ABSTRACT

Title of dissertation: THE ROLE OF RACIAL IDENTITY AND RELIGIOUS BELIEFS IN THE ATTITUDES OF AFRICAN AMERICAN CANCER PATIENTS TOWARD AND INTENTION TO ENROLL IN THERAPEUTIC CANCER TRIALS

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There is increasing evidence that societal inequities and cultural differences in attitudes toward cancer and its treatment drive health outcomes. Therapeutic clinical trials represent a promising treatment option for cancer patients, yet the percentage of African American patients who enroll in clinical trials is lower than the national average. This creates a racial imbalance that limits the extent to which research results from clinical trials can be generalized. Studies of African Americans report some attitudes toward trial participation are based on trust and fear. Enrollment of minority patients is necessary to collect group specific data, and adapt treatments as may be necessary. To that end, interventions aimed at shifting attitudes hol promise, but hinge upon a better understanding of the interplay between attitudes toward trial participation, cultural constructs, and enrollment.

The purpose of this dissertation was to examine interrelationships between two socio-cultural constructs, and four attitudinal barriers to clinical trial participation among African American cancer patients. Specifically, the study sought to (1) understand the relationship between attitudinal barriers to clinical trial participation and the subsequent

intention to enroll; (2) understand the contribution of racial identity (racial centrality) and religious belief (specifically a belief in 'God as healer') to intention to enroll. The study was guided by elements of the Theory of Planned Behavior and theories of racial identity and religiosity. Interviews were conducted with 111 African American cancer patients in a purposive sample from an urban, community-based teaching hospital in Washington, D.C.

Logistic regression analyses explored the predictive value of four attitudinal constructs in patients' intention to enroll. Three of the four attitudinal barriers were significant predictors of intention for this sample. The concern about ethical conduct of investigators was the only attitudinal barrier that remained statistically significant in the unadjusted model (OR =0.85, p=0.04). Racial identity and a belief in God as healer were not significant predictors of intention to enroll. Finally, a moderation analysis explored the effect of levels of racial centrality and religious belief on attitudes and on intention. A belief in God as healer significantly moderated the association between the concern about ethical conduct of investigators and intention to enroll in a therapeutic clinical trial. Among participants with a low belief in God as a healer, a lower level of concern about the ethical conduct of investigators predicted a greater intention to enroll than those with a higher level of concern about ethics. Racial centrality did not significantly moderate any of the attitudinal barriers.

The extant literature is scant in terms of addressing the role that socio-cultural constructs play in clinical trial decision-making for African American patients. In particular, implications of this study suggest that the historical legacy of research abuse and unethical treatment of African Americans in research continues to color attitudes

towards clinical trials. This study provides a basis for further exploration of socio-cultural moderators among African Americans, an understanding of which may enable tailoring of interventions on these factors, which may improve intervention effects.

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Dedication

This dissertation is dedicated first and foremost to the patients who shared their experiences, candid thoughts, and true feelings with me. Thank you for helping me to better understand your reality and for making this research possible. Also, to my parents, who have always cultivated my thirst for knowledge, and sacrificed all they could to give me boundless opportunities. Thank you for raising me to expect that no dream was ever too big or beyond my reach. I could not have reached this point without your unconditional love and unwavering support, particularly through the challenges of the last few years.

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CHAPTER ONE: INTRODUCTION

"…..*And if I was going to die [from my cancer] today, or that day, or two years from now, I still say it's in God's hands, and they can't tell me anything about it." 'Vanessa'*
- Breast cancer survivor

"…..The fact that you believe in God don't mean that you don't use your mind. You use your mind in conjunction with your faith in God." 'James'- Prostate cancer survivor

"…Well, I've never known anyone who participated in a clinical trial, first of all. And then the average Black person, we tend to stay away from it because the things that I've heard from older Black people" 'Rebecca' – Osteosarcoma survivor

"….All the faith I have; I'm a missionary in my church; very active in my church. But all that went out the window. I didn't think about God, or nobody. I just knew my life was over, you know, because of cancer." - 'Diane'- Kidney cancer survivor

Source: African American Cancer survivors and clinical trial participants interviewed for the patient education video development.

