
2 categories	0.0150[3]**	0.0276[3]**	0.0188[3]*
Favor human use			
5 categories	0.0069[3]**	0.0592[3]*	0.0251[3]**
3 categories	0.0049[3]**	0.0555[3]*	0.0204[3]*
Neutrals deleted			
2 categories	0.0437[3]**	0.3226[3]	0.1561[3]
Trust in researchers			
Continuous	0.0911[1]*	0.0954[2]*	0.0806[2]*
2 categories	0.2329[3]	0.2218[3]	0.2089[3]
Neutrals deleted			
2 categories	0.0188[3]**	0.0127[3]**	0.0122[3]**

Note: You are asked to participate in a clinical research study that consisted of TAKING A MEDICATION (DRUG) that will have some side effects from the medicine, such as feeling sick to your stomach (nausea) or throwing up (vomiting).
If you were asked today, would you be willing to take part in this clinical research project if it would NOT BENEFIT YOUR HEALTH NOW or in the future but will ADD TO SCIENTIFIC KNOWLEDGE?

Shaded column considered the most robust analysis, see document for discussion.

**P* <0.05, **P* < 0.10 level.

[1] ANOVA, [2] T Test, Cochran-Mantel-Haenszel Statistics: [3] Nonzero correlation, [4] Row means score, [5] General association.

CHAPTER V

CONCLUSIONS

Introduction

The final chapter will be presented in five parts. First, I will review why the Theory of Planned Behavior was chosen as the theoretical model for this project, and following that I will comment on the background factors associated with measures of behavioral beliefs and attitudes as a precursor to intention of willingness to participate (Specific Aim 2). Findings of this part will be compared to the existing body of literature. The third part details examination of associations between behavioral beliefs and attitudes and the respondents' reported intention of willingness to participate (Specific Aim 3). The fourth will address limitations of this project and the need for future research. Lastly, I propose the practical implications stemming from the findings of this study and how the findings may be used to impact future generations of research participants.

The Theory of Planned Behavior as the Theoretical Model

While other researchers have investigated factors associated with willingness to participate in clinical research, they have typically studied the direct relationship between background factors and the reported willingness to participate in clinical research without consideration of intermediate factors. For example, several investigators reported the effects of demographic factors, such as race, gender, and socioeconomic status (SES) on willingness to participate in clinical research (Advani et al, 2003; DeFreitas, 2010; Ding et al, 2007; Durant et al, 2009; Golub et al., 2005; Katz et al, 2009; Lara et al 2005; Lee, et al, 2005; Peterson et al, 2004; Priddy et al., 2006; Shavers et al., 2002; Wendler et al, 2005). Reflecting on these findings from other investigators, it seems that linking background factors directly to willingness to participate may not provide the total picture of what impacts an individual's

willingness to participate. For example, race, gender, or SES may not have a direct effect on the intention of willingness to participate in clinical research; rather, it may be that these factors shape how the individual sees the world around them, that is, one's beliefs and attitudes. The notion of background factors shaping beliefs and attitudes that go on to effect behavior is well documented in the literature (Kraus et al., 2012; Piff et al., 2012; Rocca & Harper, 2012). For example, Rocca and Harper (2012) found that Black, Latina, and White women have varying attitudes regarding contraception and as a result had differing behavior regarding the types of contraception they used.

How background factors may shape attitudes toward clinical research as a precursor to the intention of participating is not well described. Therefore, I used a novel approach to study the associations between background factors and the stated intention of willingness framed by the Theory of Planned Behavior (TPB) as the theoretical model. The TPB states that intention is the critical determinant in performing any behavior: the stronger the intention, the more likely the behavior will be performed. The TPB proposes three conceptually independent determinants of intention: 1) behavioral beliefs and attitude toward behavior; 2) subjective social norms (e.g. concern about family and friends' opinions about the behavior); and 3) perceived behavioral control (e.g. ability and opportunity to perform the behavior). It follows that each of these factors can be influenced by background factors, such as demographic variables or knowledge. Based on of the TPB, I investigated the linear progression from background factors to behavioral beliefs and attitudes to the intention of performing the behavior under study to performing the actual behavior.

I first examined the associations between background factors and participants' behavioral beliefs and attitudes regarding clinical research. I then examined the associations

between beliefs and attitudes and the stated intent to participate in clinical research (see Figure 5.1). As demonstrated by the following reports, the TPB was well suited to be the theoretical model for this study. Findings from my research demonstrated the associations between background factors to behavioral beliefs and attitudes and then behavioral beliefs and attitudes to the intent of being willing to participate in clinical research.

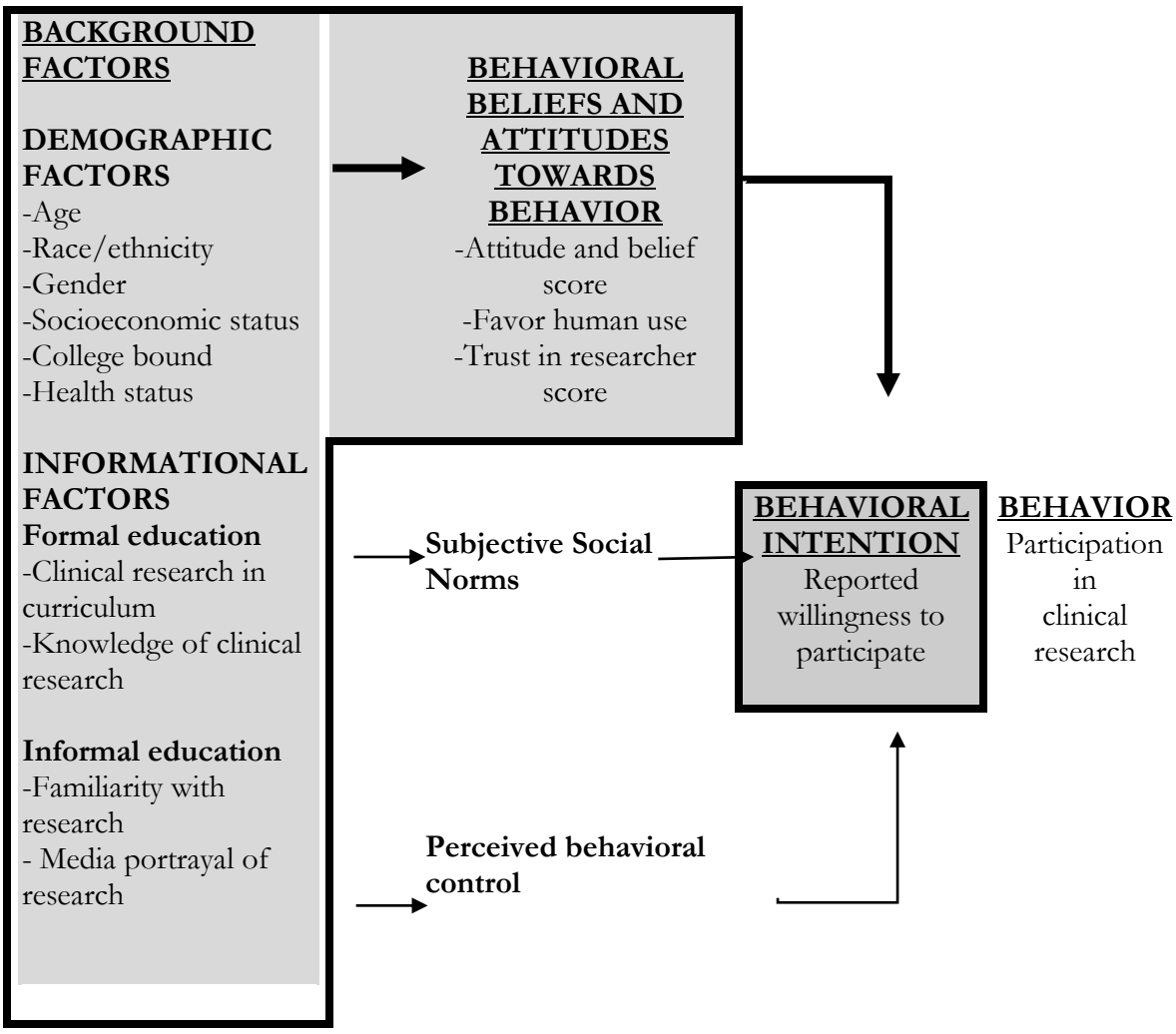


Figure 5.1. Theory of Planned Behavior

Background Factors Associated with Behavioral Beliefs and Attitudes Measures (Specific Aim 2)

