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Understanding the Perspectives of Potential Minority Participants on Clinical Trial Enrollment

Saliha Akhtar
saliha.akhtar@student.shu.edu

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Dr. Deborah A. DeLuca, MS, JD (Chair)

Dr. Michelle L. D'Abundo, PhD, MSH, CHES

Dr. Terrence F. Cahill, EdD, FACHE

Submitted in partial fulfillment of the requirements for the degree of

Doctor of Philosophy of Health Sciences

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This doctoral journey has been a long and grueling one but rewarding at the same time. Looking back at it now, it makes sense why it's called a journey. As I end this stage of my life, I want to thank some individuals who supported me along the way.

First of all, everything in my life is due to the will of God. God has blessed me in more ways than I can count. Completing my doctoral degree is just another great blessing in my life and I cannot be more thankful to him for what he has helped me achieve.

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I am grateful for the support that I have received and it has motivated me to continue to achieve life's successes.

DEDICATION

To my loving parents, Farhat and Arif Akhtar.

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ABSTRACT

UNDERSTANDING THE PERSPECTIVES OF POTENTIAL MINORITY PARTICIPANTS ON CLINICAL TRIAL ENROLLMENT

Saliha Akhtar

Seton Hall University

2017

Dissertation Chair: Dr. Deborah DeLuca, MS, JD

Research has shown that there continues to be insufficient recruitment of minorities in clinical trials. By eliminating this group from research, not only does it impact the success of clinical trials by making it more difficult to achieve recruitment targets, but it also leads to an inability to identify appropriate treatments and interventions for all individuals, especially as racial/ethnic factors can play a role in the efficacy and safety of a treatment and intervention. The purpose of the study was to understand the perspectives of minority healthcare students/professionals on clinical trial enrollment. Focusing on this population would shed light on how minority individuals feel about clinical trial enrollment and whether healthcare professionals can be used as an avenue to share clinical research opportunities with the general minority population. The study was a general qualitative study utilizing a semi-structured interview guide to collect the data. The interview guide was designed to explore the thought process of minorities when it comes to enrollment and understand what would influence their

decision. The sample population consisted of 20 individuals who were recruited in an educational setting with the participants being graduate healthcare students either working at the same time as healthcare professionals or who would work in the near future as healthcare professionals. The data analysis strategy was data driven, also known as inductive analysis, and was done through coding. Eight themes that influence clinical trial participation by minorities emerged from the interviews which were benefits, negative aspects, need for information, support, diversity, religion and faith values, family and friends, and wanting better collective health. The Ottawa Decision Support Framework was used as a lens to interpret the themes and found that it explained some of the themes. The results of the study show that while minority healthcare students/professionals find clinical trials innovative and important, they do not understand the specifics about them and not all are open to participating. Therefore, there is a need to address potential minority participants' decisional needs and in general, educate, or there will continue to be an inequality in treatments and interventions.

Chapter I.

INTRODUCTION

As the healthcare industry grows, there has been an increase in the number of clinical trials that play a key role in the prevention, intervention, and treatment of many medical conditions that affect both mental and physical health. As of February 2016, Clinicaltrials.gov noted having an outstanding 242,099 studies listed across 198 countries (Clinicaltrials.gov, 2016). Although they may be different in their disease-focus and study design, similar issues are generally experienced. One of the biggest challenges for the clinical research industry is the issue of recruitment and retention, particularly relating to minority populations. Participant enrollment has proven to be difficult in all therapeutic and disease areas and especially difficult when it comes to the inclusion of minority populations. Researchers have acknowledged this as an ongoing problem with effects seen throughout the clinical trial process. Furthermore, minorities entail many different ethnicities and races, but for the purposes of this dissertation, the intent was to evaluate them as a whole, for reasons which will be discussed in Chapter II.

Before delving into the issues surrounding minority recruitment, it is first important to understand the definition of a clinical study and the purpose of conducting this type of research. A clinical study is research conducted with human volunteers who are also called subjects or participants, with the intent of contributing to medical knowledge (National Institutes of Health,

2015). For purposes of this dissertation, the term participants will be used. The Food and Drug Administration (FDA) categorizes clinical trials by Phases I-IV, which are categories for describing the characteristics of the study based on its objectives and number of participants. For example, a Phase I clinical trial typically requires the least number of participants and is usually focused on evaluating the safety profile of a treatment. On the other hand, a Phase IV clinical trial is when the treatment becomes marketed, and thus, is available for use to the wider population the treatment is intended for, while allowing for the collection of long-term use safety data.

Every clinical trial has a specific planned design explaining how the study will be conducted and why, which is also known as the protocol. The organization that is sponsoring the study (ex: pharmaceutical company, academic center, government organization) has the overall responsibility for conducting the study. The organizational aim is to meet recruitment targets (i.e., enrolling a certain number of patients in a certain period of time) in order to minimize the costs related to the conduct of the study and to be able to evaluate the results of the study within a timely manner. The principal investigator (in conjunction with the other site personnel involved in the study) is responsible for identifying potential patients and confirming their eligibility against the entry criteria. With the support of other healthcare professionals from the site, the investigator must take the time to evaluate the best patients for the trial. Consequently, the principal investigator, often a medical doctor,

plays a key leadership role in the clinical trial process, having the primary responsibilities to adhere to the protocol while helping ensure patient safety. Finally, the third key player is the patient who plays an equally important role in the decision-making process. By enrolling in a research study, the patient can partake in evaluating whether a treatment is effective and safe for them, whereas there might not be any other appropriate treatment currently approved.

Despite the increase in the number of clinical trials, the issue of recruiting minorities (along with women) remains salient. The Society for Women's Health Research, FDA, and the Office of Women's Health (2011) describe this systemic issue as "Women and ethnic/racial minorities routinely and disproportionally have been excluded from medical product research throughout history" (p. 3). The National Medical Association created Project I.M.P.A.C.T. to increase minority participation and awareness of clinical trials. This organization stated that "African Americans are underrepresented in important medical research to find treatments for the very diseases that affect them such as diabetes, hypertension, HIV/AIDS, and lung cancer. Your good health depends on knowing whether a treatment affects women or men differently, or affects a minority differently" (Project I.M.P.A.C.T., 2008b, ¶4). For minorities, health disparities relating to disease prevalence and risk, health care quality, and health care access are indicators that recruitment and retention practices need to change.

There are important systemic issues that affect recruitment and retention of minorities in clinical trials. The Society for Women's Health Research, the FDA, and the Office of Women's Health (2011) have identified some of the reasons for low-representation of minorities in clinical trials which involve patient attitudes as well as industry practices. Project I.M.P.A.C.T. (2008_a) summarized reasons given by African Americans regarding why they do not participate in clinical trials, which include lack awareness of trials, lack of access to healthcare, their health care providers didn't recommend it, fear and/or distrust, cultural beliefs, and discrimination, some of which will discussed further in the next chapter. With the history of exploitation in research, it is understandable that any participant, specifically minorities, would have concerns about participating in clinical trial research. Consequently, from an industry perspective, minority participants may be perceived as difficult to recruit and costlier to engage. There are National Institutes of Health (NIH) funded studies that have diversity requirements. However, there are no regulations that require industry sponsors to include minorities in clinical trials. Therefore, the complicated issue of increasing minority participation in clinical trials must first be understood from the individual perspective of potential participants. The next chapter will discuss research that has been conducted so far to evaluate the perspective of potential minority participants.

Insufficient Recruitment of Participants in Clinical Trials

A clinical trial or intervention study is designed with the intent of enrolling a certain number of participants who are to receive a specified treatment that could be a drug, procedure, or behavioral program. The general purpose of clinical trials is to add to medical knowledge related to the treatment, diagnosis, and prevention of diseases or conditions, or to evaluate the efficacy of one or more interventions for the treatment of a disease or condition. Participants may be assigned to an intervention group where they receive a new treatment, to a control group where they receive placebo, or to no intervention (ClinicalTrials.gov, n.d.). However, if there are not enough participants included in the clinical trial, then the clinical trial may be delayed or even cancelled. In fact, trials frequently discontinue, even in late stage Phase III trials, due to failure to accrue (Schroen et al., 2010). A paper by prominent cancer researchers from the University of Virginia, Dana Farber, Duke University, University of Pittsburg, the Mayo Clinical, the Southwest Oncology Group research collective, and the University of South Florida examined the reasons for trial failure in the Clinical Trials Cooperative Group (CCTG) setting. The CCTG model, funded by the National Cancer Institute, seeks to foster large working groups of clinical trial sites to ensure access to trials and consistency of late stage development across Oncology trials. A study of one large CCTG demonstrated a 40% failure rate of trials to accrue to full enrollment for therapeutic interventional trials and a whopping 68% failure rate for non-therapeutic trials (Schroen et al., 2010). The study found

that a trial that falls behind planned enrollment levels by at least one-third is likely to be closed due to insufficient accrual (Schroen et al., 2010).

Therefore, clinical trial recruitment remains a difficult undertaking with many barriers to enrollment and conduct resulting in a drastic number of trials not accruing to goal. Even in diseases such as oncology and hematology, participation in clinical trials is about 3% of the eligible population (Lara et al., 2001). A study at the University of California Davis looked to evaluate cancer clinical trial participation levels for open protocols at the center. It found that a number of factors were barriers to trial participation, including clinicians not considering trials for patients, exclusion to protocol parameters, patients' lack of interest, insurance denials, and the distance from the cancer center (Lara et al., 2001).

Insufficient Recruitment of Minorities in Clinical Trials

Additionally, research has shown that there is an insufficient enrollment of minorities in clinical research. For example, one review found that minorities were significantly less likely than White individuals to be asked to participate (Wendler et al., 2005). In order to address the issue of minority recruitment in clinical trials, it is important to analyze the issue from a patient perspective as the ultimate decision of whether to participate is their decision. This understanding is important in exploring why minority participation is insufficient, and in turn, identify what needs to be done in order to make a

change. The next chapter will discuss what has been determined so far when it comes to why potential minority participants do not enroll in clinical trials.

Problem Statement

Although some studies have been performed to evaluate why this issue exists and to attempt to mitigate the gap, more information is needed from potential participants to advance understanding as to why they continue to not participate in clinical trials. In the end, the ultimate decision of enrolling is up to them and as research has shown, individuals are taking more ownership of their health care. Therefore, there is a need for more research across all disease areas to understand what these factors are from their perspective. A lot of research has been performed on only African Americans. As Durant et al. (2007) also observed, there is less data existing on recruitment of other minority groups such as Hispanics and Asian Americans. The same can also be said for general medicine (i.e., non-oncology) trials as research has mostly focused on oncology/cancer research. However, the issue of insufficient minority recruitment has been seen across all diseases areas and all racial groups. This is why there is a need for research to explore these factors across all disease areas and racial groups to better understand why minorities do not enroll in clinical trials. With this information, researchers can then develop appropriate strategies to address these gaps. Without further research, insufficient enrollment in clinical trials will continue to exist across disease areas and racial groups.

Purpose of the Study

The purpose of this study was to explore whether potential minority participants experience decisional conflict when deciding whether they would participate in a clinical trial in terms of feeling uncertain and factors that contribute to that uncertainty including feeling uninformed about the alternatives, benefits, and risks, being unclear about personal values, and feeling unsupported in making a choice.

Significance of the Study

The failure to recruit the necessary number of participants can have an effect on the overall success of the study (Embi et al., 2005). In fact, it can have an effect on many aspects of a study including leading to delays in the approval of necessary medications and leading to higher costs due to the extended recruitment period. These consequences also have an impact on all stakeholders involved in the recruitment process including the researchers who need to take on the higher cost, the investigators who will need to continue to spend valuable time seeking participants to enroll, and most importantly, the patients who will need to wait to receive access to vital treatments.

More specifically, the insufficient recruitment of minorities has a large impact on the minority population who are not adequately represented in clinical trials. It potentially contributes to a disparity where all populations do not have access to the same healthcare treatments or interventions. This can

prove to be detrimental for some individuals who have life-threatening conditions and do not have many treatment options. In a way, they are being withheld a potential treatment which might have a positive impact on their condition. As noted by Cox and McGarry (2003), these potentially eligible patients are being denied clinical trial entry which may be associated to improved survival.

Furthermore, the lack of diversity in clinical trials contributes to a lack of generalizability. Treatment options for a patient are based on their individual characteristics including ethnicity. By not being adequately represented in a research study, there is an inability to potentially identify specific genetic factors that may be linked to their condition and the treatment under study. Researchers cannot determine which factors or effects are specific to a minority population. Moreover, a lack of generalizability of the treatment to the desired population can affect not only the efficacy of the drug but also raise safety concerns. Therefore, the exclusion of minority populations challenges the external validity of trial findings and questions whether there is equity in healthcare opportunities (Hussain-Gambles, Atkin, & Leese, 2004).

This health disparity directly impacts the minority population, limiting their ability to reap the maximum health benefits that are available to others. For example, according to the release of Healthy People 2020 (and also noted in Healthy People 2010), there is a need to eliminate health disparities (such as this one) among Americans and improve the health of all groups (U.S.

Department of Health and Human Services, 2015). Furthermore, in the 2002 report by the Institute of Medicine, it was emphasized that there are health disparities in care (Institute of Medicine, 2002). However, although the problem is recognized by many, including its' effects, it still exists and solutions still need to be proposed.

Chapter II.

LITERATURE REVIEW

With the growth of the healthcare industry, there has been an increase in the number of clinical trials, and specifically, a focus on research that involves specialized medicines. Many treatments have been produced for diseases that are common and affect a large number of individuals. However, as the market has become saturated with these types of medicines, researchers are now looking to find treatments where the market is untapped, such as rare diseases, or working to develop treatments that are better targeted to patients. For example, instead of prescribing a medicine empirically where everyone might not react in the same manner, researchers are trying to identify ways in which it can be determined whether a patient will respond well to a particular treatment (Trusheim, Berndt, & Douglas, 2007). Understanding the mechanisms underlying diseases and the drug response, coupled with genetic profiling, helps best match patients to a particular treatment (Trusheim et al., 2007). This trend presents a set of challenges, including those related to participant recruitment.

One challenge which has been acknowledged by researchers as an ongoing problem is the insufficient recruitment of minorities in clinical trials. Not only does the adequate inclusion of minorities in clinical trials allow for a better understanding on how to identify and treat disorders, but it also leads to more accurate diagnoses (Ma et al., 2014). As noted by researchers Anwuri

et al. (2013), "comprehensive inclusion of diverse participants in clinical trials is essential in assuring generalizability of prevention, diagnostic, and treatment recommendations" (p. 1798). Without this, there is a standstill of the proper healthcare treatment of minorities as it is known that racial/ethnic factors can play a role in the efficaciousness of a treatment. It is therefore essential to take a closer look at the problem in order to understand how the identification of effective treatments can apply to all sectors of society (Anwuri et al., 2013).

There have been steps taken in an attempt to mitigate the problem. For example, the National Institutes of Health developed a set of guidelines to address part of the issue. These guidelines on the inclusion of women and minorities require researchers to include various racial and ethnic minorities in clinical trials (NIH, 2011). Furthermore, these guidelines require a valid analysis to detect differences in intervention effects (NIH, 2011). The guidelines illustrate the importance of minority enrollment in clinical trials through the analysis process. There are also federal rules that require investigators to take appropriate steps to include minorities. Specifically, the investigators need to demonstrate that there was sufficient representation of minorities in the study samples (Anwuri et al., 2013). For example, the National Institutes of Health Revitalization Act of 1993 sanctioned that minority groups are sufficiently represented in clinical trials (Fracasso et al., 2013). Other disease-specific organizations have also followed a similar

path. One example is the Strategic Plan on Health Disparities Research of the National Institute on Drug Abuse. This plan aims to motivate research which will decrease the inequalities in treatment and healthcare research (National Institute on Drug Abuse, 2008). Despite these guidelines, the issue of enrolling a diverse group of participants in clinical trials remains an important issue affecting health status and health care in the United States.

In order to address the issue of minority recruitment in clinical trials, it is important to analyze the issue from both a patient perspective and investigative site personnel perspective. This type of understanding is important in exploring why minority participation is insufficient, and in turn, identify what needs to be done in order to make a change. The literature was searched for these types of barriers. The three most common themes for each perspective are described below.