1.0 Background

There is an underrepresentation of minorities in cancer clinical trials. As we continue to struggle to find cancer treatments that show efficacy in all subgroups of the population, this lack of representation presents a significant problem. Cancer is the second leading cause of mortality in the United States, with differential outcomes by race/ethnic group (American Cancer Society, 2010). Clinical trials represent a promising treatment option for cancer patients; however, the underrepresentation of minority groups in these clinical trials likely plays a role in health disparities. Health disparities in cancer outcomes, in part, may be driven by biological differences (Stark et al., 2010); however, there is increasing evidence that societal inequities and cultural differences in attitudes toward the disease and its treatment drive health outcomes (Moore et al., 2010; Smith et al., 2009; Morris et al., 2010). Culturally appropriate behavioral interventions could potentially impact the differential rates of participation in clinical trials; however, our understanding of patient factors contributing to decisions to participate is limited. This dissertation, focusing on African American cancer patients, seeks to (1) understand the

relationship between attitudinal factors that present barriers to clinical trial participation and the subsequent intention to enroll in therapeutic clinical trials; (2) understand the contribution of racial identity and religious belief to the intention to enroll in therapeutic clinical trials.

1.1 Cancer and Clinical Trials

The current standard of care for cancer treatment is based on data from therapeutic clinical trials. Since 1990, cancer mortality rates have declined by 15% and over 65% of all patients now survive at least 5 years beyond diagnosis (Petrelli et al., 2009). To continue to improve outcomes, the development of better therapeutic options for cancer patients is contingent on their voluntary participation in therapeutic clinical trials. Trial participation also represents an opportunity for cancer patients to receive state-of-the-art care, close monitoring of their disease, and careful attention to their quality of life (Joffe, 2010).

Studies find that patients who enroll in clinical trials have longer survival and overall better prognosis than patients who do not participate in clinical trials (Joffe, 2010). Despite this evidence, of all US adults diagnosed with cancer, fewer than 3% will participate in a therapeutic clinical trial (Du et al., 2009; Baquet et al., 2008). The accrual of diverse patients to clinical trials remains one of the biggest challenges to advancing treatment and improving cancer outcomes, especially for underrepresented racial minorities (Park et al., 2007).

1.1.2 African Americans, Cancer and Clinical Trials

Despite a lower overall incidence for most cancers, African Americans suffer from a disproportionately higher cancer mortality and worse five-year survival than other

racial/ethnic groups (American Cancer Society, 2010). The percentage of African Americans who enroll in clinical trials is also lower than the overall national average for all other racial groups (Du et al., 2009; Baquet et al., 2008; Ford et al., 2008). Enrolling African American patients is necessary to collect group specific data, evaluate the effectiveness of existing treatments for different races/ethnic groups, and adapt treatments as may be necessary by race/ethnic group (Park et al., 2007). Such an imbalance in enrollment limits the extent to which research results from clinical trials can be generalized.

One of the National Cancer Institute's strategies towards overcoming cancer health disparities is to characterize and understand the factors that cause them. In 1993, the National Institutes of Health (NIH) Revitalization Act was intended to encourage representation of minorities and women in research funded by the NIH including clinical trials (Tejeda et al., 1996; Stewart et al., 2007). Despite the allocation of a considerable amount of federal budget towards this end, cancer disparities have not changed drastically since this act was passed (Morris et al., 2010).

Studies show that equitable racial representation on clinical studies in the US is possible (Hutchins et al., 1999; Hutchins et al., 1999; Stewart et al., 2007; Tejeda et al., 1996). This suggests a need to not only identify the factors preventing this from being the norm, but also to identify, to test and to implement effective interventions that ensure equitable representation is achieved. Given the documented benefits of trial participation, it follows that the inclusion of African-Americans in clinical trials is an integral part of addressing disparities in cancer outcomes. It may also improve the delivery of healthcare services to minority populations (Stewart et al., 2007).

1.1.3 Addressing the Disparity: Culturally Sensitive Interventions

African American populations in particular have deep-rooted historical reasons that need to be accounted for in the development of any intervention, educational or otherwise (Gamble, 1997; Heintzelman, 2003). There is a gap in the literature when it comes to describing and testing strategies to overcome the barriers of minority recruitment in clinical trials. A major issue confronting medical practitioners and public health researchers is how to effectively design interventions so that they are culturally relevant and salient for populations for whom specific and attitudinal barriers may exist (Kagawa-Singer et al., 2010). With increasing diversity in the United States, there is a growing need to determine how culturally specific attitudes can be addressed to improve health behavior.