One aim of this study was to examine the associations between background factors (demographic and information factors) and measures of behavioral beliefs and attitudes. First, I discuss the associations between demographic variables and behavioral beliefs and attitudes, including how these findings relate to the literature review. Then I discuss the associations between the information factors, first formal then informal, and behavioral beliefs and attitudes, again including how my findings relate to the literature review.

Demographic Variables

Findings from my study suggest that few of the investigated demographic factors were associated with the measures of behavioral beliefs and attitudes in this sample. Race and gender were each associated with only one of the behavioral beliefs and attitudes measures, that is, white respondents had higher trust in researcher scores compared to all other races (OR=2.24) and males were more likely to favor the use of human beings in clinical research. Health status was associated with one belief and attitude measure, that is, favoring human use. This may suggest that the demographic factors play a small part in reported willingness to participate.

Previous investigators examined the direct effect of demographic variables on willingness to participate (Advani et al,; DeFreitas, 2010; Durant et al, 2009; Golub et al., 2005; Lara et al 2005; Lee et al., 2005; Katz et al, 2009; Peterson et al., 2004; Priddy et al., 2006; Shavers et al., 2002; Wendler et al, 2005). Of those investigators who reported on race and ethnicity, the majority reported no difference between racial and ethnic groups in willingness to participate (DeFreitas, 2010; Durant et al, 2009; Golub et al., 2005; Katz et al, 2009; Peterson et al., 2004; Priddy et al., 2006; Shavers, Lynch, & Burmeister, 2002; Wendler

et al, 2005). Although a few studies that did report a difference, there were disagreements about whether whites or minorities were more likely to participate (Advani et al, 2003; Lara et al 2005; Lee et al., 2005). Reports of gender having an effect on willingness to participate were inconsistent as well, as some investigators suggested males were more likely to indicate willingness to participate in clinical research (DeFreitas, 2010; Ding et al, 2007; Peterson et al., 2004), but one publication suggested females were more likely to report willingness to participate (Golub et al, 2005).

The weak association between demographic variables and beliefs and attitudes regarding clinical research seem to be supported by the mixed results of the effect of demographic variables on willingness to participate by other investigators. However, it should be noted that previous investigators used either minority populations or populations burdened by illness and those factors may have affected the results when compared to my sample of Iowa high school seniors. It is also possible that the unique sample of my study population limits the ability to make comparisons to the results of other studies.

Informational factors

The present study also examined the associations between informational factors and behavioral beliefs and attitudes regarding clinical research. Informational factors were categorized as either 'formal education' or 'informal education'. The findings suggest that information about clinical research, acquired both by formal education and informal education, was associated with behavioral beliefs and attitudes about clinical research; these will be discussed respectively.

Formal Education

I examined formal education as measured by asking whether respondents thought their education included learning about clinical research as follows: "The education I

received during school included learning about clinical research". The results indicated that the minority of the respondents perceived clinical research to be part of their curriculum, and interestingly, respondents who indicated that their education included learning about clinical research had greater trust in researchers (OR=2.3). Information about the presence or absence of formal education about clinical research has not been reported to date. It is beyond the scope of the results of this study to speculate that the addition of curriculum regarding clinical research results in improvement in respondents' attitudes about clinical research. However, this may be an interesting area to explore in the future.

Formal education was measured by asking questions about the process and procedures of clinical research. Respondents' who were more knowledgeable about clinical research were more likely to: 1) have a more positive attitude towards research, 2) were more favorable towards the use of human beings in clinical research, and 3) had more trust in researchers. Formal education, measured by accurate knowledge about the process and procedures of clinical research, has been reported to have a positive effect on willingness to participate (Dunlop et al, 2011; Lara et al 2005; Priddy et al., 2006). Similar to the present study, these investigators examined the knowledge of focused populations, either minorities (Dunlop et al, 2011; Priddy et al., 2006) or oncology patients and their families (Lara et al 2005). Interestingly, despite our sample differences, our findings are approximately the same; in effect, the present findings reinforce the notion that accurate knowledge regarding the process and procedures involved in clinical research may impact individuals' willingness to participate.

Informal Education

Informal factors, such as relative familiarity with the research process (measured by respondents reporting having participated or knowing someone who had participated) were

associated with a more positive attitude toward research, were more favorable towards the use of human beings in clinical research and had more trust in researchers. Note, in the present sample, the numbers of respondents who reported having participated or knowing someone who participated in clinical research were small; therefore, this association may be specific only to the present sample. However, other investigators who examined the effect of having participated in a previous clinical trial, or having someone close who participated in a clinical trial, reported that it was positively associated with willingness to participate in future research (Advani et al, 2003; DeFreitas, 2010; Durant et al, 2009; Holman et al, 2010; Volkmann et al., 2009). These concordant findings, despite our differences in the samples of populations, suggest that familiarity with the research process and procedures has a positive impact on willingness to participate.

The present findings suggest that informal knowledge gained via the media, another type of informal education, was also associated with respondents' behavioral beliefs and attitudes scores. Specifically, respondents who were aware of research or researchers in the media were more likely to favor the use of human beings in clinical research. More interesting is that respondents who felt the media depicted researchers as trustworthy were associated with more positive attitudes regarding clinical research and higher trust in researcher scores.

Media were rarely addressed in other research related to willingness to participate in clinical research. Only two studies examined the influence of the media on willingness to participate and their reports regarding the effect of media were discordant. One study reported that the media exposure resulted in a positive first impression for the majority of people who were willing to participate, but the majority of the participants reported they thought media reports about clinical research were false (Pentz et al, 2002). The other study

reported increased accrual in cancer trials advertised in a mass media campaign; however the same authors also reported that is was unclear if the increased accrual was the result of the campaign or other variables (Umutyan et al, 2008).

Although the literature review shows discordant views about the effect of media on willingness to participate in research, it has been long accepted that the media can have a powerful impact on attitude formation and subsequent behavior (Petty, Brinol, & Priester, 2007; Turow, 1996). For example, investigators have demonstrated that media can affect adolescents' attitudes and decisions on topics such as initiating sexual activity, smoking, and alcohol consumption (Bleakley, Hennessy, Fishbein, & Jordan, 2008; Chock, 2011; Collins et al, 2004; Escobar-Chaves et al., 2005; Evans et al., 1978; Ho, Scheufele, & Corley, 201; Lou et al., 2012; Smith & Foxcroft, 2009). The findings from this novel investigation suggest that media may also be associated with the beliefs and attitudes of young adults regarding clinical research and researchers. While the present results may have been affected by the specificity of my sample (that is Iowa high school seniors), it is certainly an area worthy of further exploration.