Barriers from a Participant Perspective

The number of minorities in the U.S. is growing at a fast rate. In fact, the fastest growing population in the U.S. is Asian Americans (Ma et al., 2014). However, despite this, they are the least represented by any U.S. ethnic group in clinical trials (Ma et al., 2014). This gap in research can have serious implications to minorities, especially related to the effectiveness of a treatment. From a patient perspective, common reasons for not enrolling in a clinical trial or research study include distrust or having a negative perception

of research, lack of understanding, and lack of accessible and affordable healthcare, all which are further discussed below.

Distrust/negative perception.

Many common themes have emerged in attempts to explain why there is not sufficient representation of minorities in clinical trials. The most common theme from a patient perspective is related to trust. In fact, in a review of the literature performed on the topic by Ford et al. (2008), mistrust was the most frequently reported barrier. With good reason, minorities have a lack of trust in clinical research. They have concerns about receiving inadequate treatment or misdiagnosis due to their racial or ethnic background, or in other words, being discriminated (Mendoza, Williams, Chapman, & Powers, 2012). In a study that interviewed stakeholders of the recruitment process, all of the stakeholders felt that there was a level of skepticism by minorities when it came to participating in clinical trials (Durant et al., 2014). They felt that this reluctance was due to inherent uncertainty or negative connotations of clinical trials (Durant et al., 2014).

Past cases of discrimination have contributed to the mistrust. A well-known case that deals with the discrimination of minorities is the U.S. Public Health Tuskegee Syphilis Experiment. In this case, rural African American men who had syphilis were not diagnosed or treated properly by the U.S. government. As noted by Durant et al. (2014), this case and other past cases have led to the mistrust of clinical research perceived by African Americans

and Native American. However, Durant et al. (2014) also feel that with other minorities such as Asians and Latinos, there is more of general fear of being mistreated in clinical research.

With the repeated mistakes that have been made in the past with specific minority populations such as African Americans, there continues to be a lack of trust in experimental research and the researchers. Minorities have raised concerns about the trustworthiness of the site personnel and during their time in a clinical trial (Roberson, 1994). Participants are skeptical about having similar experiences based on these cases. Specifically, research has shown that they have expressed mistrust about the investigators' motives (Corbie-Smith, Thomas, Williams, & Moody-Ayers, 1999). Participants want to either further healthcare research and knowledge or have access to potential treatments or interventions, but want to be fully informed about the research process and not be discriminated. Fouad et al. (2000) also found that minorities have distrust about the purpose of informed consent and incentives which they feel are inappropriate.

Moreover, in a study performed to evaluate the attitudes and beliefs of African Americans toward participation in medical research, it was found that that the majority of participants tend to be in favor of medical research, as long as they were not "guinea pigs" (Corbie-Smith et al., 1999). Participants are wary of healthcare research and have distrust in researchers who conduct

it. They want to be fully disclosed the benefits and risks and benefits of clinical trials and what it will entail.

Lack of understanding.

Another barrier viewed by minorities as preventing them from enrolling in healthcare research is a lack of understanding of research. In the study surrounding African American perceptions of medical research, it was found that they have limited understanding of the informed consent process (Corbie-Smith et al., 1999). This is surprising as the informed consent process is required for experimental studies with the intent to ensure that the participant is aware of all the risks, benefits, and procedures associated with the trial. Furthermore, the informed consent process ensures that their consent is received, ensuring that they understand and agree to the care. However, in the study by Corbie-Smith et al. (1999), participants felt that the consent process was more for the legal protection of researchers rather than for their benefit and protection.

Linked with the process of informed consent and healthcare research in general is the lack of understanding of terminology. In the same study by Corbie-Smith et al. (1999), participants described the difficulty with understanding technical, medical, and legal terminology, along with other aspects of the research study such as the efficacy and safety profile. This has also been noted by other researchers. Ryan, Prictor, McLaughlin, and Hill (2008) recommend that additional research be performed to determine

what interventions or tools could be used to explain complex concepts of clinical trials to ensure participants have a better understanding of the informed consent, and thereby, will potentially be more willing to participate.

Finally, there is a lack of understanding on the purpose of research studies. Sinclair et al. (2000) found that African Americans have a discomfort with participation because of their lack of knowledge about the research process and what is required. Without the basic knowledge of the research design, there will be a lack of understanding of the procedures associated with it. For example, in a study by Fouad et al. (2000), barriers to participation included factors such as whether or not blood would be drawn and whether radiation would be utilized. Without an understanding of the basic research purpose, treatment, or research design, potential participants will question participation to the study. Therefore, Fouad et al. (2000) recommend holding workshops in order to provide more information on clinical trials.

With the lack of knowledge about the informed consent process, research designs, and clinical research in general, potential participants will continue to not have an understanding about the potential benefits of participating. This means that these potential participants will make the decision to not enroll without adequate knowledge about what the research entails.

Lack of accessible and affordable healthcare.

Another common theme seen as a barrier is lack of accessible and affordable healthcare. In fact, as noted by Ma et al. (2014), in some studies, lack of accessible and affordable research were seen as common obstacles/barriers. More specifically, in a study performed by Durant et al. (2014), minorities felt that lack of insurance was a factor which made them less likely to be offered an opportunity to participate in clinical trials. These studies show that there is a perception that lack of insurance or access to research studies is linked to an inability to participate. Other studies have reported similar findings. In a study by investigators from the University of California Davis, it was found that patients who had non-government insurance were statistically less likely to participate in a clinical trial compared to those who had some type of government insurance (Lara et al., 2001). Other studies have also shown a link between participation and those who have insurance. In a study that interviewed community leaders, it was found that there was a perception that insurance will not cover participating in a clinical trial (Fouad et al., 2000). Moreover, socioeconomic factors such low income may be associated with lack of access to healthcare, and therefore, have an effect on the enrollment of trials. This was emphasized by Hussain-Gambles et al. (2004), who found that "low ethnic minority accrual to clinical trials might be caused in part by 'racially' constructed socio-economic factors which allow less utilization of healthcare, and hence, a reduced opportunity to take part in trials" (p. 385).

Therefore, concerns with insurance issues, whether it's lack of insurance or issues with insurance coverage, limit minority participation in clinical trials. Potential participants feel that they do not have access to the opportunity of participating in a clinical trial because of the lack of access to affordable healthcare.

Theories

As mentioned previously, the ultimate decision of enrolling in a clinical study lies with the potential participant. Therefore, it is necessary to look at some conceptual frameworks which could be used evaluate the issue of insufficient enrollment from the participant perspective.

Theory of Planned Behavior and Health Behavior Model.

The first conceptual framework that will be presented has been commonly used in past studies and research to help explain the issue and focuses on the overall intrapersonal perspective of potential participants. This conceptual model was created in an attempt to explain a patient's willingness to participate in clinical research. Researchers Brown and Topcu (2003) combined aspects of the theory of planned behavior with the health behavior model. Figure 1 illustrates the conceptual framework.

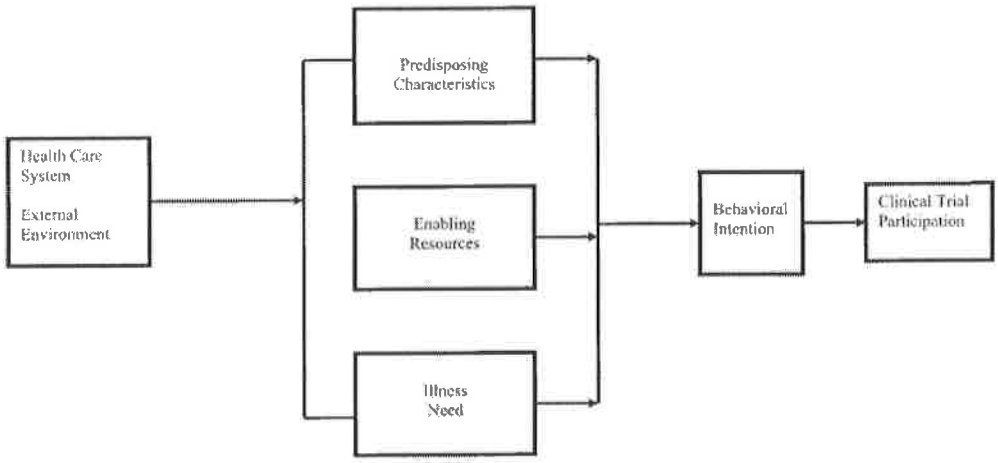


Figure 1. Conceptual framework that combines the theory of planned behavior and health behavior model to predict clinical treatment trial participation (Brown & Topcu, 2003).

Researchers have used the theory of planned behavior to explain behavior that is voluntary while the health behavior model encompasses predisposing, enabling, and illness need factors (Brown & Topcu, 2003). In terms of the conceptual framework, the theory of planned behavior is used to explain how participation in a clinical trial is preceded by a person's behavioral intention or willingness to take part in the study determined by predisposing characteristics, enabling resources, and illness need factors (Brown & Topcu, 2003). In regard to the health behavior model, "the predisposing and enabling components establish the conditions within which a person is or is not likely to express a behavioral intention to participate in clinical treatment research when stimulated by an illness need such as having a diagnosis of disease" (Brown & Topcu, 2003, p. 2). Overall, the framework

focuses on cognitive factors along with a set of individual and social structure factors (Brown & Topcu, 2003). It is used to explain how a patient's willingness to participate in a clinical trial is influenced by a combination of the patient's predisposing characteristics, enabling resources, and their illness and need, which determines behavior intention, and thus, leads to the decision on whether or not to participate in a trial. For example, in a study performed to examine factors that affect the willingness to participate in a clinical trial, it was found that African American men that had higher education were more likely to participate in health-related research (Robinson, Ashley, & Haynes, 1996). Therefore, the conceptual model clearly notes the factors that can influence a participant from enrolling in a clinical trial.

The predisposing characteristics, enabling resources, and the patients' specific illness need to be further explored to determine the best recruitment strategies that need to be developed. While the model highlights the factors that can influence an individual from participating in a clinical trial, it is not measurable. There have been no tools developed that aim to measure all of the factors set forth by the model or their impact on the desired outcome – the behavioral intention to participate, and subsequently, the decision to participate. Therefore, although this theoretical framework sets a foundation for understanding the problem, it is not ideal as it does not suggest a solution to the problem.

Change Model.

Another conceptual framework that is appropriate in understanding why a sufficient number of minorities do not enroll in clinical trials is a framework known as the transtheoretical model which conceptualizes the process of intentional behavior change. The literature has shown that participants have a lack of trust and understanding when it comes to research. As has been summarized earlier, minorities are wary about researchers and clinical research because of past cases of discrimination. Furthermore, the literature has shown that they have a lack of understanding of research including its' purpose, risk/benefit profile, and the procedures involved in it. Some strategies have been test to help mitigate this gap but additional research needs to be done to understand if participants continue to not enroll because they are not willing or ready to change their mindset about enrolling. Before delving into how this research can help solve the problem, it is first necessary to understand the change model in more detail. The model attempts to explain behavior change through a series of six stages of change (pre-contemplation, contemplation, preparation, action, maintenance, and termination). Figure 2 illustrates the conceptual framework.

Figure 2. Conceptual framework that illustrates the stages of the transtheoretical model that explains health behavior change (Pro-Change Behavior Systems, Inc., 2014).

As seen in Figure 2, the different stages propose that individuals move through these stages when modifying behavior (Pro-Change Behavior Systems, Inc., 2014). An individual will spend time in each stage completing certain actions before moving to the next stage. These tasks incorporate reducing resistance, facilitating progress, and preventing relapse and include decision balance, self-efficacy, and processes of change (Pro-Change Behavior Systems, Inc., 2014). Therefore, when it comes changing the mindset of potential participants to enroll in clinical studies, this means that the change will occur over time and progress will be made through a series of stages.

Although this model was originally developed for evaluating smoking cessation, it can and has been used as a model to describe other health behavior changes. Research has shown that by looking at each stage

separately and developing specific strategies and procedures, improvements can be made with both recruitment and retention (Prochaska & Velicer, 1997). For example, the first stage is the pre-contemplation stage where the individual(s) are uninformed or under informed about the behavior. Therefore, they might not be ready for help, be unmotivated, or even resistant to the change. In this stage, it can be thought that potential participants are not even aware about clinical studies. They are uninformed about the issue and no change will occur. On the other hand, the second stage is the contemplation stage or in other words "getting ready." In this stage, the individual(s) are aware of the benefits of changing, and to a smaller degree, the risks. The potential participants are contemplating whether to make the change but are not ready to take action immediately. Furthermore, it is in this stage where they are given sufficient information regarding the risks and benefits about enrolling in a clinical trial, along with information on the procedures and what they should expect during their time in the study. The next step would be preparing to make the change.

By understanding which stage most potential minority participants are in (ex: pre-contemplation, contemplation, or preparation), research site personnel can utilize the most appropriate recruitment strategies for that stage. For example, if it is found that participants are in the pre-contemplation stage, then discussions that only focus on asking them if they would be willing to participate in a clinical trial would not be appropriate.

Instead, this would mean that these potential participants do not even have a general understanding of what clinical studies are. Research site personnel and public health professionals would need to educate these individuals about what clinical research is and why it is conducted. If it is found that these potential participants are in the pre-contemplation stage, then this means that they do not have a firm understanding about the impact their participation can have in the healthcare field or the benefits and risks related to their participation. In consequence, research site personnel would need to share more information on the benefits and risks of clinical research and from the specific study.

This model is useful for exploration of the issue from a participant perspective and can be used to pinpoint which stage of change individuals are in and to evaluate if potential participants are ready to make a change or are even fully aware of the issue. It can be used to evaluate the level of readiness of minorities to participate. Furthermore, it can also be used by research site personnel and organizations to develop strategies that would get this population to the action stage (making the decision to participate). Unlike the theory of planned behavior with the health behavior model, the results can be specifically used to determine if changes need to be made at an organizational level in order to raise the issue as a priority and to inform the investigator and other site personnel of their responsibility to educate minorities about clinical research and specific clinical studies. The literature

has shown that these types of changes might need to be made at the organizational level in order for the prioritization of the minority recruitment to be mandated to healthcare providers from a higher level within their organization. In addition, it would be beneficial to provide these healthcare professionals with the tools and resources to make the change possible. On the other hand, the model might not be the most ideal to utilize as it focuses on relatively small increments of change. It could be difficult to differentiate between the different stages as the same change/action could occur across multiple stages.

Self-Efficacy Theory.

The next theory that can be used to explain the issue of insufficient recruitment of minorities in clinical trials is the self-efficacy theory. A recurring theme in the literature is the lack of understanding from minorities about clinical research and the role they play in the decision process. The ultimate decision about whether to participate is their decision. However, as shown in the literature, minorities do not have an understanding of the informed consent process or its' purpose. Therefore, it is important to evaluate whether participants even feel empowered to make the decision about whether to participate. If they do not feel empowered to make the decision, then the gap of them not participating in clinical research will continue to exist, even when they are approached by researchers. This leads to the self-efficacy theory which aims to study this notion of empowerment.

The self-efficacy theory which originated from the social cognitive theory is the "extent to which people believe they are capable of performing specific behaviors in order to attain certain goals" (Consumer Health Informatics Research resource, 2012, ¶1). In fact, efficacy is a major factor in determining the choice that individuals will make when it comes to taking an action (Bandura, Adams, & Beyer, 1977). This includes how much effort they will put in and for how long they will persist in making the effort (Bandura et al., 1977). This means that self-efficacy is an important element when one makes a decision, including whether they will take a certain action or make a change to a behavior.

The self-efficacy theory centers on measuring a particular behavior or set of behaviors. It hypothesizes one's ability to perform a specific behavior also known as perceived self-efficacy. As Bandura stated (1994), "perceived self-efficacy is defined as people's beliefs about their capabilities to produce designated levels of performance that exercise influence over events that affect their lives" (p. 71). This means that perceived self-efficacy is the expectation that taking a certain action will lead to a desired outcome. For example, having confidence in making the decision to participate in a clinical trial will be an informed one. As Bandura et al. (1977) found, when people feel that they do not have the ability to deal with a situation, they will have fear or tend to avoid the uncomfortable situation. People who do not have self-efficacy will be more likely to not deal with a situation or take any action. In

fact, this low sense of efficacy means that they have low motivation or aspirations and a weak commitment to achieve a goal (Bandura, 1993). As further noted in Bandura (1993), people's beliefs in their capabilities affect their level of motivation.