Specific to improving cancer outcomes, Moore and colleagues (2010) suggest establishing a framework that incorporates culture and identifies promising strategies using culturally sensitive communication. Cultural beliefs and values are becoming increasingly recognized as integral to decision-making about the prevention and control of cancer, begging further inquiry in this arena. Recent recommendations to addressing health disparities specifically suggest exploration of an individual's attitudes toward disease (Moore et al., 2010). They acknowledge the role of poor quality of care and limited access to treatment in many cases but implore researchers to further study attitudes to disease and treatment and target interventions accordingly (Moore et al., 2010).

A variety of intervention approaches have already attempted to increase clinical trial participation by addressing cultural issues (e.g.,Wang et al., 2008; Outlaw et al.,

2000). Du and colleagues (2009) concluded that an educational video is a cost effective way to educate patients about clinical trials and address specific cultural and attitudinal barriers. Several patient education videos have been created about cancer clinical trials (Du et al., 2008; Du et al., 2009; Hutchison et al., 2007; Zapka et al., 2004); however, there are currently no known patient education videos that address the particular attitudes and cultural barriers faced by African Americans with cancer. Further there has been no known intervention specifically targeting African Americans to attempt to address their attitudes toward clinical trials.

1.1.4 Relevance of Culturally Sensitive Interventions

Du and colleagues state that to increase participation and diversity in clinical trials, new strategies are needed to have an impact on barriers experienced by a wide spectrum of the population (Du et al., 2009). Health education programs for minority groups need to be culturally targeted in terms of content and presentation format (Mishra et al., 2007). There are arguments to the contrary suggesting such interventions lack utility (Kotkin & Tseng, 2003); however, these arguments state that youth in particular benefit the least from racially targeted interventions. Since children are typically not included in clinical trials, tailoring is likely still beneficial for interventions for the many cancer patients potentially eligible for a trial.

The efficacy of videos as a means to address health issues has been well demonstrated (Gagliano, 1988; Zapka et al., 2004; Taylor et al., 2006; Williams et al., 2008). Simple, practical, effective, theory-driven patient-level interventions that can be rapidly and widely disseminated, utilized and implemented at a relatively low cost offer promise in increasing African American participation in clinical trials. Video-based

interventions offer a pragmatic mechanism for delivering health information due to their relatively low cost to reproduce and implement and their likely acceptability for clinical use (Warner et al., 2008). They also represent an ideal format to present information regardless of literacy level. Given the current healthcare climate, simple low-cost video-based interventions may facilitate much needed patient education within the context of time-restricted clinics, hospital settings and physician's offices. What is first needed, however, is a thorough understanding of how the uptake of such interventions may be affected by individual attitudes and specific socio-cultural factors.

1.1.5 Barriers to Trial Participation

African Americans have poorer access to quality cancer treatment (Siminoff & Ross, 2005) and the literature identifies a multitude of barriers found to relate to clinical trial participation. These encompass socio-cultural barriers, research barriers, economic barriers, and individual level barriers (Swanson & Ward, 1995). Systematic and structural factors, such as socioeconomic conditions, insurance status and questions of eligibility, are well documented for their relationship to unequal trial participation (Adams-Campbell et al., 2004; Branson et al., 2007). One aspect requiring particular focus is cultural differences that may breed particular attitudes and create and propagate further disparity. The role of culture in the causal pathway of disparities and the potential impact of culturally competent cancer care on improving cancer outcomes in ethnic minorities has been underestimated (Kagawa-Singer et al., 2010). A person's cultural context or lived experience may significantly influence their attitudes towards clinical trials ultimately preventing or promoting their participation in spite of the seemingly more tangible barriers, such as access to treatment. For African Americans, this may be even more salient given the history of exploitation and abuse by the US government and healthcare system (McCaskill-Stevens et al., 1999).

This dissertation will consider four particular attitudinal barriers that are the leading individual barriers to trial participation for African Americans cited in the literature. These are 1) fear and distrust of the medical establishment (doctors, scientists and the government); 2) concern about the ethical conduct of investigators in general; 3) fear of losing one's rights by signing a research informed consent; and 4) worry that

investigators will treat poor Black patients unfairly (e.g. the patient becomes a guinea pig because of their race or SES).

Since there is no consensus on the relative influence or interrelationship of these barriers, designing culturally relevant and targeted interventions can prove to be a poorly guided undertaking. To understand the decision-making process of a person enrolling in a clinical trial, a consideration of how barriers interact to impact attitudes will prove valuable. Further, very little research has investigated other cultural factors such as religion and racial identity (both important in the context of African American populations), and how these influence the intention to participate in clinical trials.