Behavioral Beliefs and Attitudes Measures Associated with Reported Intention of Willingness to Participate (Specific Aim 3)

The intention of willingness to participate was examined using three scenarios consisting of a blood draw, a biopsy, and a drug trial with anticipated side effects. Each scenario was further divided into three different levels of potential benefit. Those situations described the research as: 1) benefiting the respondent, 2) would not benefit the respondent but benefiting someone close, and 3) would not benefit the respondent but the results would add to scientific knowledge. Behavioral beliefs and attitude measures (attitude and belief

scores, favoring human use, and trust in researcher scores) that were associated with willingness to participate in each situation were examined.

The findings from this study suggest that respondents' attitude and belief scores and whether or not they favored human use in research were associated with the respondents' reported intention of willingness to participate in clinical research. That is, respondents who demonstrated a more positive attitude toward research were more likely to report that they would be willing to participate in clinical research involving a blood draw that benefited themselves (OR=3.3) or a skin biopsy (OR=3.7).

Previously, other investigators reported that personal benefit is a strong influence on reported willingness to participate in populations diagnosed with cancer (Advani et al., 2003; Hall et al., 2010), mental illness (Dunn et al, 2009; Zullino et al., 2003), and connective tissue disorders (Lee et al., 2005; Holman et al., 2010). To these populations, 'personal benefit' was described as the possibility of free medical care or the access to treatment that would not otherwise be available due to its experimental nature. The real burden of illness and disease in these populations and the concern about obtaining adequate treatment may have affected their attitude towards clinical research and thus their reported intention of willingness to participate. In contrast, the present study examined the attitudes and intention of willingness to participate in a sample of community dwelling young adults who reported themselves to be in generally good health. Health status was only weakly associated with beliefs and attitudes as a precursor to the intention of willingness to participate in clinical research. These results may suggest that in different populations, background factors may have varying affects on beliefs and attitudes regarding clinical research. In other words, attitudes regarding clinical research may not be static, but instead may continue to evolve as background factors change.

The other measure of behavioral beliefs and attitudes, the trust in researcher score, was only associated with respondents' reported willingness to participate in research that adds to scientific knowledge. That is, respondents with higher trust in researcher scores were more likely to indicate a willingness to participate in clinical research that was of no benefit to the participant but added to scientific knowledge (OR=1.6). This is of interest to me because while clinical research participants *may* benefit in some way from participating, much research is conducted that does not directly benefit the participant (Grady, 2007). Dr. Christine Grady, chief of the Department of Bioethics at the NIH Clinical Center explained that, "the goal of clinical research is to generate knowledge useful to improving medical care or the public health and thus serve the common or collective good" (2007, p 15). Therefore the association between trust in researchers and willingness to participate in clinical research that does not directly benefit the participant but adds to scientific knowledge is an important consideration.

The finding regarding the association between trust in the researcher and the willingness to participating in research that only adds to scientific knowledge is in agreement with previous investigations cited in the literature review. Of those studies reviewed, six studies reported that *mistrust* was as a factor affecting *unwillingness* (Ding et al, 2007; Dunlop et al., 2011; Durant et al., 2011; Lee et al., 2005; Shavers et al., 2002; Volkmann et al., 2009). However, as noted in Chapter 2, previous investigators may have been looking at how patients view their physicians as researchers given these studies were conducted in populations in which all participants were diagnosed with a disease and most likely under the regular care of a physician. The present study, on the other hand, used respondents that generally denied the presence of a chronic illness or having been hospitalized in the past year and therefore were unlikely to be under a doctor's care. Although the present study sample

has limitations, it does suggest that trust in researchers may be an important consideration for research that does not benefit the participant and is worthy or further investigation.

Study Limitations and Future Research

There are limitations to my research. As presented in Chapter 4, the overall response rate of the Iowa schools districts superintendents was 2.9%. The low response rate by superintendents or the high school contact person limited my access to the desired study population. However in schools that did allow access, the response rate of distributed packets was 75%. None the less, the lack of response from superintendents or the contact person from the high school lead to a low *overall* participate rate considering the number of Iowa high school seniors. This overall low participation rate raises concerns about nonparticipation bias (also referred to as nonresponse bias). As defined by Galea & Tracy, nonparticipation bias occurs when systematic errors are introduced if reasons for study participation are associated with the area of interest (2007, p 647). In the present case, this would imply that the respondents who were in schools that allowed me to approach their senior class and then the seniors that elected to participate are inherently different in some way than the individuals who we were not allowed to approach or seniors who refused to participate. Additionally, analyses demonstrated that those who did participate in my study were not representative of the entire population of Iowa high school seniors by race/ethnicity or socioeconomic status (as measured by participation in the free/reduced rate lunch program). Both of these factors may affect the results and generalizability to the population of young adults.

Another limitation is that, as with the studies identified in the literature review, respondents indicated their intention of willingness to participate in hypothetical clinical research scenarios. Hypothetical scenarios have been used in studies in various disciplines

for many years (Herskovits, 1950; Hughes & Huby, 2002; Kim, 2012; Schoenberg & Ravdal, 2000). A reported advantage of using hypothetical situations is that it allows the researcher to "obtain information beyond the informant's current personal situation…particularly important when assessing how awareness and attitude might shape future behaviors" (Schoenberg & Ravdal, 2000, p 64). On the other hand, a disadvantage of hypothetical situations is that the responses may not be an accurate reflection of what the individuals would really do (Schoenberg & Ravdal, 2000). In the present study, it is not possible to surmise if respondents would actually participate in future clinical research if they were approached.

In contrast, a strength of this research is the reporting and analysis of novel information regarding young, community-dwelling adults' attitudes and beliefs about willingness to participate in clinical research. The findings from this research may be used to generate ideas for future studies regarding participation in clinical research. For instance, one possible line of study would be to examine the other variables in the Theory of Planned Behavior. As previously discussed, this study only examined part of the model of TPB due to the novelty of the research. Future research should expand to consider the other variables in the theory, i.e. Subjective Social Norms (the impact of how *others*, such as parents or friends, view the behavior) and Behavioral Control (the perceived ease or difficulty of performing the particular behavior) as precursors to the intention of being willing to participate.

Another area of research that would be a valuable addition to the field would be a longitudinal analysis of the variables that I examined. As pointed out in Section 3, factors, such as health status, associated with willingness to participate may change over time.

Further research is needed to establish whether attitudes regarding clinical research change over time and to investigate which background factors are associated with such changes.

Practical Implications

A germane finding of this research project is that there were more informational factors associated with behavioral beliefs and intentions than demographic factors as precursors to the intent of being willing to participate in clinical research. This is excellent news for those who conduct research as *informational factors may are inherently changeable*. That is, the addition of information about clinical research to high school curricula may result in increased participation rates when individuals are presented with an opportunity to participate in clinical research at a later date. This practical implication is plausible given that, as presented in Chapter 1, attitude susceptibility is high during young adulthood and attitudes formed in young adulthood are difficult to change (Visser & Krosnick, 1998). Additionally, I also found that respondents who were more knowledge about the processes and procedures of clinical research had a more positive attitude regarding clinical research, were more in favor of the use of human beings for clinical research, and had higher trust in research which are precursors to the intention of willingness to participate. Therefore, addressing the informational factors associated with a positive attitude towards clinical research may be one piece of the puzzle to impact future participation in research.