When it comes to enrolling in a clinical trial, the application of the self-efficacy theory would be whether the potential participant has the power or ability to enroll in a clinical trial. Perceived self-efficacy would be the minority's perception of their ability to achieve the target of enrolling in a clinical trial. Therefore, minorities with low self-efficacy will tend to make the decision to not participate in the clinical trial because they may not feel confident or even motivated to participate. On the other hand, if they do have high self-efficacy, then they will be more likely to make an effort to make the best informed decision. It is the potential participant who has the power or ability to enroll in a clinical trial and through the utilization of the self-efficacy theory, it can be determined if they are even prepared to make the decision to enroll. If it is found that they do not have the confidence to make the best decision, researchers could then develop strategies to help potential participants feel more empowered to making a confident decision. They can utilize strategies that would motivate them and help them feel more confident about making an informed choice. Moreover, some of these strategies would include empowering them by improving their understanding of clinical trials and the role they play, especially when it comes to the decision process.

Decisional Conflict Theory.

Another theory that focuses on the same theme from the literature, the lack of understanding from minority participants about clinical trials, is the decisional conflict theory. More specifically, the literature has shown that there is a lack of understanding from minorities about the purpose of research studies. Not only do they not know what is required to conduct a study or the purpose behind the procedures and assessments, but they are also not completely informed about the benefits of enrolling in a research study. They have a mistrust of research based on past cases of discrimination which has contributed to this misunderstanding and skepticism. However, it is evident from the literature that they want to be fully informed about clinical research and the options that are available to them.

The decisional conflict theory aims to evaluate the decision process of individuals and specifically notes that decisional conflict is "a state of uncertainty about a course of action" (O'Connor, 1997, p. 4). This conflict or uncertainty exists when an individual has to make decisions which involve either risk or uncertainty of outcomes (O'Connor, 1997). They need to determine whether the potential gains outweigh the risks. The uncertainty can occur for a variety of reasons and are greater in certain situations. For example, the uncertainty could occur when an individual feels that they are not informed about the situation, are unclear about their personal values, or experiences unwanted pressure (O'Connor, 1997). More specifically,

uncertainty could be greater when an individual feels that they are uninformed about the alternatives, benefits, and/or risks, when they are not clear about their personal values, or when they feel they do not have the support in making the best choice or feel pressured in making one (O'Connor, 2010). Hence, decisional conflict can be decreased if they feel they do have sufficient information and support in understanding the different options available to them and making the best choice. Researchers can play a role in decreasing the decisional conflict by providing the applicable support, whether it is providing more information about the options that are available, the benefits of each option, or even the risks of each option. O'Connor (2010) noted that strategies that include describing outcomes in more sufficient detail, including physical, emotional, and social impact of each option could decrease the decisional conflict. This also means that sharing the decision-making process between the healthcare professionals and patient will make the patient feel more comfortable and satisfied with the decision that they decide to make as they will feel more supported (O'Connor, 2010).

In relation to clinical trials, the decisional conflict theory can be used to explain that potential participants do not have a complete understanding about clinical trials or the benefits of enrolling in one. They could be focusing on the past cases of discrimination and not realizing the steps that researchers now have to follow to ensure those types of cases do not happen again. For example, having to obtain approval from Institutional Review

Boards (IRBs), who review the protocol and plan for the participants to ensure they will be protected during their time in the study, along with having in place the informed consent process, which aims to ensure that every participant has agreed to understanding the trial and participating in it. Moreover, the decisional conflict theory is relevant to clinical trials as it aims to evaluate the uncertainty an individual has about making a choice between different options. For example, an individual could experience conflict in making the choice of whether to enroll in a clinical trial which will evaluate the efficacy of one or more interventions for the treatment of a disease or condition, or to continue taking treatments (if there are any) that are already on the market but which may not be highly effective or may have significant risks/side effects.

Important to also discuss is the Ottawa Decision Support Framework which includes decisional conflict as a component in the framework. The framework illustrates the connection between decisional needs, decision quality/actions/impact, and decision support. More specifically, the framework explains that a participant's decisional needs will affect their decision quality, action, and have an impact on health outcomes, emotions, and appropriate use and cost of services (Figure 3).

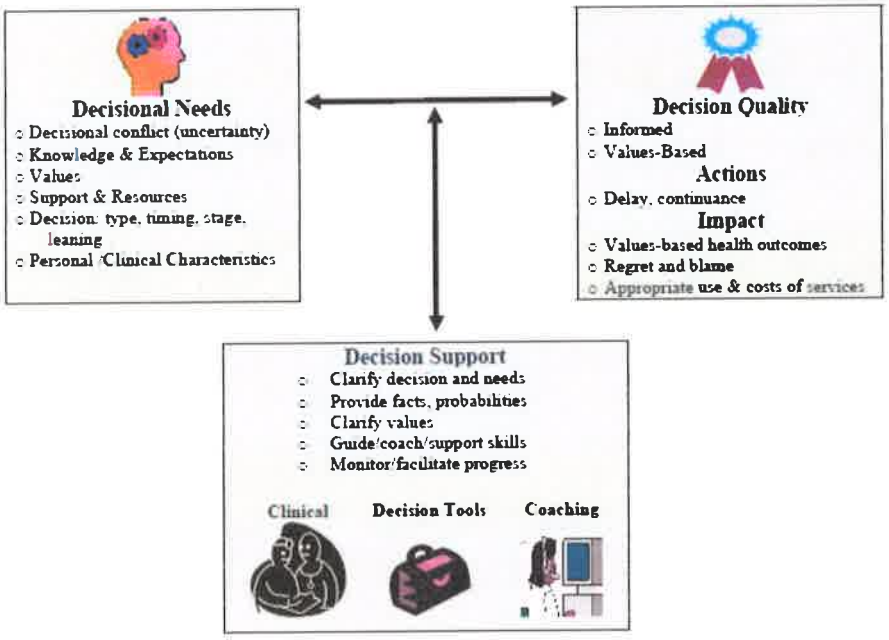


Figure 3. The Ottawa Decision Support Framework explains that a participant's decisional needs will affect their decision quality, which consequently affect actions or behavior, health outcomes, emotions, and appropriate use and costs of services (O'Connor & Jacobsen, 2006).

Unlike the self-efficacy theory, this framework specifically highlights the role that all stakeholders who are involved in the decision-making process play. This would include both the individual and health professional such as the investigator or another member of the research site. Decisional conflict is one decisional need that can affect decision quality and action. Other factors include inadequate knowledge and unrealistic expectations; unclear values; inadequate support or resources; complex decision type; urgent timing; unreceptive stage of decision-making; polarized leaning toward an option;

and participant characteristics such as cognitive limitations, poverty, limited education, or physical incapacitation (O'Connor & Jacobsen, 2006).

Decisional conflict can be resolved by addressing the factors that are contributing to that uncertainty (O'Connor & Jacobsen, 2006). For example, as mentioned earlier, an individual's uncertainty can be due to a lack of knowledge or understanding. However, this can be addressed by helping the individual obtain information related to the situation, along with the options available, and the outcomes of those options (O'Connor & Jacobsen, 2006). In doing so, they will have enough information/details to understand the benefits and risks of each option and will feel more confident making a decision. Another way to minimize the uncertainty is to ensure that expectations are realistic. This includes providing the likelihood of the outcomes for each option and providing situations that the individual can relate to (O'Connor & Jacobsen, 2006).

Decision support is also included in the framework as it is used to help address the unresolved needs of the individual. The decision support can be in the form of clinical counselling, decision aids, and coaching (O'Connor & Jacobsen, 2006). This means that the healthcare professionals or the research site staff would be the ones helping to clarify the different options, providing facts and probabilities, and moreover, being there to guide and support the individual (O'Connor & Jacobsen, 2006). Relating it back to clinical trials and the key stakeholders, the research site personnel need to

serve as the decision support to the potential participants who have the decisional needs. They need to enable the participants to make an informed decision. This means that they need to be ones to provide the potential participants with the information on each option and ensure that expectations are aligned. Guiding the potential participants through the steps in the decision-making can minimize the uncertainty. Moreover, the literature has shown that potential participants are not always given the time to discuss the different options available to them. For example, the physician's lack of time and opposing responsibilities make it difficult to spend sufficient time with each patient. The literature also says that patients who are given more time to make a decision are more likely to participate in clinical research. This is in line with the framework that illustrates that individuals have a decisional need for adequate support and resources such as time. Without this, there will continue to be a negative impact on the decision outcomes, which could be the reason for the insufficient enrollment of minorities.

The decisional conflict theory and Ottawa Decision Support Framework can be used to understand an individual's decision-making process and what prevents them from making an informed decision and one that is aligned with what they value. For example, understanding what factors lead to their uncertainty or why they have difficulty in making a decision. With this information, researchers can develop and use strategies to ensure that potential participants have the information they need to make an informed,

value-based decision. This information can also be used to emphasize to research site personnel, and especially investigators, the importance of providing support and sufficient time to minorities and prioritizing this activity amongst their responsibilities.

Healthcare Professionals' Role

In the first chapter, the stakeholders of the recruitment process were identified and the role that they play in the recruitment of participants for clinical trials was described. In order to continue to understand why the problem with recruitment exists, it is also important to understand the role of healthcare professionals. "Health professionals study, diagnose, treat and prevent human illness, injury and other physical and mental impairments in accordance with the needs of the populations they serve" (Transformative Education for Health Professionals, n.d., ¶1). Furthermore, they provide guidance on or help apply preventative or treatment measures for individuals and populations (Transformative Education for Health Professionals, n.d.). Therefore, they are also essential in the recruitment process of clinical trials. While they wear many different hats depending on the type of care they provide to patients and their role in the healthcare field, all of them have a responsibility to improve healthcare, which includes the success of clinical research.

In a study by Durant et al., (2014), it was found that all stakeholders of the recruitment process felt that there was a level of skepticism by minorities

when it came to participating in clinical trials. There can be steps taken to decrease this skepticism, which would in turn increase the patients' confidence in research opportunities, specifically when looking at the role that healthcare professionals could play. Mendoza et al. (2012) felt that it was important to assure confidentiality of the subject and to reach out to the minority community. Both of these strategies will help increase trust in the researcher and the clinical trial being presented. Another strategy could be to "increase the knowledge about clinical trials including randomization procedures, the informed consent process, participants' right, and benefits of clinical trials" (Ma et al., 2014, p. 13). Finally, Durant et al. (2014) also suggested using facilitators, who could be healthcare professionals, to increase awareness of opportunities for participation. Hence, the role of healthcare professionals is important in clinical trials although it is overlooked at times. Although they may not be directly responsible to recruit participants in clinical trials, they still have the responsibility to introduce patients to new research and clinical trials. They are at the frontlines of creating the bridge between those research opportunities and the patients. Therefore, it is important to understand the increasing role that they could hold in the clinical trial recruitment process.

Summary

Based on what is in the literature regarding the gaps with minority recruitment in clinical trials, it is known that the problem continues to exist and

that no effective strategies have been implemented across investigative sites. Although some reasons as to why minorities do not enroll in clinical trials have been proposed, the majority are based on research that has been conducted on a specific minority population (ex: African Americans) or a disease area (ex: Oncology). Therefore, this means that there is a need for further understanding as to why minorities in general continue to not participate in clinical trials, especially as the problem has been shown to exist across all minority groups and disease areas.

The factors set forth by the decisional conflict theory – lack of knowledge, un-clarity in values, and lack of support – need to be evaluated to understand whether they are affecting potential minority participants' difficulty in making the decision of whether to enroll. Furthermore, more insight would be provided by exploring the issue from the perspective of minority healthcare professionals who could also be potential participants in clinical trials. Not only would understanding their perspective as potential participants shed light on the issue, but there would be information on the implications on healthcare practice. If minority healthcare professionals experience decisional conflict when deciding whether to enroll in a clinical, then the same would be expected from minority participants. In addition, the literature has shown that patients might feel more comfortable speaking to a physician who is similar to them, known as racial concordance. Therefore, minorities are more likely to choose physicians who are culturally and linguistically similar to them (Saha,

Komaromy, Koepsell, & Bindman, 1999). If minority healthcare professionals do not enroll in clinical trials, then it would make sense as to why other potential minority participants would also not consider enrolling.

Chapter III.

METHODOLOGY

As explained in the first two chapters, there is a health disparity directly impacting the minority population which is limiting their ability to reap the maximum health benefits that are available to others. Although the problem is recognized by many, including its' effects, it still exists and solutions still need to be proposed. More importantly, the barriers prohibiting a change in healthcare for minorities need to be evaluated from a patient perspective. Therefore, the study was designed to understand why minority patients continue to not participate in clinical trials as they are the ones who need to provide the final consent.

A general qualitative study design was used to understand the perspectives of minority healthcare students/professionals on clinical trial enrollment. The exploratory nature of this study type allowed the Principal Investigator (PI) to explore the thought process of minorities when it comes to clinical trial enrollment and understand what influences their decision. It is important to note that the five types of qualitative study designs that are traditionally used – phenomenological studies, case studies, ethnographic studies, grounded theory studies, and case studies – did not fit the nature of the study. The exploratory research design used in this study was appropriate as it fit the exploratory nature of the purpose and research questions. Furthermore, the study design was both descriptive and

exploratory in nature. It was descriptive in that it involved describing a group of individuals on a set of variables (Portney & Watkins, 2000). For this study, the PI wanted to describe the demographic characteristics of the minority healthcare students/professionals included in the study. It was exploratory in that the researcher was examining a phenomenon of interest and exploring its' dimensions. The PI used the Ottawa Decision Support Framework as a lens to explore whether minorities experience decisional conflict when deciding whether to enroll in a clinical. More specifically, the PI used the factors set forth by the decisional conflict theory as a guide to evaluate what influences a minority's decision when deciding whether to enroll in a clinical trial. These factors are "the modifiable factors contributing to uncertainty such as feeling uninformed, unclear about personal values, and unsupported in decision making" (O'Connor, 2010, p. 1). As the research study was purely qualitative in scope, there were no hypotheses accompanying the research questions. To this extent, there was one overarching research question guiding the study, which is:

- What influences potential minority participants' decision on whether to participate in a clinical trial?

This research question is important because conflict or uncertainty exists when an individual has to make decisions which involve either risk or uncertainty of outcomes (O'Connor, 1997), and by understanding what influences or contributes to the uncertainty when potential minority

participants have to choose whether to participate, researchers can create appropriate strategies to help mitigate the gap that exists in clinical trial enrollment. Following the overarching research question, three primary questions were guiding the study:

1. What do potential minority participants associate with clinical trials?
2. What role do values play in clinical trial enrollment for potential minority participants?
3. What role does support play in clinical trial enrollment for potential minority participants?

Moreover, it was cross-sectional in nature as only one interview was conducted with each individual.

Sample Population

Data was collected from graduate healthcare students/professionals from Seton Hall's School of Health and Medical Sciences. Purposeful sampling was used as the sample population, graduate healthcare students/professionals, was targeted due to the purpose of the study – understanding the perspective of minority healthcare professionals. Purposeful or purposive sampling "is based on the assumption that the investigator wants to discover, understand, and gain insight and therefore must select a sample from which the most can be learned" (Merriam, 2001, p. 61). By interviewing minority healthcare students/professionals who can also be potential minority participants in clinical trials, it allows for an

understanding on the issue from their perspective as potential participants, but more importantly, the implications on healthcare practice. Healthcare students/professionals have the responsibility to make patients aware of research opportunities. Therefore, it is important to evaluate their viewpoints as this may affect their interactions and communications with patients when it comes to potential clinical trial enrollment. Furthermore, as mentioned previously, the literature has shown that patients feel more comfortable speaking to a physician who is similar to them, known as racial concordance. Therefore, by understanding what influences the decision of a healthcare student/professional to enroll or not enroll, it helps explain why potential minority participants are not currently enrolling. If healthcare students/professionals are experiencing decisional conflict and choosing not to enroll, then it provides insight on how recruitment practices need to change in order to increase minority enrollment.

The study required a sample size of at least 20 individuals who met the inclusion and exclusion criteria. With qualitative studies, g-power is not used to calculate the sample size. Instead, a literature search was performed to determine what ranges are generally recommended. As per the literature, with qualitative research, data is collected until the point of saturation, which is when the categories or themes that emerge become saturated (Charmaz, 2006) (i.e., no new categories/themes do not emerge). However, there are also more specific guidelines that have been recommended by researchers.