1.1.6 Attitudes Toward Clinical Trials and Related Cultural Factors

Both qualitative and quantitative studies of African Americans and clinical trials report some attitudes towards clinical trial participation are based on trust and fear (Advani et al., 2003; Ford et al., 2008; Branson et al., 2007). Current behavioral research points out that ethnic group identification operates as a type of reference group and exerts both normative and informational influence on an individual's behavior and attitudes (Simpson et al., 2000). It therefore seems reasonable to explore group identification as an influence on health behavior. Racial identity could therefore be a key influence on individual attitudes including those that may impact clinical trial participation. This however has rarely been studied. It could be that the extent to which an individual identifies with their race or ethnicity is related to the types of attitudes they form about participation in a clinical trial, particularly since the historical experience with research in the US varies for different races/ethnicities.

An altruistic attitude has been cited as a factor influencing clinical trial participation independently of other socio-demographic, psychosocial, and clinical factors (Rosenbaum et al., 2005; Aby et al., 1996). The argument can be made that for minority participants, this extends to a feeling of "helping one's community" (Hussain-Gambles, 2004) and acting for the sake of helping others like themselves. Thus, strong identification as a part of a specific racial/ethnic group, or an individual's possession of a healthy racial identity, may impact their attitudes toward clinical trials. Further, the fact that the experiences of African Americans are not heterogeneous yields a variability in the significance and qualitative meaning they attribute to Black racial group membership (Sellers et al., 1998b). Therefore, it is necessary to examine the influence of racial identity on the intention to participate in clinical trials. A better understanding of the decision-making process may help to target interventions and consequently increase enrollment.

Racial Identity

The United States Office of Management and Budget (OMB) defines race and ethnicity based on five race categories and two ethnicity categories. Race categories include American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and White. Ethnicity includes Hispanic or Latino and Non-Hispanic or Latino. There is a growing recognition that each of the established categories in reality has multiple, diverse subgroups with different cancer risk and responses (Kagawa-Singer et al., 2010). The aggregated categorization could lead to misleading assumptions about individuals and may obscure the true differences between

them. This may be even more so when considering how health behaviors and attitudes may vary between people belonging to the same category.

There is considerable diversity within African descent populations (Agyemang et al., 2005), and the category 'Black or African American' does not account for the heterogeneity within the group. Waters (1994) explored the racial and ethnic identities adopted by a sample of second-generation West Indian and Haitian Americans in New York City and their subjective understanding of being Black, in contrast with those of first-generation immigrants from the same countries. She reported three types of identities: a Black American identity, an ethnic or hyphenated national origin identity, and an immigrant identity, each of which relate to different perceptions and understandings of race relations in the United States (Waters, 1994). Ponterotto and Park-Taylor (2007) recommend disaggregating data from African Americans, Caribbean Americans, and African internationals, all of whom may share the "Black" designation but vary on the socially constructed nature of their racial identity experience in North America.

Racial Identity and Clinical Trials

In the context of this dissertation, it is important to investigate how attitudes towards clinical trial participation may vary within the group, especially considering that not all individuals who are otherwise categorized as "Black or African American" have experienced the same history in the United States. The US Public Health Service Study (more colloquially known as the Tuskegee Syphilis Study) begun in 1932 has a continuing impact on African-Americans' trust of medical research studies (Shavers et al., 2000). However, it is conceivable that many African Americans may not identify

with a history of Tuskegee, for example, if they are recent African or Caribbean immigrants, and therefore their attitudes towards research and clinical trials may stem from a different perspective. For instance, individuals in the US self-identifying as Black, may have just arrived from Ethiopia, recently immigrated from Haiti, or been raised in the rural South or the urban North and have very different cultures especially with regard to health-related practices (Jones, 2001). Foreign-born Blacks may or may not feel a sense of connectedness to or identify with Black people in the United States or native-born Blacks. As a result it is possible that they may or may not feel connected to the same historical abuses or struggles of native-born Blacks. Accordingly, their attitudes towards research and clinical trials may vary. It is thus informative to distinguish between subgroups as self-identified within the African American population to contextualize any existing differences in attitudes that may exist.