Media may also be useful tools for providing information towards cultivating a positive attitude regarding clinical research with hopes of impacting participation in clinical research. This is reasonable given that reports show that all forms media can provide information that influences attitudes and subsequent behavior, including volunteerism (Kwak, Poor, & Skoric, 2006; Morgan, Shanahan, & Signorielli, 2008; Shah, Rojas, & Cho, 2008; Shah, Schmierback, Hawkins, Espino, & Donovan, 2002). The influence of media

related to participation in clinical research calls for further examination via well designed studies as previous investigations were unable to sort out the effect of media from other intervening variables (Umutyan et al., 2008). Considering this, it may be possible to envision a program of education utilizing the media aimed at young adults. One might propose using clips of existing media programs depicting clinical research as a springboard for discussion pointing out the truths and fallacies. Thereby, promoting correct knowledge of clinical research and human subjects protection.

Conclusions

This study helped to identify factors associated with community-dwelling young adult's beliefs and attitudes regarding clinical research and how these are associated with the intention of willingness to participate in clinical research. Knowing which factors are associated with young adults' attitudes and willingness to participate will be of benefit to those who conduct research as they can work to identify and rectify such barriers to participation. In this sample, data analyses suggest that informational factors had a greater influence on young adults' perceptions about clinical research than demographic factors. Interventions aimed at providing information about clinical research process and procedures to young adults may be of benefit to attitude formation and thus may impact rates of future enrollment in clinical research. The media may a useful venue for providing such information.

APPENDIX A

EMAIL COMMUNICATION TO IOWA PUBLIC SCHOOL DISTRICT SUPERINTENDENTS

Hello Superintendent (..*NAME*..).

I have received your name from the University of Iowa Department of Education Cooperating Schools Program as the contact person for obtaining a Statement of Cooperation. The Statement of Cooperation is to allow me to conduct a research project within your school district. I am a PhD candidate at the University of Iowa College of Nursing and currently working on a research project for my dissertation. My research will examine what affects young adults', ages 18 to 20, willingness to participate in future clinical research. This involves students completing a paper/pencil survey with approximately 50 questions. The survey will take about 15 minutes to complete.

I would like to ask if you would be willing to let me come to your high schools to recruit senior students who are 18 years of age or older to participate in my study. I would work with each of your high school officials to determine the exact dates and times of my presence. My goal is conduct my research project across the state of Iowa in the month of May. My research project will take one day at each high school. I am willing to work with your administration, principals, and teachers to avoid any inconvenience or burden on their part.

I will have completed the University of Iowa Institutional Review Board (IRB) approval prior to coming to your school. I am attaching a brief description of my research project and draft copy of the Informed Consent document that will be used. Since I am only recruiting students who are over the age of 18, they do not need parental permission to participate in this study. I am also attaching a draft of the survey that I will be using. I am happy to furnish you with a copy of the IRB approval, approved Informed Consent document and finalized questionnaire prior to coming to your school.

If you are willing to have me come to your school, please respond to this email with a note stating that you are willing to allow me to come to your school to recruit students that will serve as the Statement of Cooperation. Most importantly, please include the name of a contact person at each high school. I will contact this person to work out the days and how to implement my research project with as little disruption as possible.

If I have erroneously contacted you, please let me know. If there is someone else that I should contact, please also include that information.

Please do not hesitate to contact me if you hav e any questions or concerns via email or at my cell phone 319-400-7120. Thank you in advance for considering my project.

Warmest regards,
Debra Brandt, MSB, MSN, RN

Lay abstract sent to Iowa Public School district Superintendents

TITLE: WHAT FACTORS INFLUENCE YOUNG ADULTS' ATTITUDES AND BELIEFS REGARDING WILLINGNESS TO PARTICIPATE IN FUTURE CLINICAL RESEARCH? (version 3.2.2012)

Principle Investigator: Debra Brandt, MSB, MSN, RN

Recruitment of an adequate number of volunteers is crucial to the completion of human subjects research, but historically researchers have experienced a multitude of problems in recruiting volunteers to participate in clinical research. Overall clinical research participation rates have decreased in the past thirty years and it is anticipated that rates of clinical research participation will continue to decline in the upcoming years.

Attitudes and reasons relevant to participation in clinical research have been examined by a number of researchers. Research has been primarily focused on populations either impacted by an illness/disease or minority populations. One population seldom studied is community-dwelling young adults and their views on participating in research. This is a *critical* population as this is the potential pool of participants for future prevention and treatment studies.

The purpose of the proposed study is to examine the factors that influence the community-dwelling young adults' attitudes and willingness to participate in clinical research. To investigate this, approximately 100 participants will be recruited for a cross-sectional study at high schools across the state of Iowa. School officials will be contacted for permission to recruit study participants from their student population prior to recruitment. The investigator will seek approval to conduct this study by the University of Iowa Institutional Review Board (IRB)-02 prior to the initiation of any study recruitment of any participants or study procedures.

For this study, a one-time paper-and-pencil questionnaire will be administered and collected from willing research participants. Inclusion criteria for the proposed study include high school students who are ages 18 and older. All interested and eligible high schoolers will receive a packet that contains an informed consent document, the questionnaire, and instructions on how to return the questionnaire. Participants can read the consent (consists of one page) and complete the questionnaire (approximately 50 questions) at their convenience throughout the day. Based on the Theory of Reasoned Action, the questionnaire will include items that explore attitudes, knowledge, and trust in clinical research and willingness to participate in (see attached copy). The packet will contain a sheet with instructions on how to return the questionnaire prior to going home for the day. Participants who complete the questionnaire will be compensated for their time and effort with a small gift card, such as iTunes, which is given to the participant upon completion of the questionnaire.

All information will be coded without identifying information, such as names. The data will be analyzed to identify how demographic information, knowledge about clinical research and the media affect willingness to participate in future clinical research. All data will be stored in a computer file that is password protected at the University of Iowa in accordance with University of Iowa policies.

Draft Informed Consent sent to Iowa Public School district Superintendents

INFORMED CONSENT DOCUMENT (version 3.5.2012)

We are inviting you to participate in a research study. The purpose of the study is to see what factors affect young community-dwelling adults, ages 18-20, willingness to participate in future clinical research.

We invite you to be in this study because you are a young adult community-dwelling adult between the ages of 18-20. Approximately 100 people will take part in this study conducted by University of Iowa researchers.

If you agree to participate, we would like you to complete the attached survey that asks about what you know about clinical research and how you feel about participating in future clinical research.

If you would like to participate in this study, complete the enclose survey and return it to the collection point (mutually agree upon area) by the end of school today. Returning the completed survey or questionnaire will indicate your willingness to participate in the study. You will be given a small gift card as a thank you for completion of the study survey at the time you return your survey.

If you do not want to participate in this study, please return the blank survey to the collection point.

PLEASE FOLLOW THE DIRECTIONS AT THE END OF THE PACKET FOR RETURNING THE SURVEY.

If you decide to complete the survey, we will keep the information you provide confidential, however federal regulatory agencies and the University of Iowa Institutional Review Board (a committee that reviews and approves research studies) may inspect and copy records pertaining to this research. Your name will be removed from your answers to the survey and from that time on your completed survey will be marked with a code number. If we write a report about this study we will do so in such a way that you cannot be identified.

There are no known risks from being in this study, and you will not benefit personally. However we hope that others may benefit in the future from what we learn as a result of this study. You will not have any **costs** for being in this research study.