For example, as per Guest, Brunce, and Johnson (2006), when the goal is to understand common perceptions, 12 interviews should be sufficient for a relatively homogenous population. In addition, as per Green and Thorogood (2009), "The experience of *most qualitative researchers* (emphasis added) is that in interview studies little that is 'new' comes out of transcripts after you have interviewed 20 or so people" (p. 120). Therefore, as this study was also an interview study, the sample size was at least 20 graduate-level healthcare students.

The graduate students were contacted through their department representatives, such as the department secretaries. It was important to contact the students through their department representatives and not the Program Chairs in order to avoid subtle, although unintended, coercion. A solicitation email that briefly described the study and its' purpose was sent to the Program Chairs for further distribution. See Appendix B for the email that was sent to the students about the study. The Chairs for the following programs at Seton Hall University's School of Health and Medical Sciences were contacted and agreed to send the solicitation email for further distribution: Interprofessional Health Sciences and Health Administration, Physician Assistant, Occupational Therapy, Athletic Training, and Speech-Language Pathology. Furthermore, flyers with the study information were posted in each department's bulletin board. The entry criteria consisted of graduate students at Seton Hall University's School of Health and Medical

Sciences who were characterized as a minority based on race based on the U.S. Census Bureau, able to understand and speak English, not involved in the recruitment of participants in clinical research at the time of participation in the study, did not participate as a patient in a clinical trial in the last year, and a U.S. Citizen or Permanent Resident. According to the U.S. Census Bureau (2013), minorities include those who are Hispanic or Latino, Black or African American, American Indian or Alaskan Native, Asians, Native Hawaiian or Other Pacific Islander, or those who are two or more races. It is important to note that the focus was not just healthcare professionals because the PI was looking at the influence of the healthcare system, whether it's now or later, and the research questions did not differentiate between the two. In addition, only individuals who were U.S. citizens or permanent residents were included as the focus of the study was on the U.S. healthcare system, and therefore, only individuals who have some influence on healthcare practices in the United States were included.

Data Collection

There were two data collection methods in this study. First, there was a questionnaire on demographics (Part A) and the advantages and disadvantages of participating in a clinical trial (Part B). This online survey, which was called the Participant Survey, was available through Survey Monkey. See Appendix D for the Participant Survey. The advantages of using an online survey as a method to collecting data are related to reduced

costs, rapid deployment, real-time reporting, higher cooperation and survey completion rates, speed to collecting data, and decreased data entry error (Ilieva, Baron, & Healey, 2002; Wharton, Hampl, Hall, & Winham, 2003; McDaniel & Gates, 2005; Gaide, 2005). In other words, using an online survey permits the researcher to reach many respondents in a short period of time and at lower cost than other methods. Due to these reasons, an online survey was selected for this portion of the study.

The purpose of the Participant Survey was to obtain information on the participant such as their age, gender, race, education, and their role in healthcare if they were also working. By collecting this information, the PI would be able to describe the sample population, especially the minority groups that participated in the study. The second part of the survey was to collect each participant's responses on the advantages and disadvantages of clinical trials prior to the interview. However, when the data began to be collected, it turned out that this information would not bring value to the results. Therefore, these responses were not analyzed and will not be presented in this paper.

The second and main data collection method of the study was the one-on-one interview with each participant. The one-on-one interviews took place over the phone or on campus. By giving the individual the option of conducting the one-on-one interview over the phone or on-campus, the data could be collected in a setting that was convenient and comfortable for the

participant. If the individual wished to interview on campus, an area that is free from distractions was be chosen. The in-depth interviews were audiotaped – 1) For the interviews that place over the phone, FreeConferenceCall.com was used, which had an option to record the call, 2) For the interviews that took place in-person, Dragon Recorder was used to record the interview. By the fact that this was a qualitative study, there were specific questions that were used as a guide to interview the participants and collect the data through a semi-structured interview approach. Please see Appendix F for the Interview Guide. A semi-structured interview is when the PI has specific questions or topics they want to ask during the interview; however, there is flexibility in how the interview goes (Edwards & Holland, 2013). For example, the researcher "can probe answers, pursuing a line of discussion opened up by the interviewee, and a dialogue can begin" (Edwards & Holland, 2013, p. 29). This type of interview is more advantageous than a structured interview because it allows for more probing, or in other words, the ability to ask follow-up questions, while at the same time ensuring that certain questions or topics are covered. As the PI wanted to cover specific topics during the interviews, the decision was made to use the semi-structured interview approach. There were specific questions guiding the interview but the PI had the flexibility to ask follow-up questions based on the participant's responses. The questions in the Interview Guide

were developed based on the three main modifiable factors set forth by the Decisional Conflict Theory.

It is also important to touch upon confidentiality of the subjects. Assurance of confidentiality was of critical importance; protection and confidentiality were maintained throughout the duration of the research project. In the Participant Survey, participants were asked for their contact information (phone and/or email address) in order to schedule the 1:1 interview with the PI. However, after the survey was completed, the PI assigned the individual a participant number utilizing the Participant Confidentiality Coordinator Sheet. For example, the first individual who completed the Participant Survey was assigned as Participant #1, the second individual who completed it was assigned Participant #2, etc. The participant number was used to identify the participant during the transcription and coding phases to maintain confidentiality and will be used to identify the participants in the latter chapters of this paper.

Study Procedures

As the sample population and data collection methods have been described, it is now important to discuss the flow of the study procedures. After receiving approval from Seton Hall's IRB to start collecting data (see Appendix A), the PI entered the Participant Survey to surveymonkey.com and made it available to the population. The PI then sent an email to all of the Program Chairs who had provided their approval to access their student email

database (through their department secretary or representative). This email contained the solicitation email with a link to the Participant Survey. After an individual clicked on the link, they were directed to surveymonkey.com to complete the survey. After reading the solicitation letter (see Appendix C) and agreeing to continue in the study, they were directed to the entry criteria to confirm they were eligible to participate. Then, after confirming they met the entry criteria, they were directed to complete the survey. Finally, after answering all of the questions (no answer can be skipped), the respondent submitted their responses to the survey. Once the PI received the completed survey, the PI assigned a participant number to the individual. Next, the PI contacted the individual to schedule the one-on-one interview and to obtain a written informed consent. The written obtained informed consent had to be obtained prior to the start of the one-on-one interview. In addition, the PI gave the participant a copy of the informed consent form and kept the signature page for record-keeping.

At the start of each interview, the PI ensured the interviewee that his/her responses would remain confidential. The PI then gave an introduction along with an explanation of the goals of the research in broad terms and then started recording the interview. Finally, the PI followed the general script of the study for the remainder of one-on-one interview. See Appendix E for the general script used for the interviews. After each interview was completed, the PI began the transcription and data analysis process.

Transcription and Data Analysis

Overall strategy.

The overall data analysis strategy was to only develop codes based on the emerging information collected from the participants (Creswell, 2013), a process referred to as inductive analysis (Patton, 1990). This is the opposite of using a pre-conceived list of codes. The purpose of the study was to use the data collected to see what emerged. The PI did not want to already create bias in the data by using a pre-conceived list of codes that were expected to be found and then try to make it fit the data that was collected. In addition, by coding through an inductive analysis approach, it helps eliminate the use of incorrect assumptions. When an apriori framework is used to start analyzing the data, which means analyzing the data according to an existing set of ideas or framework, there is little discovery of new ideas (Jacelon & O'Dell, 2005). In addition, this can lead to the use of incorrect assumptions set forth by other researchers (Boyatzis, 1998).

As the PI, I also want to explain my positionality/subjectivity, which is important to understand because I acted as the primary instrument by collecting the data and filtering through it. This is also a measure to be aware of and limit personal bias throughout the process and avoid utilizing incorrect assumptions (Boyatzis, 1998). My positionality and subjectivity comes mainly from working in the pharmaceutical industry. I have worked on various clinical trials in my experience in the industry and have been involved in the

recruitment process. Being involved in the recruitment process of a clinical trial has allowed me to become aware of the difficulty investigative site personnel face when they need to recruit participants. I have been involved in clinical trials that attempt to understand these difficulties by working directly with the investigative site personnel to gain insight into the recruitment process and challenges encountered. Therefore, through this time up until now, I continue to try to understand how to mitigate the gaps in order to allow a trial to successfully complete according to the planned timelines. In addition, being characterized as a minority myself, I have my own perspectives about clinical trial enrollment and being a potential participant. Again, this self-reflection is meant to explain my position in the study and the decisions that I made as the PI.

Transcription.

As each interview was finished, it was downloaded and saved on a USB and kept in a locked, secure physical site. With qualitative studies, the transcription and data analysis process starts as soon as the first piece of data is collected. Therefore, each recorded interview was transcribed in Microsoft Word verbatim (increasing the reliability) after each interview was completed. Furthermore, a transcription key was used in order to add depth to the data (See Appendix G). All personally identifiable information was removed and confidentiality of the participants was maintained through the transcription process. Participants were only be referred to by their

participant number. After each transcription was completed, the transcript was checked to make sure that no obvious mistakes were made during the transcription (Creswell, 2013). This was done by playing the recording back and ensuring that what was in the transcript matched the recording. The next steps will discuss how the PI began the data analysis process through the interpretation of the data.

Understanding the data and focusing the analysis.

After transcribing the data, it is important to read through the data several times. This helped the researcher become familiar with what was discussed during the interviews. As data collection continued and the PI began to delve into the ideas that came up, the PI found it surprising to see some points raised and some that were not. The ideas that were jotted were based on the PI's own perspective, which is based on the PI's background and experiences of working in the pharmaceutical industry.

The next step was to determine how to analyze data. Unlike quantitative data, qualitative is not always clear on the best approach to analyzing the data. For example, the literature shows many different ways of how to look at the data. Some ways could be by focusing by question or topic, or focusing by each case, individual (Taylor-Powell & Renner, 2003). Therefore, the first decision that needed to be made was whether to look at the responses of each question or topic separately and across participants. If this approach was used, this would have already created separations in the

data that possibly weren't there. The PI would have already assumed that themes were specific to a question, which was not the case. Furthermore, in the interviews it was apparent that this was not true as some ideas overlapped across questions. For example, the unknowns in clinical trials and the support that is needed were mentioned across questions and topics. In addition, with qualitative research, it is important to understand the purpose of the research in order to help determine the best way to analyze the data. Again, the purpose of the research was to be exploratory, open-ended, the PI was not pre-conceived by any categories, so it was really important to identify the emerging themes. Therefore, the decision was made to take a holistic approach and look at each participant separately first.

Coding.

After the decision was made on how to analyze the data, the coding process began. The coding process is when the researcher starts to develop the organization of the data (Spiggle, 1994). It's really the first step in adding value (Spiggle, 1994) and bringing meaning to the words (Taylor-Powell & Renner, 2003). This process started as soon as the first interview was completed and transcribed. The PI went through all of the text for every single participant and start assigning values, also known as codes, to the text (Ryan & Bernard, 2000). Specifically organizing the data by bracketing chunks of text and writing a word or a few words that represent the text (Rossman & Rallis, 2012, as cited in Creswell, 2013). The Comment feature

of Microsoft Word was used to assign the codes to the text. It is important to clarify that researchers have emphasized that it cannot just be done by a sentence by sentence view. Instead, codes are assigned based on the meaning of the words so each idea gets a separate code. Therefore, the length of the text could be part of a sentence or several sentences long (Spiggle, 1994). In addition, as mentioned previously, as an inductive analysis approach was use to analyze the data, the codes that were assigned were based on the emerging data rather than pre-conceived categories and themes. Researchers have started to recommend using software to complete this step as it can be very overwhelming and time-consuming. For this study, the coding process was a very extensive process as all of the data was coded by hand. Furthermore, qualitative data is also unique in that there is no fast and hard rule of assigning codes. However, as data continued to be collected and coded, the above process continued to be followed.

After all of the data was collected and coded, another individual was included in the process called a Peer Reviewer. As explained by Qualitative Expert Merriam (2001), the process of peer examination helps to increase trustworthiness and internal validity of the data. The Peer Reviewer was an individual who also works in the pharmaceutical industry and has a background on clinical trials. In addition, they were trained on qualitative data to ensure they understood the data analysis process. The Peer Reviewer reviewed the codes that were developed by the PI to ensure they accurately

reflected the text. After they completed their review, the PI and Peer Reviewer went through the feedback and discussed the true meaning of the text to determine what changes were needed. Once agreement was reached on the changes that needed to be made, the PI incorporated those changes accordingly. After completing the coding process, there was a list of over 100 codes that were developed based on the emerging data from the 20 participants.

Forming categories.

As recommended in the literature, the researcher should begin to write down some themes or patterns that are found through the coding process (Jacelon & O'Dell, 2005). Through the process of coding, there were some themes that jumped out. The PI wrote them down, beginning to create the major categories. Some major categories included potential to have benefits, try something new, and unknowns. The PI then went through the list of codes that had been developed and began to file them under the major categories. This process is almost like taking documents and putting them in filing cabinets that are labeled with what should go into each one. For example, filing the code "prevention" under the major category "benefits". As the process continued, the list of categories was revised with the PI adding and editing them as necessary. There were some codes that were not major ideas (ex: only mentioned once) and thus they were not filed under a category. One participant had mentioned that they would be wary of enrolling

in a clinical trial due to the fear of being addicted to the drug under study (Participant #1). This code, drug addiction, was not a major category as it was only mentioned once, and thus, was not filed under any major category.

In general, this categorization process involved taking the detailed codes and putting them into more general conceptual classes. After completing the process, there were a little over 30 categories formed, which is in line with the literature. According to Creswell (2002), after completing this process, there will be about 30-40 categories.

Themes.

The next step of the analysis was to delve into the categories and see where connections lied. According to Taylor-Powell and Renner (2003), the researcher needs to identify the patterns and connections both within and between the categories. Furthermore, begin to create larger categories also known as super categories (Taylor-Powell & Renner, 2003), which would eventually become the themes. This process required the PI to spend time looking at the data and understanding where there were overlaps and redundancies. For example, originally there were two categories – Benefits and Compensation. It became evident based on what the participants had said when the relevant codes were used was that being compensated would be an additional benefit to them for participating and something that would influence their decision. Therefore, "Compensation" was moved under the category of "Benefit." Another example is the need to be educated and have

information, and stereotypes. Originally these were two separate categories. However, when the PI delved into the data behind each category, the connection became clearer. Individuals have stereotypes because of what is portrayed on the media about clinical trials (the negativity) and their lack of understanding of what clinical trials really involve. However, through information and education, a lot of these stereotypes could be clarified or at least bring about a wider view of what clinical trials are about besides the negativity they noted seeing in the media. Furthermore, it also needed to be determined whether two or more categories were found together consistently in the data (Taylor-Powell & Renner, 2003), in which case they could potentially be combined. In the data, unknowns and the negative perspective of unknowns were found consistently together in the data so they were combined them.

Throughout the process of looking at the categories and understanding where connections or patterns existed, the PI was constantly going back and re-visiting the transcriptions to verify that the ideas were accurate and the decisions made were in line with what the participants had said. The impact of this process it to aggregate the data into a smaller number of themes such as three to eight (Thomas, 2006). By the end of this process, eight major themes had been formed, aligned with the recommendation from the literature.

Data interpretation.

After forming the eight themes, the last step was to bring significance to what had been found. The lens that had been picked for interpreting the themes was the Ottawa Decision Support Framework. The framework was used to understand if it explained some or all of the themes that had been formed, or in other words, explaining the findings (Taylor-Powell & Renner, 2003). Specifically, whether it helps to explain what influences a minority individual's perspective on clinical trial enrollment. In addition, in this step, it was necessary to realize the lessons that were learned (Creswell, 2013).

Reliability and Validity

In order to help increase the trustworthiness of the results that will be presented, it is important to describe the steps that were taken to increase the trust. As this is a qualitative study, ensuring reliability and validity are done differently compared to quantitative studies. In qualitative studies, reliability and validity are increased at a process-level.