Religious Beliefs

Religion and spirituality are an integral part of all socio-cultural systems, particularly in African American cultures (Carter, 2002) . Various religious factors have been associated with physical and mental health, citing improved outcomes and even decreased mortality (Brown & Gary, 2010; Brown & Gary, 2010; Levin et al., 2005; Levin et al., 2010; Holt et al., 2005; Strawbridge WJ et al., 2010). Evidence supports an overall protective effect of religion on morbidity and mortality (Levin et al., 2005; Holt et al., 2009) and the exact mechanisms responsible for this effect have yet to be elucidated. The literature posits behavioral modification based on religious beliefs as individuals who are involved with religion tend to engage in lifestyles that are healthier. They tend

to not include as an example excessive alcohol consumption, illicit drug use or tobacco use (Koenig et al., 1999; Holt et al., 2005; Ellison & Levin, 1998a).

Religious beliefs may influence specific aspects of an individual's attitudes toward disease and treatment (Ellison & Levin, 1998b; Smitherman, 2009). For example, research in some older African Americans show they have faith-based explanatory models of illnesses and their ability to heal or be cured from them (Wittink et al., 2009). A 2005 review of recurrent themes describing how spirituality or religiosity may influence treatment preferences among African Americans found that some see God as responsible for their physical and spiritual health and that only God has the power to decide life and death (Johnson et al., 2005c).

Religious Beliefs and Clinical Trials

Research shows a tendency for African Americans to use religion as a coping mechanism when diagnosed with cancer (Holt et al., 2009; Smitherman, 2009); however, little research has considered religion in the decision-making process for enrolling in a clinical trial. What warrants further exploration is how certain religious beliefs may influence the consideration of a clinical trial for cancer treatment. Specifically how might the intention to enroll in a clinical trial be impacted given evidence that some African Americans believe that God acts through doctors to cure illness and that God's will is the most important factor in recovering from illness (Johnson et al., 2005b). The belief of God's role in healing may have particularly important implications for one's perceived potential utility of a clinical trial, and subsequently, their intention to enroll. Holt and colleagues (2009) developed a measure for the religious construct 'God as healer', found to be one of several identified as important in cancer coping for African Americans. The construct assesses an individual's perception of God's dual role as a direct healer, or a healer through doctors. How this construct relates to the intention to enroll in a clinical trial, and how it impacts the four attitudinal barriers to participation is worthy of exploration.

1.2. Conceptual Underpinnings of the Study

A review of the literature on African American participation in cancer clinical trials reveals a limited theoretical influence. Theory driven work is critical to understanding health behavior. A few existing studies have used elements of the Theory of Planned Behavior and the Health Belief Model (HBM) (e.g. Yang et al., 2010) but have done so in an inconsistent manner (Yang et al., 2010; Moore et al., 2010).

This dissertation draws elements from multiple theoretical models including those of health behavior, racial identity and religiosity. The Theory of Reasoned Action (TRA) (Fishbein & Azjen, 1975) is a health behavior theory to which attitudes and intentions are central. The dissertation utilizes aspects of TRA by focusing on how an individual's experience with two constructs (i.e., racial identity and religious belief) relates to their attitudes towards clinical trials and the manner in which they affect the intention to enroll in a clinical trial (See Conceptual Model. Figure 1). It is through the TRA also, that a sense of directionality in the proposed relationships between the constructs is inferred such that attitudes precede the intention, which ultimately leads to engaging in the desired behavior, enrolling in a therapeutic trial. Further, Fishbein and Azjen (1975) suggest a mediating role for intention. However, given the inability to ascertain actual enrollment in the patients studied, exploring the extent to which constructs specific to African Americans vary with established attitudes could be particularly informative.

The experience of African Americans in the United States differs significantly from those of all other racial/ethnic groups (Sellers et al., 1998b). A consideration of race, racism and racial identity thus seems central to any theoretical consideration of attitudes of African Americans towards clinical trials. There are several theories and models of racial identity development, most of which were developed primarily for African Americans to understand the black experience in the United States (Chavez & Guido-DiBrito, 1999). For this study, the focus will be on the role, significance and meaning African Americans place on race in defining themselves. Thus, this study will focus on racial identity as conceptualized by Sellers and colleagues' Multidimensional Model of Racial Identity (MMRI) (Sellers et al., 1998). Specifically, the construct of

racial centrality and how this construct may moderate attitudes towards clinical trials and impact intention to enroll in clinical trials.

The literature on the connection between religion and health proposes several explanatory mechanisms rather than established models or theories (Ellison, 1998). The mechanisms propose ways in which religious involvement may yield positive health outcomes (Ellison, 1998). This study focuses more on the actual religious belief one holds. Specifically a belief in the role God may play in healing cancer and how that relates to the intention to participate in a clinical trial.