Taking part in this research study is completely voluntary. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

If you have any questions about the research study itself or experience a research related injury, please contact Debra Brandt at 319-356-1736 or e-mail debra-brandt@uiowa.edu. If you have questions about the rights of research subjects, please contact the Human Subjects Office, 105 Hardin Library for the Health Sciences, 600 Newton Rd, The University of

Iowa, Iowa City, IA 52242-1098, (319) 335-6564, or e-mail irb@uiowa.edu. To offer input about your experiences as a research subject or to speak to someone other than the research staff, call the Human Subjects Office at the number above.

Thank you very much for your consideration.

Sincerely,

Debra Brandt, MSB, MSN, RN
University of Iowa Clinical and Translational Science and University of Iowa College of Nursing

APPENDIX B

PERMISSIONS TO USE INVESTIGATORS' SURVEYS

RE: Survey willingness to participate

Jeanette Trauth [trauth@pitt.edu]
Sent: Tuesday, January 24, 2012 10:09 AM
To: Brandt, Debra
Attachments: ADULT SCIENCE LITERACY Sur~1.doc (169 KB)

Dear Deb.,

Thank you for your interest in my research. I have attached the survey instrument and you may use it if you like. Please acknowledge the source. To be honest, this was done so long ago, as I recall, we developed the questionnaire based on issues that we perceived had not been addressed in the literature at the time—the mid-1990s. To the best of our knowledge, this was the first survey of the general public on this topic that was ever done.

Hope this helps.

Jeanette Trauth

From: Brandt, Debra [mailto:debra-brandt@uiowa.edu]
Sent: Tuesday, January 24, 2012 8:41 AM
To: trauth@pitt.edu
Subject: Survey willingness to participate

Good morning Dr. Trauth.

I am a PhD candidate working on my dissertation at the University College of Nursing. I am interesting in conducting a study that examines attitudes and factors which affect willingness to participate in medical research in young adults.

I would like to potentially use the survey you describe in your article "Public attitudes regarding willingness to participate in medical research studies" written with Musa, Siminoff, Jewel and Ricci.

Would you be willing to share your original questionnaire with me and allow me to use them (or a portion of them) in my study?

RE: Permission to use the scale in Attitudes and views of the general public toward research.

Karen Burns [BurnsK@smh.ca]
Sent: Wednesday, March 28, 2012 7:52 AM
To: Brandt, Debra

Yes. Thank you for agreeing to acknowledge and reference it's use.

my best,

karen

Karen E.A. Burns MD, FRCPC, MSc
Critical Care Medicine
St. Michael's Hospital
30 Bond Street, Office 4-045 Queen Wing
Toronto, Ontario
M5B 1W8

From: Brandt, Debra [debra-brandt@uiowa.edu]
Sent: March 27, 2012 6:43 PM
To: Karen Burns
Subject: RE: Permission to use the scale in Attitudes and views of the general public toward research.

Hello Dr. Burns.
I wrote to you in January expressing an interest in possibly using the questionnaire that you used in the paper "Attitudes and Views of the General Public Toward Research Participation". As you may recall, I am a PhD student at the University of Iowa College of Nursing.

I would like to use parts of your questionnaire ""Attitudes and Perceptions Toward Participation in Clinical Research" with your permission. I most likely will not use the entire questionnaire as I am adding other questions and am trying to be mindful about subject burden. Dr. Jeanette Trauth (Pittsburg) has also granted me permission to use her questionnaire.

I will acknowledge and reference your questionnaire in any publications

If you agree to allow me to use your questionnaire, please respond affirmative to this email.
Please also include your name printed at the bottom.

Best,
Debra Brandt, MSB, MSN
University of Iowa College of Nursing

RE: Measuring trust instrument.

Mark Hall [mhall@wakehealth.edu]
Sent: Tuesday, January 31, 2012 5:05 PM
To: Brandt, Debra
Attachments: Wake Forest University Thu~1.doc (52 KB)

Yes, you're welcome to use and adapt our survey(s), with appropriate acknowledgement.

Attached is complete info.

Best of luck,

Mark A. Hall
Professor of Law and Public Health
Wake Forest University
Winston-Salem NC
http://law.wfu.edu/faculty/profile/hallma/

From: Brandt, Debra [mailto:debra-brandt@uiowa.edu]
Sent: Tuesday, January 31, 2012 11:44 AM
To: Mark Hall
Subject: Measuring trust instrument.

Good morning.

I am a PhD candidate working on my dissertation at the University of Iowa College of Nursing. I am interesting in conducting a study that examines attitudes and factors which affect willingness to participate in medical research in young adults in the United States.

I have read your articles regarding the development of your 'medical trust' questionnaire. With your permission, I would like to use the questionnaire.
I would adapt it to look at trust in researchers as opposed to physicians.

Would you be willing to share your original questionnaire and scoring system with me and allow me to use them (or a portion of them) in my study?

Thank you in advance for your help.
Debra Brandt, MSB, MSN.

Re: Public attitude towards biomedical research at outpatient clinics of King Abdulaziz medical city, Riyadh, Saudi Arabia

Mostafa Abolfotouh [mabolfotouh@gmail.com]
Sent: Saturday, January 28, 2012 4:26 AM
To: Brandt, Debra
Cc: Mohammed Jumah [jumahm@gmail.com]
Attachments: Final Questionnaire form.pdf (682 KB)

Dear Debra,

It gives me pleasure to share with you the Arabic questionnaire used for the below mentioned manuscript. I appreciate you would kindly acknowledge us (King Abdullah International Medical Research Center' King Saud Bin-Abdulaziz University for Health Sciences, Riyadh, Saudi Arabia) in your thesis or any report out of your study. This questionnaire was constructed based on revision of many other previous studies on this topic. The questionnaire was tested for reliability (Test-retest reliability) and assessed for its validity by expert opinion. You need to translate the attached questionnaire and do back translation to assess its validity.

I appreciate you would kindly acknowledge the receipt of this message and attached questioonaire

Best regards

Prof. Mostafa Abolfotouh

On Tue, Jan 24, 2012 at 11:13 PM, Brandt, Debra <debra-brandt@uiowa.edu> wrote:

> Hello.
>
> I am a PhD candidate working on my dissertation at the University College of Nursing. I am interesting in conducting a study that examines attitudes and factors which affect willingness to participate in medical research in young adults in the United States.
> I would like to potentially use the survey you describe in your article above.
> Would you be willing to share your original questionnaire and scoring system with me and allow me to use them (or a portion of them) in my study? I am particularly interested in the "Attitude to biomedical research scale".
>
> If you are willing to allow me to use your survey, I will need to defend the use of your questionnaire to my dissertation committee. I have read the methods section of your article and do not see a description of how your questionnaire was developed. Can you tell me how you developed the questionnaire? Did you do factor analysis or internal consistency or reliability or validity testing? Anything you can share would be appreciated.
>
> Lastly, did you have a theoretical model in mind when you developed your questionnaire. To me, I can imagine this may have been based on the Theory of Reasoned Action or the Theory of Planned Behavior.
> Thank you in advance for your help.
> Deb Brandt.

APPENDIX C

ATTITUDES AND FACTORS AFFECTING YOUNG ADULTS' WILLINGNESS TO PARTICIPATE IN CLINICAL RESEARCH QUESTIONNAIRE

Hello,
I am conducting a survey to find out your thoughts about participating in clinical research studies. Your input will help me to understand factors that affect young adults' willingness to participate in clinical research studies.