In regards to reliability, there were several steps taken to maximize the quality of the data. First of all, interviews were recorded and the interviews were transcribed verbatim. Once done, transcriptions were checked to make sure no obvious mistakes were made during transcription (Creswell, 2013). In order to be transparent in how the data was managed, an audit trail was also created. This audit trail included information on how the data were collected, how the categories were derived, and the decisions that were made throughout the process (Merriam, 2001). In addition, it was especially

important to ensure clarity in the steps that were taken during the coding process. For example, it was ensured that there was not a shift in the definition/meaning of the codes (Creswell, 2013), increasing the reliability of the data. This was accomplished by constantly comparing data with the codes and by writing memos about the codes and their definitions. Furthermore, with qualitative data, there is a likelihood of bias being introduced as the PI will have experiences or certain knowledge of the topic. This may have an impact on the coding process. Therefore, it is important to explain the investigator's position (Merriam, 2001; LeCompte & Preissle, 1993). This includes explaining the assumptions and theory, his/her position in regards to the topic and population that are being studied, and the reason for selecting the population and a description of them. These points were explained earlier in this chapter.

There were also strategies put in place to increase the validity of the study. Similar to reliability, validity also requires understanding the PI's perspective and decisions that were made. Therefore, it is also important to note the PI's assumptions and biases (Merriam, 2001). As stated by Creswell (2013), "self-reflection creates an open and honest narrative" and should "comments by the researchers about how their interpretation of the findings is shaped by their background, such as their gender, culture, history, and socioeconomic origin" (p. 251). Further, reflection is a fundamental characteristic of qualitative research. These assumptions and biases were

discussed earlier this chapter. Another step taken to increase validity was using a peer examiner. For all of the coded and themed data, there was a peer examiner who checked and confirmed the themes that were produced and the interpretation of them. The process of peer examination is to help increase trustworthiness and internal validity (Merriam, 2001). A peer examiner was included in this study and reviewed the codes that were produced after approximately 10 interviews were completed and coded, and then after the last interviews had been completed and coded.

Validity was also increased in the way that the data was presented. For example, rich, thick descriptions were presented to convey the findings (Creswell, 2013; Merriam, 2001). These descriptions give the reader a better understanding of the settings and a closer look at the experiences, such as different perspectives about a theme. By doing so, the results become more realistic and richer. Furthermore, negative or discrepant information that runs counter to the themes will also be presented (Creswell, 2013). Unlike quantitative data, "outliers" are not removed from qualitative data. Instead, it is important to present all data as each individual has their own experience to share. While the PI should present information to build a case for the theme, information that contradicts the general perspective should also be presented (Creswell, 2013). In fact, real life is based on different perspectives and by discussing the contrary information, credibility is added to the findings and it

becomes more realistic and valid. The next chapter will discuss the themes that emerged along with some contradictory findings.

Chapter IV.

RESULTS

There will be two sets of results presented in this chapter. First the demographic information from the participants included in the study will be presented. This information is based on the participant responses to the Participant Survey, which was made available through Survey Monkey. The second set of results will be the themes that emerged from the interview data.

Demographics

Participants in the study were required to answer all demographic questions on the Participant Survey. 75% of the individuals that participated in the study were females while 25% were male (Figure 4). This is an interesting result because the literature has noted that besides minorities, women are also under-represented in clinical trials. Although they are less likely to participate in a clinical trial, they were more likely than males to participate in this study and provide their perspective on clinical trial enrollment.

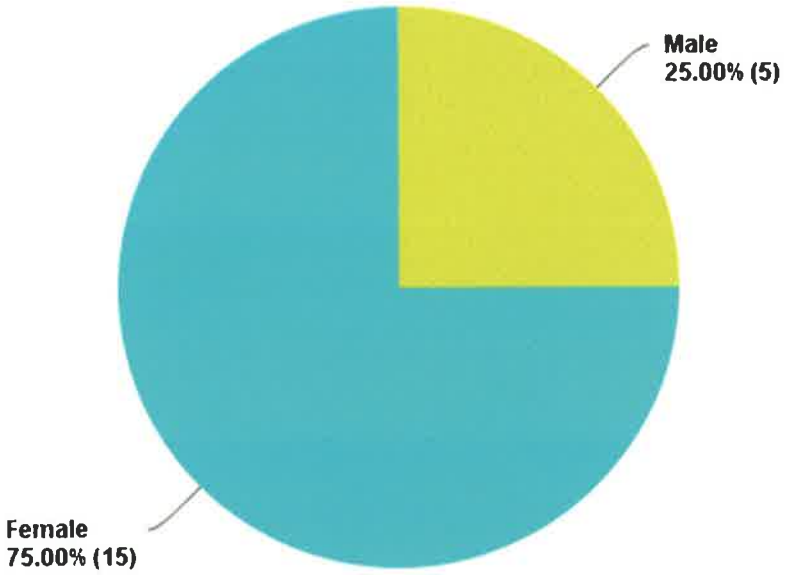


Figure 4. The pie graph illustrates the representation of each gender in the study.

In regards to age, the representation of the different age groups is aligned with the literature. As shown in Figure 5, there was good representation of individuals between the age of 18 and 40 but then it started tapering off with no representation of individuals who were older than 60. The literature says that although the elderly population is growing at a fast rate, especially due to the increased life expectancy, and the fact that these individuals make up a good portion of those who have certain health conditions such as cancer, cardiovascular disease, arthritis, and Parkinson's disease, they are underrepresented in clinical trials (Shenoy & Harugeri, 2015). In addition, "clinical trials conducted in the adult population typically only include patients between the ages of 18 and 64 years" (Shenoy &

Harugeri, 2015, p. 184). It is also important to highlight that the representation of the age groups is also attributed to the fact that the study took place in an educational setting.

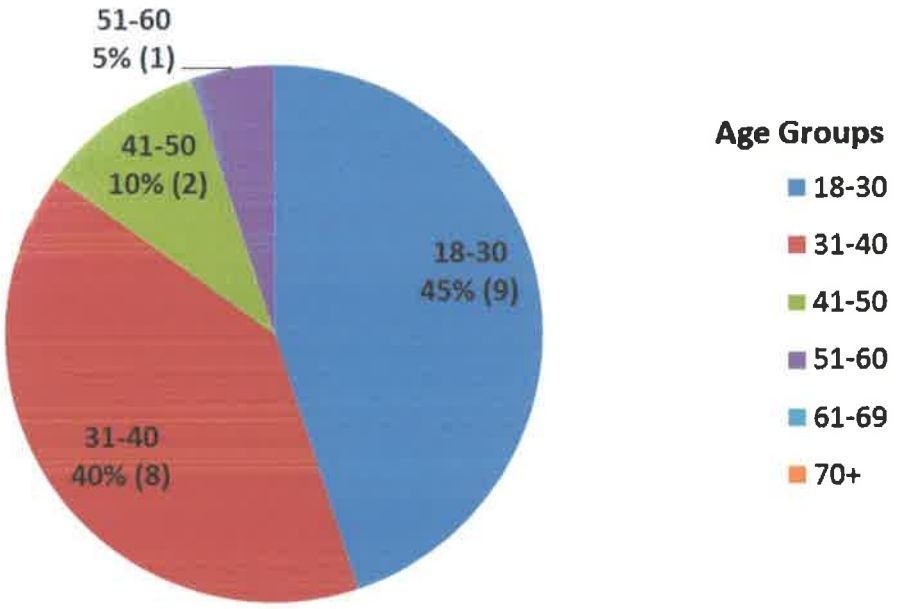


Figure 5. The pie graph illustrates the representation of each age group in the study.

Figure 6 shows the representation of the ethnicity groups, with 80% selecting that they are not Hispanic, Latino, or of Spanish origin and the remaining 20% selecting that they are. The ethnicity groups are as per the U.S. Census.

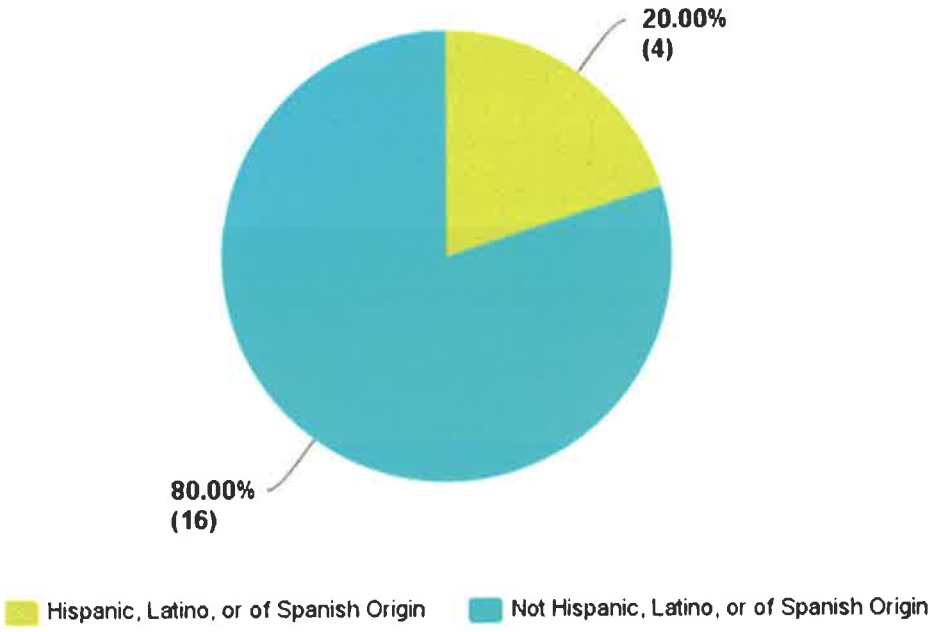


Figure 6. The pie graph illustrates the representation of each ethnicity group in the study.

All individuals were also asked to answer which race(s) they identify with. These categories are also according to the U.S. Census. As shown in Figure 7, almost half of the participants identified as being Black or African American. There was also some representation from Asians, which is important as they are now the fastest growing population (Ma et al., 2014). The individuals who selected "Other" identified themselves as being two or more races, Indian, Latino, and Middle Eastern Arab. Typically, an individual who is Indian is usually categorized as being Asian. However, the responses written in the "Other" field were not adjusted as the question asked them to select the category(ies) they identify with. It was possible for the participants to select multiple categories (as many as they identify with).

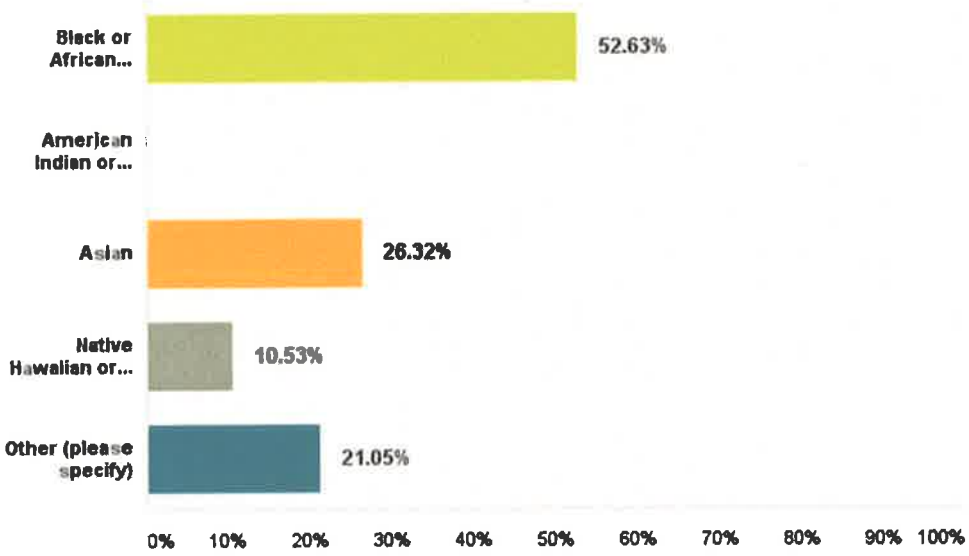


Figure 7. The bar graph illustrates the representation of each race in the study. Participants were allowed to pick as many races that they identified with.

The next three questions the participants were asked to answer were to gather information on their education level. Figure 8 illustrates their responses for the highest degree they had attained with 65% having a Master's degree and 25% having a Bachelor's degree. The two individuals who selected "Other" were in a combined Bachelors/Masters program and would receive their Bachelor's degree later in their programs. Overall, the individuals in the study were well-educated. However, again, this can be attributed to the sample population being from a higher education setting. In relation to the literature, the literature says that investigative site personnel feel that minorities won't make good study participants because they won't be able to understand the research of the study (Joseph & Dohan, 2009).

However, minorities are typically well-educated. For example, according to U.S. Census Bureau (2016), Asians are the largest percentage of individuals who have Bachelor's degree or higher compared to 54% for other races.

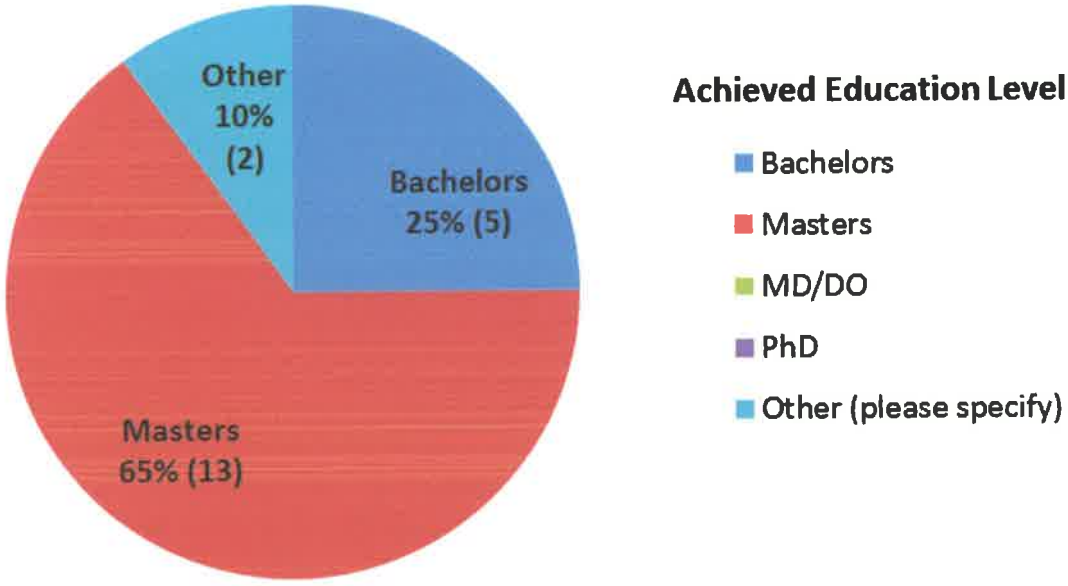


Figure 8. The pie graph illustrates the achieved education level of the participants in the study.

Figure 9 shows the level of education the participants were working towards completing with 65% of the participants in the doctoral program.

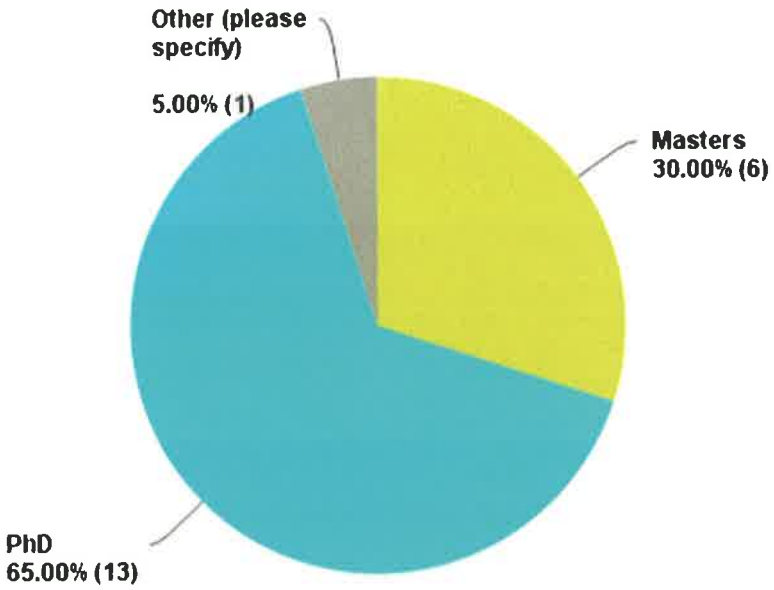


Figure 9. The pie graph illustrates the education level the participants in the study were completing at the time of the study.

Figure 10 illustrates the program the participants were enrolled in. In line with the above results, a majority of the participants, 65%, were in the PhD in Health Sciences program. There was also some representation from the Physician Assistant, Occupational Therapy, and Athletic Training programs. Although the students in the Speech-Language Pathology were also asked to participate, no students completed the Participant Survey, and thus, were not represented in the study.