This survey will take about 20 minutes to complete. To receive payment for participating you must respond to every question. I have included an option of 'prefer not to answer' for questions that you do not want to answer for any reason.
Please return the completed survey to the collection point.
Thank you for considering participating in this survey**.**
Debra Brandt, MSB, MSN, RN

"Clinical research" is the study of human biology, health, and illness involving human beings. The goal of clinical research is to add to the knowledge about human health and illness. There are many different types of clinical research studies, such as studies that lead to better ways to diagnose and prevent physical or mental illnesses to studies that help determine the best way to treat illnesses, such as new drugs. Clinical researchers use people or things that come from people, such as blood, tissue, thoughts, and feelings, for their studies. The results of these studies are intended to be used to improve medical care or public health. The clinical research team can include doctors and nurses as well as other health care professionals.

These questions are about you. Please indicate your…
(Please check ONE response per question only)

1. **Age**	___ years
2. **Gender**	□ Male □ Female □ Prefer not to answer
3. **Race**	□ American Indian/ Alaskan native □ Asian □ Black or African American □ Native Hawaiian/ Other Pacific Islander □ White □ Other, please indicate _____ □ Prefer not to answer
4. **Ethnicity**	□ Hispanic or Latino □ Not Hispanic or Latino □ Prefer not to answer

Please answer the following questions.
(Please check ONE response per question only)

5. **Are you participating in the free or reduced lunch program?**	□ Yes □ No □ Don't know/unsure □ Prefer not to answer
6. **After you graduate from high school do you plan to go to college?**	□ Yes □ No □ Don't know/unsure □ Prefer not to answer
7. **In general, would you say <u>your</u> health is…**	□ Excellent □ Very good □ Good □ Fair □ Poor □ Prefer not to answer
8. **Have you ever been told in the past by a doctor that <u>you</u> have an illness that has lasted more than three months?**	□ Yes □ No □ Don't know/unsure □ Prefer not to answer
9. **Have you been hospitalized within the past year?**	□ Yes □ No □ Don't know/unsure □ Prefer not to answer
10. **To the best of your knowledge, does <u>someone close to you</u>, such as a family member or friend, been very sick or had illness that has lasted more than three months?**	□ Yes □ No □ Don't know/unsure □ Prefer not to answer

Please answer the following questions.
(Please check ONE response per question only)

11. **Prior to today, have <u>you</u> ever been <u>asked</u> to participate in a clinical research project?**	□ Yes □ No □ Don't know/unsure □ Prefer not to answer
12. **Prior to today, have <u>you</u> ever <u>participated</u> in a clinical research project?**	□ Yes □ No □ Don't know/unsure □ Prefer not to answer
13. **To the best of your knowledge, has <u>someone close to you</u>, such as a family member or friend, ever participated in a clinical research project?**	□ Yes □ No □ Don't know/unsure □ Prefer not to answer

When someone participates in a clinical research study, do you think that they are always, sometimes or never…
(Please check ONE response per line only)

	Always	Sometimes	Never	Don't know/ unsure	Prefer not to answer
14. told that they are participating in a research project.	□	□	□	□	□
15. told about the possible risks of the clinical research study.	□	□	□	□	□
16. told how they might benefit from the clinical research study.	□	□	□	□	□
17. told they must participate in order to receive medical care.	□	□	□	□	□

The following are some statements about how clinical research studies are conducted. Do you think these statements are always true, sometimes true, rarely true, never true, don't know/unsure.
(Please check ONE response per line only)

		Always true	Sometimes true	Rarely true	Never true	Don't know/ unsure	Prefer not to answer
18.	**Clinical research studies determine how well a treatment works.**	□	□	□	□	□	□
19.	**Clinical researchers start with a set of research questions they want to answer before starting a clinical research studies.**	□	□	□	□	□	□
20.	**In a randomized clinical research study, you get to choose the treatment you want.**	□	□	□	□	□	□

21. **The education I received during school included learning about clinical research.**
(Please circle ONE response)

Strongly Agree	Agree	Not sure	Disagree	Strongly Disagree	Prefer not to answer

Please read the following statements and circle ONE answer about how YOU feel…

22. **In general would you say that you favor or oppose the use of human beings for clinical research?** ***(Please check ONE response)***

Strongly Favor	Favor	Neutral	Oppose	Strongly Oppose	Don't know or unsure	Prefer not to answer

23. **Clinical research will result in cures for many diseases.**

Strongly Agree	Agree	Not sure	Disagree	Strongly disagree	Prefer not to answer

24. **Research on humans goes against my religious beliefs.**

Strongly Agree	Agree	Not sure	Disagree	Strongly disagree	Prefer not to answer

25. **If I donate blood, for example to the Red Cross, it would be OK with me to use a small part of it (1 tablespoon) for research.**

Strongly Agree	Agree	Not sure	Disagree	Strongly disagree	Prefer not to answer

26. **If I had surgery, I would be willing to allow the use of some of my surgical tissue for clinical research.**

Strongly Agree	Agree	Not sure	Disagree	Strongly disagree	Prefer not to answer

27. I would allow my name to be put on a registry or list to be contacted for future research.

Strongly Agree	Agree	Not sure	Disagree	Strongly disagree	Prefer not to answer

28. **Doctors who do clinical research care only about what is best for each patient.**

Strongly Agree	Agree	Not sure	Disagree	Strongly disagree	Prefer not to answer

Please read the following statements and circle ONE answer about how YOU feel…

29. **Clinical researchers have no selfish reasons for doing research studies.**

Strongly Agree	Agree	Not sure	Disagree	Strongly disagree	Prefer not to answer

30. **There are some things about clinical research that I do not trust at all.**

Strongly Agree	Agree	Not sure	Disagree	Strongly disagree	Prefer not to answer

31. **A doctor would never ask me to be in a clinical research study if the doctor thought there was any chance it might harm me.**

Strongly Agree	Agree	Not sure	Disagree	Strongly disagree	Prefer not to answer

32. **Clinical researchers do not tell people everything they really need to know about being in a research study.**

Strongly Agree	Agree	Not sure	Disagree	Strongly disagree	Prefer not to answer

33. **The only reason doctors do clinical research is to help people.**

Strongly Agree	Agree	Not sure	Disagree	Strongly disagree	Prefer not to answer

34. **Its safe to be in a clinical research study.**

Strongly Agree	Agree	Not sure	Disagree	Strongly disagree	Prefer not to answer

35. **Some doctors do clinical research for selfish reasons.**

Strongly Agree	Agree	Not sure	Disagree	Strongly disagree	Prefer not to answer

36. **A doctor would never recommend something that is not the best treatment, just so he or she can study how it works.**

Strongly Agree	Agree	Not sure	Disagree	Strongly disagree	Prefer not to answer

Please read the following statements and circle ONE answer about how YOU feel…

37. **Doctors tell their patients everything they need to know about being in a research study.**

Strongly Agree	Agree	Not sure	Disagree	Strongly disagree	Prefer not to answer

38. **Clinical researchers treat people like "guinea pigs."**

Strongly Agree	Agree	Not sure	Disagree	Strongly disagree	Prefer not to answer

39. **I completely trust doctors who do clinical research.**

Strongly Agree	Agree	Not sure	Disagree	Strongly disagree	Prefer not to answer

In the following questions, "media" refers to things you see or hear on the following:

- **television (TV)**
- **movies**
- **radio**
- **internet**
- **magazines or newspapers.**

Please read the following statements and circle ONE answer.

40. **The MEDIA portrays doctors who do medical research as caring only about what is best for each patient.**

Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	Don't know or unsure	Prefer not to answer

41. **The MEDIA portrays medical researchers as having no selfish reasons for doing research studies.**

Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	Don't know or unsure	Prefer not to answer

Please read the following statements and circle ONE answer.

42. **When I watch TV or movies, it makes me think that there are some things about medical research that I can not trust at all.**

Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	Don't know or unsure	Prefer not to answer

43. **The MEDIA depicts doctors as not doing their medical research study if the doctor thought there was any chance it might harm the person.**

Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	Don't know or unsure	Prefer not to answer

44. **The MEDIA shows medical researchers as not telling people everything they really need to know about being in a research study.**

Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	Don't know or unsure	Prefer not to answer

45. **The MEDIA portrays that the only reason doctors do medical research is to help people.**

Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	Don't know or unsure	Prefer not to answer

46. **The MEDIA portrays that it's safe to be in a medical research study.**

Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	Don't know or unsure	Prefer not to answer

47. **The MEDIA portrays some doctors as doing medical research for selfish reasons.**

Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	Don't know or unsure	Prefer not to answer

48. **The MEDIA portrays doctors as never recommending something that is not the best treatment, just so he or she can study how it works.**

Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	Don't know or unsure	Prefer not to answer

49. **The MEDIA portrays doctors as telling their patients everything they need to know about being in a research study.**

Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	Don't know or unsure	Prefer not to answer

50. **The MEDIA portrays medical researchers as treating people like "guinea pigs."**

Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	Don't know or unsure	Prefer not to answer

51. **The MEDIA makes me feel that I can completely trust doctors who do clinical research.**

Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	Don't know or unsure	Prefer not to answer

52. **Please write down the name of a movie or television show or on the internet that you have watched that included a character who was a researcher.**

□ I can't recall a program that had a researcher.
□ I can think of a program, but can't remember the name.
□ Prefer not to answer

Please consider the next three hypothetical (not real) clinical research studies and answer the questions following each scenario.

Scenario 1: You are asked to participate in a clinical research study that consisted of TAKING A SMALL AMOUNT OF BLOOD OUT OF MY ARM.

53. **Do you think the physical risk (the chance of being hurt or injured in this study) of this study is…*(Please circle ONE response)***

Very Risky	Risky	Neutral	Safe	Very Safe	Prefer not to answer

54. **If you were asked today, would you be willing to take part in this clinical research project if you felt it WOULD BENEFIT YOUR health now or in the future?**
(Please circle ONE response)

Yes	No	Don't know/unsure	Prefer not to answer

55. **If you were asked today, would you be willing to take part in this clinical research project if it WOULD NOT BENEFIT YOUR HEALTH now or in the future but will add to scientific knowledge? *(Please circle ONE response)***

Yes	No	Don't know/unsure	Prefer not to answer

56. **If you were asked today, would you be willing to take part in a study that you felt WOULD NOT BENEFIT YOUR HEALTH BUT WOULD BENEFIT THE HEALTH OF SOMEONE CLOSE TO YOU? *(Please circle ONE response)***

Yes	No	Don't know/unsure	Prefer not to answer

57. **Sometimes people who participate in clinical research projects are offered compensation, such as money, for their time and effort. If a person was willing to participate in Scenario 1, what do you think would be FAIR compensation?**
People should expect…(please check one of the following).

- ❑ **No** compensation.
- ❑ A **minimum of $5** or other type of compensation worth that amount.
- ❑ A **minimum of $10** or other type of compensation worth that amount.
- ❑ A **minimum of $50** or other type of compensation worth that amount..
- ❑ A **minimum of $100** or other type of compensation worth that amount.
- ❑ Prefer not to answer

Scenario 2: You are asked to participate in a clinical research study that consisted of CUTTING OFF A SMALL AMOUNT OF SKIN (about the size of a pencil eraser), called a biopsy. This would require an injection (shot) of numbing medicine so that you did not have any pain and two to three sutures (stitches). The biopsy would be on a place where the scar would not be seen, such as you're the top of your hip. There may be mild discomfort or pain for one to two days.

58. **Do you think the physical risk (the chance of being hurt or injured in this study) of this study is…*(Please circle ONE response)***

Very Risky	Risky	Neutral	Safe	Very Safe	Prefer not to answer

59. **If you were asked today, would you be willing to take part in this clinical research project if you felt it WOULD BENEFIT YOUR health now or in the future?**
(Please circle ONE response)

Yes	No	Don't know/unsure	Prefer not to answer

60. **If you were asked today, would you be willing to take part in this clinical research project if it would NOT benefit your health now or in the future but will add to scientific knowledge?**
(Please circle ONE response)

Yes	No	Don't know/unsure	Prefer not to answer

61. **If you were asked today, would you be willing to take part in a study that you felt would NOT benefit YOUR health but would benefit the health of SOMEONE CLOSE TO YOU?**
(Please circle ONE response)

Yes	No	Don't know/unsure	Prefer not to answer

62. **If a person was willing to participate in Scenario 2, what do you think would be FAIR compensation?**
People should expect…(please check one of the following).

- ❑ **No** compensation.
- ❑ A **minimum of $5** or other type of compensation worth that amount.
- ❑ A **minimum of $25** or other type of compensation worth that amount.
- ❑ A **minimum of $100** or other type of compensation worth that amount..
- ❑ A **minimum of $500** or other type of compensation worth that amount.
- ❑ Prefer not to answer

Scenario 3: You are asked to participate in a clinical research study that consisted of TAKING A MEDICATION (DRUG) that will have some side effects from the medicine, such as feeling sick to your stomach (nausea) or throwing up (vomiting).
(Please check ONE response for each of the following two questions)

63. **Do you think the physical risk (the chance of being hurt or injured in this study) of this study is…*(Please circle ONE response)***

Very Risky	Risky	Neutral	Safe	Very Safe	Prefer not to answer

64. **If you were asked today, would you be willing to take part in this clinical research project if you felt it WOULD benefit your health now or in the future?**
(Please circle ONE response)

Yes	No	Don't know/unsure	Prefer not to answer

65. **If you were asked today, would you be willing to take part in this clinical research project if it would NOT benefit your health now or in the future but will add to scientific knowledge?**
(Please circle ONE response)

Yes	No	Don't know/unsure	Prefer not to answer

66. **If you were asked today, would you be willing to take part in a study that you felt would NOT benefit YOUR health but would benefit the health of SOMEONE CLOSE TO YOU?**
(Please circle ONE response)

Yes	No	Don't know/unsure	Prefer not to answer

67. **If a person was willing to participate in Scenario 3, what do you think would be FAIR compensation?**
People should expect…(please check one of the following).

- ❑ **No** compensation.
- ❑ A **minimum of $5** or other type of compensation worth that amount.
- ❑ A **minimum of $25** or other type of compensation worth that amount.
- ❑ A **minimum of $100** or other type of compensation worth that amount..
- ❑ A **minimum of $500** or other type of compensation worth that amount.
- ❑ Prefer not to answer

APPENDIX D

INFORMED CONSENT DOCUMENT-PILOT STUDY

I am inviting you to participate in a research study. The purpose of the study is to pilot the *Attitudes and Factors affecting Young Adults' Willingness to Participate in Clinical Research* survey. To pilot a survey means that I would like your opinion whether or not the survey is easy to read and makes sense to a senior in high school. After piloting, this survey will be used in a study to see what factors affect community-dwelling adults' willingness to participate in future clinical research. This study conducted by University of Iowa researchers.

I am inviting you because you are an adult 18 to 20 years of age. Approximately 600 people will take part in this study conducted by University of Iowa researchers. You may discuss whether or not to you want to do this with whomever you would like, such as friends or your parents.