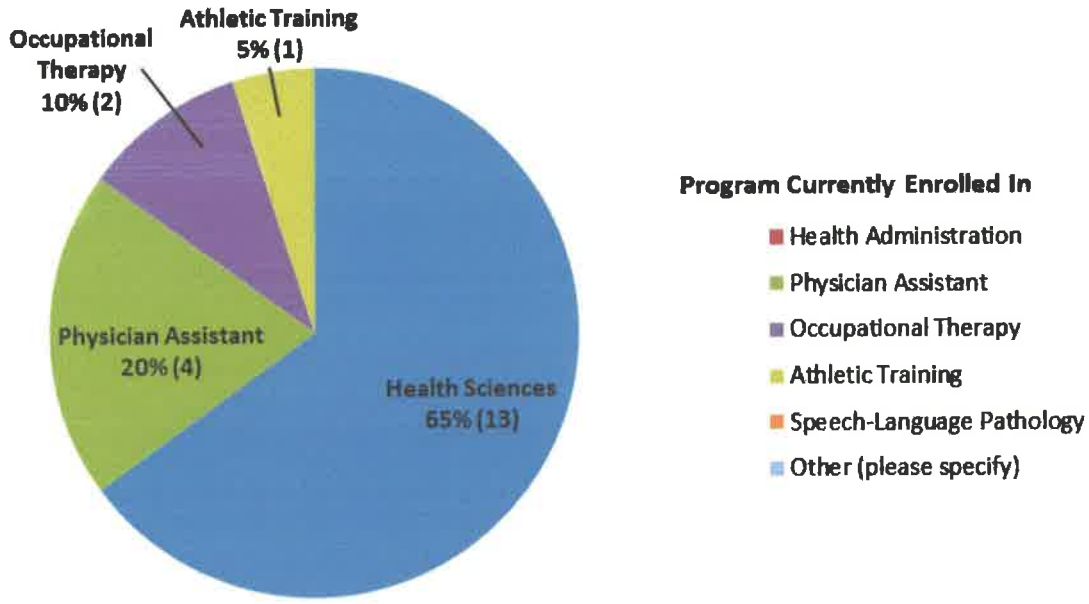


Figure 10. The pie graph illustrates the representation from each program at Seton Hall University's School of Health and Medical Sciences.

Figure 11 highlights the number of individuals who have previously been involved in the recruitment of participants. A majority of the individuals (80%) did not have previous experience with the recruitment of participants.

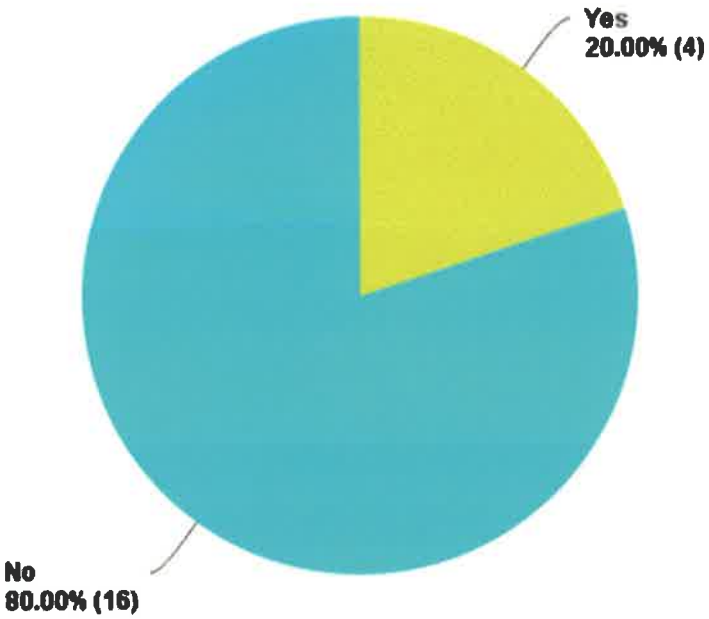


Figure 11. The pie graph illustrates how many participants in the study have previously been involved in the recruitment of participants.

Finally, the last two questions asked the individuals the extent of paid workplace healthcare experience they have. As shown in Figure 12, 60% responded with having paid workplace healthcare experience while 40% did not. The paid workplace healthcare experience consisted of diverse roles including a Provider Engagement Executive, a Clinical Research Associate, Exercise Physiologists, and a Quality Manager at a hospital.

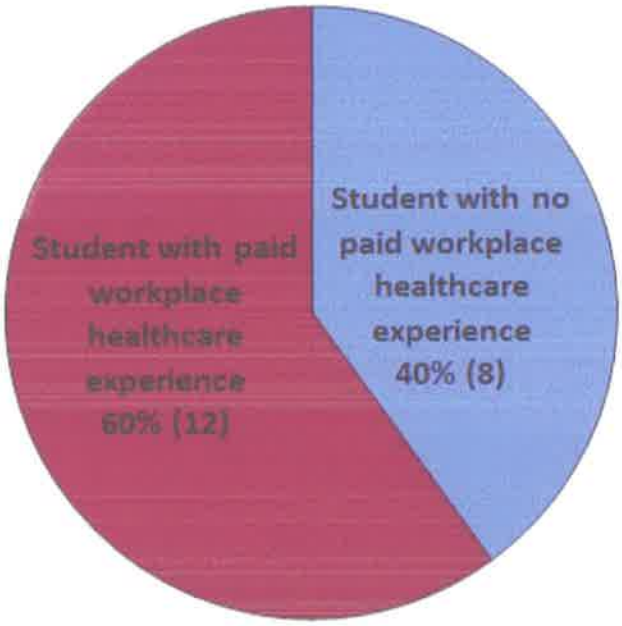


Figure 12. The pie graph illustrates how many participants in the study have paid workplace healthcare experience.

As shown in Figure 13, the number of years of experience in the healthcare field was also diverse with the number of years fairly even across the 1-5 years, 6-10 years, 11-20 years, and 21-30 years categories. There were no individuals in the study who had more than 30 years of healthcare experience.

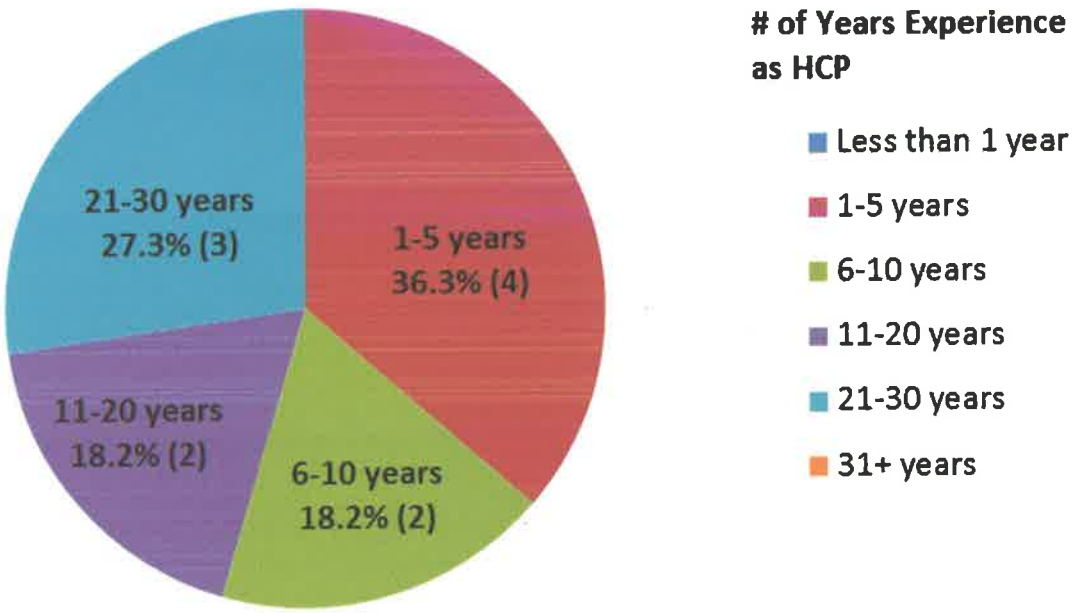


Figure 13. The pie graph illustrates the number of years of experience the participants in the study have from those who selected that they paid workplace healthcare experience.

Overall, there was good representation in the study, especially when it comes to diversity in workplace healthcare experiences.

Themes

The results that will be discussed now are based on the major ideas, including the themes, that were found through the data analysis process.

First thoughts on clinical trials.

The first question each individual was asked was what came to their mind when they thought about clinical trials. Overall, the participants recognized that clinical trials are used to develop new medications in order to be able to find new treatments for different diseases. They highlighted that it was the process of research or in other words, gathering information in a

controlled environment. In their minds, they feel that it's a controlled environment as individuals are closely monitored during their time in the clinical trial. The treatment or intervention is still in development and testing is needed before it goes a wider population. It needs to meet specific requirements and be able to accomplish the intended effects. It involves healthcare professionals and recruiting patients. Moreover, they felt that clinical trials are important and innovative. A few individuals did not seem to understand what clinical trials are as they mentioned that the study at hand was a clinical trial, which it was not as there was no treatment or intervention. After each individual answered this question, they were then given a very brief description of clinical trials in order to set the context for the discussion followed by the rest of the questions on the Interview Guide (See Appendix E).

The next section of this chapter will review the eight themes from the data on clinical trial participation by minorities.

Eight themes that influence clinical trial participation by minorities.

The first theme was the influence of benefits. Clinical trials have the potential to find a more effective, better treatment to prevent, cure, or help improve diseases and conditions. There is the potential to really improve healthcare. As Participant #2 said, "...the best thing is that it does identify new drugs that can help cure diseases" (73). There is also the benefit to gain

knowledge and understanding of different topics. As Participant #15 said, "...the benefit that I value the most is understanding and gaining some knowledge as to what is currently available" (88). In addition, there is an ability try to something new, an alternative treatment. Finally, if they were compensated in some way, such as financially or healthcare related, or if there was some type of incentive, this would be a benefit to them. As Participant #10 said, "Any type of like, compensation, whether it be a giftcard or something like that, would... motivate me to do it" (105).

The next theme is negatives, or the potential downsides of clinical trials. The biggest negative component that almost all participants in the study highlighted were the unknowns, especially as the treatment or intervention has not been completely tested yet. There is the possibility to be effected by side effects. As Participant #16 felt, "...these medications may have never been tried before, things like that can cause a lot of complications" (16). In addition, the process of clinical trials is very extensive and can be demanding, whether it's because of the time required, the requirements, or the length of the trial. Participant #11 said, "I think while I would want to participate in something, the idea of knowing that it might take years and years and years of follow-up and meetings and things like that would be a determent because it's pretty demanding and would require a big commitment" (77). There is also the possibility of getting placebo; there is the unknown of whether the individual will get the actual treatment or intervention

under study or if they will get the placebo. As Participant #17 said, "...you're like not sure if you're getting a certain medicine or not, so you come and you're agreeing to do a clinical trial and you're not sure if you're getting the placebo or you're getting the actual medicine" (31). Finally, even if the individual does get the actual treatment or intervention, there is an unknown of the response or impact on their life. There could be no response or no positive impact on their life.

The third theme that emerged is the need for information. The participants want to understand everything about the clinical trial. As Participant #11 said, "I would have to have a lot of information, so a lot of facts about...what outcome they're looking for...and then all of the details about...how they're going about conducting the research" (149). They want to see the evidence of benefits of the treatment or intervention, the science behind it. Participant #4 said, "Seeing scientific proof saying that like this is what we believe in and if I really understood what the researchers were outlining" (4-106). Further, "...knowing... what is the ultimate goal of the study, what are we trying to treat... what does it involve" (7-106). They want to be able to weigh the information, the pros and cons. Although they understand that the treatment or intervention is being studied, they wouldn't want to participate as the first participant. They want to see previous research done on the treatment and intervention. A few participants mentioned specifically wanting to see the research published. They also

mentioned that there are stereotypes and potential misconceptions about clinical trials, especially because of what they see on the media. In addition, the participants also felt taht they would be able to increase their knowledge through participation. Finally, they need information in order to increase their awareness of clinical trials and the opportunities that exist. It is really important for them to have all of the information that's available so they can weigh the information.

The fourth theme is the influence of support. All of the participants highlighted the important role of support, in both helping to make the decision and through the participation process. For Participant #4, "...support will be a key decision or a key factor in me making the decision on whether or not to participate in a clinical trial" (190). More specifically, family and friends would play the biggest role, a group of individuals who also emerged in another theme. Participation #13 said, "Participants who are enrolling should have support from their family members like maybe they need someone to take them to the...appointment...someone to remind them to take their medications" (198). The participants would also want support from investigative site personnel, whether it's specifically from the principal investigator or his/her support team. Participant #3 said, "...support from the researcher, to ensure that if I have any questions, or problems, or issues, that they're there to address any concerns I have" (127). Some participants would also want to speak with their primary care doctor and/or personal healthcare

professionals. They feel that these individuals know them better and their medical history so may be better able to advise them and from a less bias perspective. The notion of trust also plays a role when it comes to support. There needs to be a layer of trust, especially with the investigative site personnel, which in part is due to the past cases in history with minorities. Surprisingly, some participants brought up the Tuskegee case where African American men who had syphilis were withheld treatment. In addition, the participants want to know that there is an alternative treatment plan for them should the need arise. They want to know that there is a Plan B available for them.

The fifth theme is the influence of diversity. The participants want the ability to include their own characteristics in the research, such as whether it's their race or ethnicity. Participant #9 said, "...I'm an Asian American, I don't see really like a lot of Asians being represented, so in a way I kind of want to like do something like this...part of the motivation is that I just want more representation from my minority group" (62). Participant #9 discussed that they do not usually see their minority group in research that he/she comes across, and thus, would like to help mitigate that gap. The participants also want to feel as though the treatment is individualized for them and they are not just a number in a group of people. Not that "...treatment's already like set to a certain way and it's not individualized" (18-126). Furthermore, there can also be cultural influence on the decision to participate. An individual

discussed how their culture negatively views clinical trials and that belief would influence them to not participate. Finally, one of the underlying notions behind the purpose of the study is racial concordance, which also emerged from the data. Individuals feel more comfortable when healthcare professionals are like them, which may influence their decision. Participant #4 said, "I just think there is a cultural difference and some doctors when they explain things they don't understand that like some people might not understand fully what they're saying, so I feel like me, I'm Hispanic, if there was a Hispanic doctor and I needed something explained to me, I feel like they'd explain it to me in my language, they would understand certain things that I'm aware of and might not be aware of. They just understand that certain things need to be explained differently I think" (285). Therefore, culture does play a role and have an influence on clinical trial participation.

The sixth theme is religion, and overall, faith values. Almost all of the participants mentioned the strong role that religion and their faith play in their lives and would potentially play in clinical trial decision-making. In general, religion, faith is a very important value, and for most of them, if would have some influence on their decision. For example, they might not participate if some part of the clinical trial went against their religious views. Participant #20 said, "...am I making the right decisions...is this something that conflicts with our religious values" (403). In addition, Participant #7 said, "...as a Christian, I hold certain Christian values, the things that I say...the way that I

act...maybe that organization, or that doctor, or that person who is sponsoring the clinical trial, maybe I don't agree with... some of the decisions...so I might not participate in a clinical trial at that specific hospital... And how I view those things stem from my Christian values" (156). Faith is important to this group of individuals as it guides their lives and decision-making at times and would likely have influence on participation.

The seventh theme that emerged from the data is the role of family and friends. In the beginning of the data analysis process, family and friends were under support. However, when looking at the patterns in the data, the decision was made to distinguish family and friends as a separate theme. The individuals in the study consistently brought up family and friends, not just when it came to support. Family, and to a lesser extent, friends, play a key role in their lives and decision-making. They mentioned the value of them, the concern they would have about the effect their participation might have on their family. As Participant #19 said, "Affect any of the people in my life [family and friends], I wouldn't want to participate in a clinical study that would do that. Like for example, if something was to alter my mood, that would affect people around me" (373). Furthermore, they would even participate in a clinical trial just to help them. Participant #4 said, "It's important that I do all that I can, to help them [family] live better lives, live safer lives, live longer lives" (160). Family and friends would play one of the biggest roles in terms of support, but also have an overall strong influence in

their lives and decision-making. They trust their family the most, and at the same time, believe their family cares about them the most. Hence, their perspective would be the most important. In fact, they desire to have their family's perspective, approval, and encouragement. Participant #20 said, "I think immediately of my mom...that she would be my support system, that I would need to talk to, any anxiety, questions, concerns" (397). Therefore, family and friends would play a role in their decision and is a key theme.