If you agree to participate, I would like you to complete the attached survey. This survey asks 68 questions about yourself, about what you may know about clinical research, and how you feel about participating in clinical research. I estimate it will take you approximately 20 minutes to complete the survey. If you do not wish to answer a question on the survey, please select the "prefer not to answer" option on the form. Because this is a pilot study and your answers will not be used in the final analysis, you can 'make up' or use fictional answers if you wish.

After you return the completed survey, I would like to talk with you about any questions that were difficult to understand or any changes that you think might improve the survey. You may ask me questions during the survey if you do not understand a question and I will talk with you immediately after you complete the survey for suggestions on how to improve the readability of the survey.

I will keep the information you provide confidential, however federal regulatory agencies and the University of Iowa Institutional Review Board (a committee that reviews and approves research studies) may inspect and copy records pertaining to this research. Your payment form with your name will be separated from your survey form. I will use a study number to identify your survey responses in my study data. Your name will not be linked to your survey number. I will store all study materials in locked files and all study data in password protected computer files. If I write a report about this study, I will do so in such a way that you cannot be identified.

There are no known risks from being in this study, and you will not benefit personally. However I hope that others may benefit in the future from what I learn as a result of this study. You will not have any costs for being in this research study.

Taking part in this research study is completely voluntary. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify. If you do not want to participate in this study, you may leave and discard the survey in the trash.

You will be paid for being in this research study. To receive payment for participating you must respond to every question. There is an option of 'prefer not to answer' for questions that you do not want to answer for any reason. You will need to provide your name and address on the attached payment form so that a $10 iTunes gift card can be mailed to you. Your name and address will be separated from your survey and will be accessible only to the researchers on this project.

If you have any questions about the research study itself or experience a research related injury, please contact Debra Brandt at 319-356-1736 or e-mail debra-brandt@uiowa.edu. If you have questions about the rights of research subjects, please contact the Human Subjects Office, 105 Hardin Library for the Health Sciences, 600 Newton Rd, The University of Iowa, Iowa City, IA 52242-1098, (319) 335-6564, or e-mail irb@uiowa.edu. To offer input about your experiences as a research subject or to speak to someone other than the research staff, call the Human Subjects Office at the number above.

Returning the completed survey or questionnaire will indicate your willingness to participate in the study. You may keep this letter for your records.

Thank you very much for your consideration.
Sincerely,

Debra Brandt, MSB, MSN, RN
University of Iowa Clinical and Translational Science and University of Iowa College of Nursing

APPENDIX E

RECRUITMENT SCRIPT

Hello, my name is Debra Brandt. I am a researcher from the University of Iowa. I am here to invite you to participate in a research project that looks at the willingness of high school seniors. who are 18 years old or older, to volunteer to be in medical research.

You may know that new discoveries in medicine are primarily achieved by testing on people who volunteer to be in medical research. There has been research done about what affects willingness to participate in medical research, but most of this research looks on people who have been diagnosed with an illness or minorities. There are few studies that look at young adults, such as you. My research project will look at willingness of young adults to participate in clinical research and factors that may influence your decision to participate or not.

Taking part in this research study is completely voluntary—that means it is up to you. You do not have to participate if you do not want to; you may either return the packet to the drop site unopened or throw it away. I will not tell the teacher if you participated in this survey and your decision whether or not to participate will not affect your grades or other school evaluations.

If you would like to participate or consider participating in this study you must be at least 18 years old. If you are not 18, then, sorry, you may not participate. If you would like to participate in this study, I would ask you to read the information and complete the survey that is contained in these packets *(hold up the packet)*. In the packet you will find an informed consent document in the packet that tells you about the study and your rights as a study participant. Under the informed consent document is the study survey. The survey has 67 questions and I estimate that it will take you about 20 minutes to complete the survey. You may complete this today during your free time today or after school. It must be turned in by today by *(time)* to (*turn in site)*.

You will be paid for being in this research study. If you decide to participate in the study, you will find a sheet of paper at the end and you will need to write down your mailing address so that I can send you a $10 iTunes gift card. After I receive your survey I will separate your name and address from your survey, so I cannot tell how you answered the questions. When I write a paper about my research, I will do so that you cannot be indentified.

Thank you for considering participating in my research project. Are there any questions?

APPENDIX F

ANNOUNCEMENT

Debra Brandt, a student researcher from the University of Iowa, will be here on *(date)* to invite seniors who are at least 18 years olds to participate in a research study. Her study will look at the factors that affect young adults' willingness to participate in medical research. Seniors, ages 18 or older, who would like to participate will be asked to complete a survey consisting of 67 questions and will take about 20 minutes to complete. You will be paid for your time and effort to complete the survey. To participate in Ms. Brandt's study, or for more information, she will be at our school on *(date)* at *(location)*.

APPENDIX G

INFORMED CONSENT DOCUMENT

I am inviting you to participate in a research study. The purpose of the study is to see what factors affect community-dwelling adults' willingness to participate in future clinical research.

I am inviting you to be in this study because you are a community-dwelling adult between the ages of 18-20. Approximately 600 people will take part in this study conducted by University of Iowa researchers. You may discuss whether or not to participate in this study with whomever you would like, such as friends or your parents.

If you agree to participate, I would like you to complete the attached survey that asks questions about yourself, about what you may know about clinical research, and how you feel about participating in future clinical research. There are 67 questions on the survey and it will take you approximately 20 minutes to complete the survey. If you do not wish to answer a question on the survey, please select the "prefer not to answer" option on the form.

I will keep the information you provide confidential, however federal regulatory agencies and the University of Iowa Institutional Review Board (a committee that reviews and approves research studies) may inspect and copy records pertaining to this research. Your payment form with your name will be separated from your survey responses. I will use a study number to identity your survey responses in my study data. Your name not be linked to your survey number. I will store all study materials in locked files and all study data in password protected computer files. If I write a report about this study I will do so in such a way that you cannot be identified.

There are no known risks from being in this study, and you will not benefit personally. However I hope that others may benefit in the future from what I learn as a result of this study. You will not have any costs for being in this research study.

Taking part in this research study is completely voluntary. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify. Your teachers or principal will not be told by the researcher if you participated in this survey and your decision whether or not to participate will not affect your grades or other school evaluations. Answering questions in the survey does not obligate you to any future research.

You will be paid for being in this research study. To receive payment for participating you must respond to every question. There is an option of 'prefer not to answer' for questions that you do not want to answer for any reason. You will need to provide your name and address on the attached payment form so that a $10 iTunes gift card can be mailed to you. Your name and address will be kept separately from your survey and will be accessible only to the researchers on this project. .

If you have any questions about the research study itself or experience a research related injury, please contact Debra Brandt at 319-356-1736 or e-mail debra-brandt@uiowa.edu. If

you have questions about the rights of research subjects, please contact the Human Subjects Office, 105 Hardin Library for the Health Sciences, 600 Newton Rd, The University of Iowa, Iowa City, IA 52242-1098, (319) 335-6564, or e-mail **irb@uiowa.edu. To** offer input about your experiences as a research subject or to speak to someone other than the research staff, call the Human Subjects Office at the number above.

If you wish to participate, please return the completed survey to the collection point today by the designated time. You may keep this letter for your records.

If you do not want to participate in this study, please return the blank survey to the collection point or discard in the trash.

Thank you very much for your consideration.
Sincerely,

Debra Brandt, MSB, MSN, RN
University of Iowa Clinical and Translational Science and University of Iowa College of Nursing

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