Finally, the last theme that emerged is the societal perspective, wanting better collective health. This group of individuals has a high desire to help others, whether it's their patients, family, future generations, or fellow researchers. Participant #6 said, "I would like to participate in anything that helps to cure more people" (144). In addition, Participant #17 said, "...being part of something that may potentially help other people" (77). They want to help research and move it along, to be able to contribute in some way. They would be more likely to participate if they felt that they could make a strong impact through their participation. This theme makes sense as these individuals are in careers that are about promoting health. Therefore, steps that they can take to improve the lives and well-being of others is logical. As Participant #19 said, "...the reason that I would probably participate in something would be to help my future patients" (337). Finally, they would do whatever they could to become better healthcare professionals which could be through participating in a clinical trial.

Decision about enrolling or not enrolling.

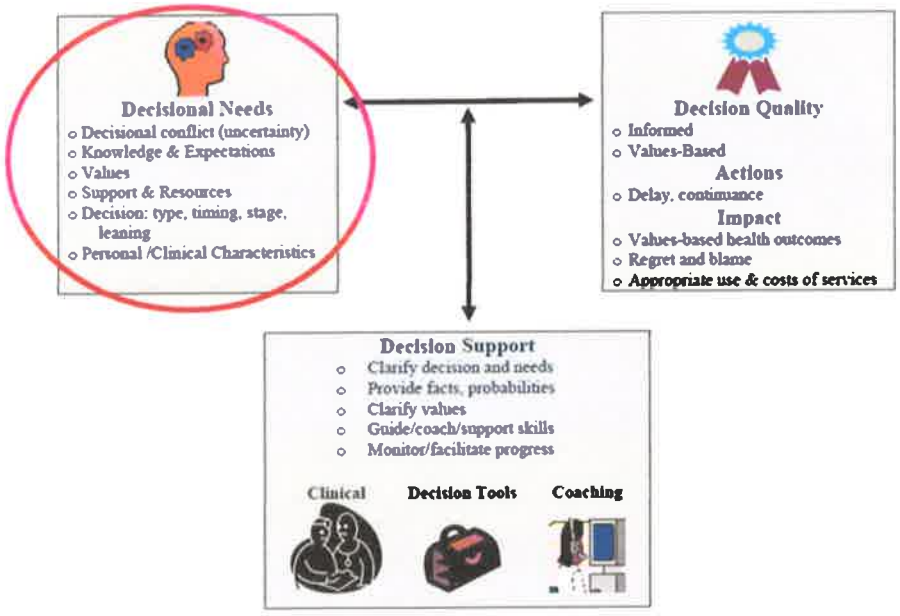
At the end of each interview, each participant was asked how they feel about participating in a clinical trial, along with their rationale. For the most part, their responses would confirm ideas that had been raised earlier in their interviews. The answers they provided in terms of their decision to enroll in a clinical trial were diverse. Some responses included that they wouldn't participate if they were healthy, they would avoid it, it needs to personally relate to them, they would participate, they need to care about it, they are open to the idea, they feel hesitant about it, it's scary, they have no problems with participating, they are unsure about their decision, they feel indifferent, they feel good about participating, and they are supportive of the idea. It's also important to note that the participants had mentioned that the answers to some of the questions asked during the interviews were dependent on the trial, and thus, they would have to see the detailed information about the clinical trial. Overall, it was eye-opening to understand what their perspectives were and for what reasons.

The next chapter will discuss in detail what these results mean.

Chapter V.

DISCUSSION

To understand the results, the Ottawa Decision Support Framework will be used as a lens to interpret the data. First, the focus will be on the decisional needs an individual has when he/she has to make the decision of whether to enroll in a clinical trial as highlighted in Figure 14.



(O'Connor & Jacobsen, 2006)

Figure 14. The circled section of the Ottawa Decision Support Framework will first be used as a lens to interpret the themes.

When looking at the decisional needs section, the theoretical framework explains some of the findings but not all. Table 1 lists the eight themes that

emerged from the data in the right column and the aspect of the Ottawa Decision Support Framework which explains the theme in the left column.

Table 1.

Using Ottawa Decision Support Framework to Explain Themes

Decisional Need/Conflict	**PI's Themes**
Knowledge/expectations	Benefits
Knowledge/expectations	Negatives
Knowledge/expectations	Need for Information
Support and resources	Support
Personal, clinical characteristics	Diversity
GAP	Religion, Faith Values
GAP (Need support from family and friends which is addressed but also value them)	Family and Friends
Values; *Personal, clinical characteristics*	Wanting Better Collective Health

As shown in Table 1, the Ottawa Decision Support Framework explains most of the themes that had emerged. The benefits, negatives, and need for information themes are all explained by the knowledge and expectations components of the framework. As per the framework, this is the information the individual has about their health situation and the expectations they have in terms of the outcomes (O'Conner & Jacobsen, 2006). The theme of support is logically explained by the use of support and resources in the framework. As explained by the framework, this means using various techniques such as decisional aids to address decisional needs (O'Conner &

Jacobsen, 2006). The themes of influence of diversity and wanting better collective health are explained by the individuals' personal and clinical characteristics along with values. These individuals are healthcare students/professionals who have the characteristics of helping others, especially when it comes to health, and its' something that they value as a benefit of the outcomes. On the other hand, there are two themes that are not explained by the framework. While the framework acknowledges that values is a decisional need, it only focuses on values being related to the benefits and risks of the potential outcomes. However, as found from the data, two other influencers on the decision of enrollment are religion/faith and family and friends. Therefore, the influence of values could be any personal value to the individual, or in other words, something important to them, not only related to the potential outcomes of the decision. For example, religion along with family and friends are values important to this group of individuals and would have an influence on their decision. Therefore, these values also need to be addressed during the decision-making process.

In addition, when looking at the whole framework, it was found that the framework was not as clear as originally thought in explaining how to address the decisional needs through support. Specifically, the relationships in the process are not as clear. The PI found the decision-making process as more of a linear process whereas the framework does not illustrate it this way.

Figure 15 illustrates the linear process that the PI developed which helps explain the decision-making process for clinical trial enrollment.

Figure 15. The linear process of decision-making starting with identifying the individual's decisional needs, then addressing them through support, and finally, making the best decision.

The first step would be to first identify the decisional needs of the individual. This would include the values that are important to them, such as their family and friends and the need for better collective health. The next step would be to address these decisional needs and ensuring that they have the information they need to be prepared to make the best decision. Finally, the individual would be ready to make the best decision for himself/herself.

Implications to Practice

One of the objectives for this research was to understand the perspectives of minority individuals when it comes to clinical trial enrollment, specifically from a healthcare professional view, to then be able to create the most appropriate strategies to recruit from the minority population. Based on the results from the study, it can be concluded that we are not at the point of

having healthcare professionals involved in the recruitment process. The first step is to share knowledge with minority healthcare professionals and have them be informed about clinical trials. Although the individuals in the study found research to be important and valuable, some of them don't understand the specifics around, especially what clinical trials entail. Another area that also comes into question is the informed consent process. The participants noted wanting specific information about the clinical trial and the treatment or intervention under study. Typically, a lot of the information they requested would be in the informed consent form and shared during this process. The informed consent process cannot just be the passing of a form to the individual to sign. The informed consent process requires a detailed discussion between the investigative site personnel and the potential participant. The information on the form should be reviewed and the questions the potential participant has should be addressed.

In addition, based on the results of the study, it leads to the notion that the recruitment process cannot just be between the investigative site personnel and the potential participant. The participants in the study highlighted the important role that their families (and friends at times) play in their lives and decision-making. Moreover, the role their family would play in the decision-making process of clinical trial enrollment. Therefore, it begs the question if family should start being included in the process. Specifically, when looking at the framework, family can be used as a means of support to

help address the decisional needs of the individual. In fact, literature on health communication has discussed the encouragement of social support such as from loved ones (du Pré, 2010). For example, as discussed by du Pré (2010), in a study done with Americans at risk of high blood pressure, it was rationalized that individuals are more likely to follow medical advice if not only recommended by their doctors. Therefore, this network of social support can not only play a role in helping individuals with decision-making, but also with adhering to a treatment or intervention. Another strategy for the recruitment process is the potential utilization of religious organizations. The participants in the study emphasized the importance that religion and associated values play in their lives, including in decision-making. A way to incorporate this aspect in recruitment is to potentially liaise with religious organizations and leaders. In fact, the National Institute of Mental Health (2005) has suggested engaging with the community through faith-based organizations and churches in order to help with recruitment and retention. Religious organizations may be a way to share information with the general population.

Finally, before researchers can even recruit, they need to bring awareness of clinical trials and opportunities. How can researchers ask minority populations to enroll in clinical trials if they don't know what they are or where to look for them? Sponsors need to educate this population so they first understand clinical trials, which may also be a way to build trust in

research and researchers along with clarifying any misconceptions. They need to communicate in ways which are understood by the population and make it relatable to them. In addition, participants in the study noted that they would be more open to participating if they could relate to the research in some way. Therefore, researchers need to be able to communicate the information in a manner that makes it relatable and illustrates the value of participation.

Limitations

As with any study, there are limitations with this study also. This study utilized a convenience sample, recruiting participants from an educational setting. Specifically, the sample population was a group of graduate students who were already healthcare professionals or who would be in the near future. The limitation is the effect that high education could have played in their perspective on clinical trial enrollment. In addition, not all of them were working at the time of their interview as a healthcare professional which may have played in their perspective versus those who were also healthcare professionals (i.e., paid workplace healthcare experience). In other words, there were some individuals who have the experience of having direct patient interaction while others did not. Another limitation is that the study focused on the intrapersonal perspective of the individuals. The intent was to understand the perspectives of clinical trial enrollment only from their view. However, as per the Ottawa Decision Support Framework and also as seen in

the results of this study, the decision-making of clinical trial enrollment cannot just be viewed from the perspective of the potential participant. The individuals' families also play a role in their perspective and the support that is needed. Therefore, it may be beneficial to get them involved in the clinical trial process, or more specifically, understanding their perspectives on clinical trial enrollment to understand the potential role they could play in clinical trial enrollment. Finally, there are a few other limitations to consider when looking at the results of the study. As this was a qualitative study, the data is only representative of those individuals included in the study and is not generalizable. In addition, the data was self-reported meaning each individual gave their own perspective on clinical trial enrollment.

Future Research

There are many future directions that can be taken to further understand the gap in clinical trial enrollment when it comes to minorities. Future research can continue with qualitative research or shift to quantitative research.

Qualitative research.

Continuing to collect data via qualitative studies may add additional rich data to the results already obtained. One specific direction may be to focus on a specific disease area as this may influence perspectives on clinical trial enrollment. For example, understanding the perspective of clinical trials centered on acute diseases and conditions versus chronic ones. Individuals

in the study had mentioned that part of their perspective depends on the disease or condition under evaluation. Some individuals mentioned that they would be more open to participating in a clinical trial which focuses on a more serious disease or condition as they would have a greater chance of making a significant impact while others were more hesitant in participating in clinical trials with these types of diseases/conditions due to the potential adverse reactions. Therefore, there may be value in getting individuals' perspectives while focusing on specific disease areas. Moreover, using a grounded theory approach in a study may provide more direction in research. In general grounded theory is a study design which also utilizes an inductive theoretical analysis approach from the data that is collected, and then collecting additional data to verify the analyses (Charmaz & Bryant, 2011). The advantage of this study design is that it allows for the formation of a theory rather than just describing or applying of existing theories (Charmaz & Bryant, 2011).

Other future directions lie with targeting different populations. As mentioned earlier, one of the limitations of the study was the sample population which was recruited from an education setting. A future study may want to target healthcare professionals outside of an educational setting. The data from this type of study may eliminate any complexities associated with individuals who are still pursuing healthcare education and who may not already have the insight associated with clinical research and direct patient

interactions. Another future direction would be differentiating between genders. As discussed in the Introduction section of this paper, women are also underrepresented in clinical trials which adds complexity to understanding the issue. Therefore, in order to further understand the issue, especially from each gender's perspective, it may be useful to compare the perspectives of female minority individuals to those of male minority individuals to understand what similarities may exist and where the perspectives of female individuals differ in order to understand why they continue to be underrepresented in clinical trials. This information would be valuable in understanding why women are underrepresented and then developing more specific strategies to recruit from this population.

Finally, the results from this study lead to the notion that family involvement may be necessary in the decision-making process. Therefore, it may be useful to conduct a study to gather families' perspectives or involve them in some way in the decision-making process. This information would not only be useful in understanding their perspective, but may also lead to strategies on how to involve them in the decision-making process.

Quantitative research.

There can also be a change in the direction in the type of study conducted by conducting a quantitative study instead. This study found some themes that shed light on what would influence a minority's perspective on clinical trial enrollment. In order to further understand the significance behind

each theme, a logical next step would be to quantify the themes. This would mean performing a quantitative study to evaluate how much each theme really contributes to an individual's decision and whether it does have a significant impact. In addition, the purpose of this study was to look at the minority population as a whole rather than focusing on one specific minority group. A future study could ensure that there is sufficient representation from all minority groups, or at least the largest minority groups in the United States to then be able to generalize the results to the general minority population.

Lessons Learned

There are lessons to be learned from the study and its' results. First of all, it is remarkable how much this group of healthcare students/professionals is willing to go above and beyond to help society. Almost all of the participants highlighted the importance of helping others whether it's someone close to them or not. This illustrates the inherent characteristic that many healthcare professionals have and the impact it has on some of their decision-making. The participants also recognized the importance of clinical trial enrollment, especially to ensure diversity. In fact, they know that their respective minority groups don't enroll and some of them would choose to enroll just to help mitigate that gap.

Surprisingly, there continues to be a mistrust of researchers and research, even amongst this educated population. Past cases of discrimination including the Tuskegee Study are still etched in their minds and

have some influence on their perspective of clinical trial enrollment. In order to be open to participating in clinical trials, there has to be trust in the processes and the researchers who are conducting these trials. This trust may be formed through education of clinical trials, highlighting the steps that have been implemented to ensure that cases like the Tuskegee Study do not occur again. While some of the education is on IRBs, a bigger step may be in the process of the informed consent. Not only is this process in place to ensure that relevant information is shared, but more importantly, to ensure that the potential participant's questions are addressed and that a dialogue takes place between the investigative site personnel and the individual. The results of this study lead to the question if the process of informed consent is really conducted the right way and if it needs to be changed. For example, is enough information and time being allocated to the informed consent process?

Finally, some of the participants mentioned that they wouldn't enroll in a clinical trial if it wasn't relevant to them. For example, if they or a family member didn't have the disease or condition. One participant specifically said that although they a trait for sickle-cell disease, that would not be a reason for them to participate in a clinical trial. Although this rationale is logical, it illustrates that even as healthcare professionals, we are not focusing on preventative healthcare, which continues to be a problem in the U.S. Healthcare in the U.S. continues to be based on treating individuals once they

have the disease or condition rather than preventing it in the first place. In addition, this point goes back to the underlying theme of the study – practice what you preach. If we as healthcare professionals do not enroll in clinical trials or see the importance of prevention healthcare practices, then how can we expect the general minority population to do so?

Chapter VI.

CONCLUSION

In 1990, Qualitative Expert Patton said, it's more important to "focus on how something happens rather than on the outcomes or results obtained" (p. 94). In other words, it is more insightful to know why a decision is made rather than just knowing what it is. This study was designed as a qualitative study as the purpose was to understand how minority students/professionals feel about clinical trial enrollment rather than just knowing what their decision would be. The study design allowed for the collection of rich data and for concepts to emerge from the participant responses when it comes understanding what influences potential minority participants' decision on whether or not to participate in a clinical trial. It was meant to be as exploratory as possible in order to not be restricted by previous assumptions, which could have led to the utilization of incorrect ideas or even biases. More specifically, the exploratory nature of the study allowed themes to emerge from the data rather than using a pre-conceived list and trying to have it fit the data, which would not have added as much value to the current literature. Based on the steps taken in the conduct of the study to allow it to be as exploratory as possible, eight themes emerged based on the participant responses. These themes included benefits, negative aspects, need for information, support, diversity, religion and faith values, family and friends, and wanting better collective health.

Furthermore, the intent of the study was to understand what the perspectives of potential minority participants are in order to then be able to create appropriate strategies to help mitigate the gap that currently exists in clinical trial enrollment. The results of the study found that healthcare professionals are not yet at the stage to be involved with clinical trial recruitment. Although healthcare professionals have a responsibility to bring awareness of research opportunities, they themselves are likely not to understand the specifics about clinical trials and potentially not enroll. Research has shown that individuals are more likely to seek out and feel comfortable with healthcare professionals who are similar to them culturally and linguistically, also referred to as racial concordance. Therefore, if minority healthcare professionals are not likely to understand clinical trials or be open to enrolling, then how can we expect the general minority population to understand them and expect them to think differently about clinical trial enrollment? Using healthcare professionals may not be an avenue to take at this time to mitigate the gap that currently exists in clinical trial enrollment when it comes to minority populations.

More importantly, if we don't try to address potential minority participants' decisional needs and in general, educate, there will continue to be an inequality in treatments and interventions. As Participant #3 said, "I know that it's very much needed but I'm very skeptical because of what I know about history and past clinical trials" (168). Support is needed to

address all decisional needs which include the need for information, along with alignment with values such as family and religion/faith. In addition, the individual needs support in making the decision from the time they are approached for the opportunity through their time in the clinical trial. The support should consist of sharing of whatever information is available on the current clinical trial and similar trials on the treatment or intervention and disease or condition, or in other words, a series of discussions. The way the informed consent process is currently conducted is questioned and whether there is a way to ensure better alignment of understanding and expectations between the investigative site personnel and potential participant. Moreover, the support should not just be limited to the investigative site personnel. The individual's family may need to be involved in the process, helping to increase trust in the process and decision that is made. Only through providing decision support will the individuals' decisional needs be addressed and decisional conflict mitigated. This is one step closer in ensuring that each individual makes the best decision for him/herself.

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APPENDICES

Appendix A. Seton Hall University IRB Approval

OFFICE OF INSTITUTIONAL REVIEW BOARD
SETON HALL UNIVERSITY

July 25, 2016

[redacted]

Dear Ms. Akhtar,

The Seton Hall University Institutional Review Board has reviewed the information you have submitted addressing the concerns for your proposal entitled "Understanding the Perspectives of Potential Minority Participants on Clinical Trial Enrollment". Your research protocol is hereby approved as revised through expedited review. The IRB reserves the right to recall the proposal at any time for full review.

Enclosed for your records are the signed Request for Approval form, the stamped Recruitment Flyer, and the stamped original Consent Form. Make copies only of these stamped forms.

The Institutional Review Board approval of your research is valid for a one-year period from the date of this letter. During this time, any changes to the research protocol must be reviewed and approved by the IRB prior to their implementation.

According to federal regulations, continuing review of already approved research is mandated to take place at least 12 months after this initial approval. You will receive communication from the IRB Office for this several months before the anniversary date of your initial approval.

Thank you for your cooperation.

In harmony with federal regulations, none of the investigators or research staff involved in the study took part in the final decision.

Sincerely,

Mary F. Ruzicka, Ph.D.

Mary F. Ruzicka, Ph.D.
Professor
Director, Institutional Review Board

cc: Dr. Michelle D'Abundo

Presidents Hall • 400 South Orange Avenue • South Orange, New Jersey 07079-2641 • Tel: 973-313-6314 • Fax: 973-275-2361

Appendix B. Email to Students about Study

Dear Healthcare Student and/or Professional,

My name is Saliha Akhtar and I am a doctoral student at Seton Hall University in the Department of Health Sciences and Human Administration. I am conducting a research study in partial fulfillment of my dissertation requirement for the PhD in Health Sciences degree on "Understanding the Perspectives of Potential Minority Participants on Clinical Trial Enrollment."

I am looking for minority healthcare students/professionals to share their perspectives on clinical trial enrollment. The study will consist of two components – a short online survey and a one-on-one interview that can take place over the phone or in-person.

If you are interested in participating in this study, please click on the following link to be directed to the participant survey: Hyperlink to SurveyMonkey after SHU IRB is obtained. Once you have completed your survey participation, please do not take the survey again. I will contact you regarding scheduling the one-on-one interview.

Upon completion of the study, all participants will receive a $5 gift card to Dunkin Donuts.

If you have any questions concerning this study or your rights as a study participant, please contact me, the primary investigator, at saliha.akhtar@student.shu.edu.

Best regards,
Saliha Akhtar

Appendix C. Participant Solicitation Letter on Survey Monkey

Study Title: ***Understanding the Perspectives of Potential Minority Participants on Clinical Trial Enrollment***

Dear Participant:
You are reading the participant solicitation letter for the above-mentioned study.

Affiliation
My name is Saliha Akhtar and I am a doctoral student at Seton Hall University in the Department of Health Sciences and Human Administration. I am conducting this research study in partial fulfillment of my dissertation requirement for the PhD in Health Sciences degree.

Purpose
You are invited to participate in this research study to share your perspective as a minority healthcare student/professional on clinical trial enrollment.

Procedure
You will be asked to complete two separate sections of this study

1) Participant Survey
    a. Part 1: Asks for your demographic information including gender, age, ethnicity, race, education, and profession.
    b. Part 2: Asks about your perspectives on the advantages and disadvantages of clinical trials.
2) One-on-One Interview
    In general, you will be asked questions on clinical trial enrollment when it comes to:
    a. Level of knowledge
    b. Personal values
    c. Support in decision-making

Approach and provide answers to the participant survey and during the one-on-one interview from your individual point of view candidly, express your perspectives regarding the above-mentioned study. Please respond honestly to all questions. It is important that you complete all sections of the study in its entirety.
The survey is brief and will take no longer than 10 minutes to complete.
The one-on-one interview could take approximately 30 minutes to 1 hour to complete. It can be done either over the phone or in-person.

Voluntary Participation

Your participation in the research study is voluntary. You may decide at any time not to participate in this study. If you decide not to participate or withdraw, you will not be penalized.

Anonymity
The participant survey will ask for your contact information (phone and/or email) so I can contact you to schedule the one-on-one interview when you are available. However, after the survey is completed, a participant number will be assigned to you. The participant number will then be used to identify you through the completion of the study. You will not be identified by name or your contact information in any reports or publications about this study.

Privacy and Confidentiality
Protection and confidentiality will be maintained throughout the duration of the research project. As mentioned previously, participants will be asked for their contact information (phone and/or email address) in order to schedule the one-on-one interview. However, this contact information will not be shared with anyone else. Furthermore, upon completion of the study, the paper data will be kept in a locked filing cabinet in the Principal Investigator's home for three years after which time all data will be destroyed. Similarly, all electronic data will be stored on a USB memory key with access to the file protected by use of a password only known to the principal investigator. The memory key will also remain in a secured filing cabinet for three years, upon which time the data will be destroyed. It is also important to note that as there is with anything online, there is the risk (although remote) of hacking.

Risk
There is no foreseeable risk factor or discomfort that is anticipated by participating the in this research study.

Compensation
There will be a small monetary compensation, a $5 gift card to Dunkin Donuts, for completing this study.

Ways to Participate
By accessing and completing the survey, you are conveying your informed consent to participate in this study. Once I have received the completed survey and confirmed your eligibility, I will contact you to schedule the one-on-one interview and provide you with another consent letter that you will need to sign prior to the interview.

Once you have completed your survey participation, please do not take the survey again. I will contact you regarding scheduling the one-on-one interview.

Contact Information

You have the right to ask questions concerning this study at any time. If you have any questions concerning this study or your rights as a study participant, please contact the Principal Investigator, Saliha Akhtar, through the office of Dr. Michelle D'Abundo, Dissertation Chair in the Department of Interprofessional Health Sciences & Health Administration in the Seton Hall University of Health and Medical Sciences at 973-761-9213 (email: michelle.dabundo@shu.edu). Additionally, for information concerning the rights of research participants you can contact Dr. Mary Ruzicka, Chair of the Institutional Review Board, in the office of IRB at Seton Hall University at 973-313-6314.

Thank you for considering participating and contributing to this research. Your time and consideration are most graciously appreciated.

Appendix D. Participant Survey

Part 1. Demographics

1. What is your gender?
    - Male
    - Female
2. What is your age? _____
3. What is your ethnicity?
    - Hispanic, Latino, or of Spanish Origin
    - Not Hispanic, Latino, or of Spanish Origin
4. What race do you identify with? Select all that apply.
    - Black or African American
    - American Indian or Alaskan Native
    - Asian
    - Native Hawaiian or Other Pacific Islander
    - Other _____
5. What is the highest degree you have attained?
    - Bachelors
    - Masters
    - MD/DO
    - PhD
    - Other _____
6. What degree are you currently pursuing?
    - Masters
    - PhD
    - Clinical Doctorate
    - Other _____
7. What program are you currently enrolled in?
    - Health Sciences
    - Health Administration
    - Physician Assistant
    - Occupational Therapy
    - Athletic Training
    - Speech-Language Pathology
    - Other _____
8. What is your profession?

a. Full-time student
b. Healthcare Professional. Specify _____
c. Other. Specify _____

9. If healthcare professional selected in Question #7 - Number of years in profession:
   - Less than 1 year
   - 1-5 years
   - 6-10 years
   - 11-20 years
   - 21-30 years
   - 31+ years
10. Have you ever been involved in the recruitment of participants for clinical research?
    - Yes
    - No

Part 2. Advantages and Disadvantages of Clinical Trials

1. What do you believe are advantages to enrolling in clinical trials?

   _____

   _____

2. What do you believe are disadvantages to enrolling in clinical trials?

   _____

   _____

If you meet the requirements for the study, you will be contacted to schedule a one-on-one interview (phone or in-person). You will receive a $5 Dunkin Donuts gift card upon completion of the one-on-one interview.

Please provide your name and contact information (phone number and/or email address) so the Principal Investigator can contact you to schedule the one-on-one interview:

_____

Appendix E. General Script during Interview

Introduction

Hi, my name is Saliha. Thank you for completing the participant survey for my study and consenting to participate in the interview portion of the study.

Before we get started with the interview, let me provide you a brief introduction of myself and on our discussion today.

My name is Saliha Akhtar and I am a doctoral student at Seton Hall University in the Department of Health Sciences and Human Administration. I am conducting this research study in partial fulfillment of my dissertation requirement for the PhD in Health Sciences degree.

Statistics have shown that minorities are under-represented in clinical trials across all disease areas. The purpose of my study is to understand the perspectives of minority healthcare students/professionals on clinical trial enrollment. I am focusing on healthcare students and/or professionals because the literature has shown that patients feel more comfortable speaking to a physician who is similar to them. Therefore, by understanding what influences a healthcare professional's or healthcare student's decision to enroll or not enroll, I will shed light on why potential minority participants are not currently enrolling, especially as they are at the frontlines of introducing potential minority participants to clinical trial opportunities.

Now, I will ask you a series of questions to get your perspective on clinical trial enrollment. But before I begin to ask you the questions, I will start recording our discussion. As mentioned in the informed consent form that you had previously signed, this recording will not be shared with anyone else.

Do you have any questions before we get started?

See the Interview Guide – Appendix F – about Perspectives on Clinical Trial Enrollment for the Questions #1-10 that will be asked.

Question #1 will be asked.

Then, a brief description on clinical trials will be provided:

Thank you for that answer. Before I continue to ask the other questions, let me provide you with a brief overview of clinical trials. Clinical trials are research studies that involve humans. They are designed to test new ways to treat, find and diagnose, and prevent diseases and conditions. Therefore, they can available for all stages of a disease or condition, and even healthy individuals can participate – such as in prevention clinical trials or clinical trials which are done with healthy volunteers.

As we continue our discussion, think of your perspective in terms of clinical trial enrollment.

Questions 2-10 will be asked.

Conclusion

Thank you so much for your participation in my study. Do you have any last comments to add or questions you want to ask me?

Thank you again. All of your responses will remain confidential and your name and contact information will not appear in any reports or publications. Please feel to contact me if you have any concerns related to your participation or questions about the study.

Appendix F. Interview Guide about Perspectives on Clinical Trial Enrollment

- ❖ First, the participant will be asked to answer the following question:

1. What comes to mind when you think of clinical trials?

- ❖ Then, a brief description on clinical trials will be provided. The participant will be asked to answer the following questions in the context of clinical trial enrollment:

2. What are some benefits of clinical trials?
   - What would be some benefits for you?
3. What are some negative aspects of clinical trials?
   - What would be some risks for you?
4. What would influence your decision to participate?
   - What would influence your decision not to participate?
5. What values are influential in your life?
6. How would these values or other values influence participating in a clinical trial?
7. What role does support play in enrolling in a clinical trial?
   - What support would you need in order to make the best decision?
8. Across all of the support that would potentially be available (investigative site personnel, primary doctor, family and friends), who would you need support from?
9. How do you feel about participating in a clinical trial?
10. Tell me your rationale for choosing or not choosing to participate in a clinical trial.

Appendix G. Transcription Key

8	**Transcription Key:**	
9	( )	words spoken, not audible
10	(( ))	researcher's description
11	^	rising intonation
12	(.)	small, untimed pause
13	(2.0)	pause time in seconds
14	(*laughs*)	action/emotion
15	Abbreviation of Interviewer: R	
16	Abbreviation for Interviewee: A	

Appendix H. Permission to Use Images in Manuscript

Appendix H-1. Permission to Use Image of Conceptual Framework that Combines the Theory of Planned Behavior and Health Behavior Model to Predict Clinical Treatment Trial Participation

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Apr 19, 2017

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Appendix H-2. Permission to Use Image of Transtheoretical Model that Explains Health Behavior Change

RE: Use of Transtheoretical Model image in Publishing of Dissertation

SJ Sara Johnson
Sun 4/16, 10:37 PM
Saliha Akhtar; Kerry Evers <kevers@prochange.com>

Reply all

Inbox

You replied on 4/16/2017 11:16 PM.

You are welcome to use the image if you cite the website as the source.

Kind regards,
Sara

Sara S. Johnson, Ph.D.
Co-President & CEO
Pro-Change Behavior Systems, Inc.
203.208.0481
www.prochange.com

From: Saliha Akhtar [mailto:saliha.akhtar@student.shu.edu]
Sent: Sunday, April 16, 2017 10:02 PM
To: sjohnson@prochange.com; kevers@prochange.com
Subject: Use of Transtheoretical Model image in Publishing of Dissertation

Hello,

I was referred to you by Dr. Janice Prochaska. I am currently a doctoral student at Seton Hall University in New Jersey, USA. I will soon be publishing my dissertation through UMI. I would like to include the image of the transtheoretical model that explains health behavior change. Can you please provide me with written permission allowing me to use it?

Link to image: http://www.prochange.com/transtheoretical-model-of-behavior-change

Thank you,
Saliha Akhtar

Appendix H-3. Permission to Use Image of Ottawa Decision Support Framework

RE: Use of ODSF in Publishing of Dissertation

Annette O'Connor

Fri 4/21/2017 1:15 PM

To:Saliha Akhtar <saliha.akhtar@student.shu.edu>;

Dear Saliha Akhtar
Thank you for your interest in the ODSF Framework
You have my permission to use it in your Dissertation
Best wishes

Annette O'Connor PhD FCAHS FRSC
Distinguished Emeritus Professor
University of Ottawa
Faculty of Health Sciences

From: Saliha Akhtar [mailto:saliha.akhtar@student.shu.edu]
Sent: April 20, 2017 1:25 PM
To: Annette O'Connor <Annette.OConnor@uottawa.ca>; decisionaid@ohri.ca
Subject: Re: Use of ODSF in Publishing of Dissertation
Importance: High

Dear Dr. O'Connor/All,

I am contacting you to confirm whether I can use the illustration of the Ottawa Decision Support Framework.

I am currently a doctoral student at Seton Hall University in New Jersey, USA. I will be uploading my dissertation this upcoming Monday for publishing through UMI. I would really like to include the illustration of the Ottawa Decision Support Framework in my manuscript. Can you please provide me with written permission allowing me to use it?

Please let me know if you need any additional information from me.

Your timely response would be appreciated.

Thanks,

Saliha Akhtar