1.3 Statement of the Problem

African Americans suffer a disproportionately greater morbidity and mortality from cancer than Whites (American Cancer Society, 2010). When compared with white cancer patients, African American patients are significantly less likely to participate in trials (Stewart et al., 2007). A 2007 study of enrollment in National Cancer Institute (NCI) cooperative group surgical oncology trials showed conclusively that overall enrollment was extremely low across the general population in the US (Stewart et al., 2007), however African Americans had much lower enrollment fractions compared with whites, Hispanic and Asian/Pacific Islanders (Stewart et al., 2007). When the four most common causes of cancer mortality and the proportion of all new diagnoses who went on to participate in a clinical trial were considered between 2000 and 2002, the enrollment fraction for African Americans cancer patients was 1.3% (Stewart et al., 2007; Murthy et al., 2004).

The low participation rates of African Americans on clinical trials limits the generalizeability of study findings about the effectiveness of cancer treatment (Du et al.,

2009). Further, the absence of adequate racial/ethnic subgroup data prevents the detection of possible interactions of treatment effect by race/ethnicity based on biological, social or cultural factors related to race.

One of the most defining socio-demographic changes in the United States is the marked increase in the proportion of minorities; the number of which is expected to increase from an estimated 83 million in the year 2000, to 157 million projected by 2030 (Smith et al., 2009). Moreover, there is an anticipated 99% increase in cancer incidence for minorities, compared with a 31% corresponding increase for whites (Smith et al., 2009). It is therefore imperative that the inherent selection bias and objectivity of clinical trial design be addressed (Adams-Campbell et al., 2004). Interventions aimed at shifting attitudes towards clinical trials hold promise but first there needs to be a better understanding of the interplay of cultural constructs with specific attitudes towards trial participation.

1.4 Purpose of the Study

The purpose of this study is therefore to examine interrelationships between two socio-cultural constructs, religious beliefs (specifically a belief in 'God as healer') and racial identity, with four attitudinal barriers to clinical trial enrollment and the overall intention to enroll among African American cancer patients. Direct associations between religious belief and racial identity with intention to enroll will be tested as will the interaction of these constructs with the four attitudinal barriers. A cross-sectional quantitative approach will be employed to better understand the problem by surveying a sample of cancer patients.

This research will focus on the experience of African American cancer patients in an urban, community-based teaching hospital in a city with the nation's largest disparity in cancer outcomes for Blacks compared with all other groups. By better understanding the barriers to participation and how they interact with one another, interventions can be better targeted for African Americans and improve their rates of participation in therapeutic clinical trials.

1.6 Significance of the Project

An appreciation of the beliefs, values, attitudes, and preferences of individuals is essential to understanding barriers to participation (Branson et al., 2007). This dissertation makes a contribution to addressing the Healthy People 2010 goal of improving cancer survival by understanding racial/ethnic health disparities. The paucity of literature on religious beliefs, racial identity and their impact on attitudes and intention to enroll in clinical trials hinders progress in what Brown and Topcu (2003) term the "*emerging science of recruitment*".

1.7 Research Aims and Hypotheses

This dissertation has four main research aims and four accompanying hypotheses:

Aim 1: To examine the effects of racial identity on the intention to enroll in a therapeutic clinical trial among African American cancer patients.

H1: Participants with higher levels of racial identity will be more likely to express intention to enroll in a therapeutic clinical trial.

Aim 2: To examine the effects of religious beliefs on the intention to enroll in a therapeutic clinical trial among African American cancer patients.

H2: Participants with stronger belief in the notion of God as healer will be less likely to express an intention to enroll in a therapeutic clinical trial.

Aim 3: To determine how the relationship between four attitudinal barriers (distrust of doctors, the healthcare system, fear of losing one's rights, concern about the ethical conduct of researchers, and the fear of being treated poorly as a minority) is impacted by racial identity.

H3: The attitudinal barriers will be moderated by racial identity, such that negative attitudes will have less influence on the intention to enroll among those with higher levels of racial identity.

Aim 4: To determine how the relationship between four attitudinal barriers (distrust of doctors, the healthcare system, fear of losing one's rights, concern about the ethical conduct of researchers, and the fear of being treated poorly as a minority) is impacted by religious beliefs (belief in 'God as healer').

H4: The attitudinal barriers will be moderated by belief in God as healer, such that negative attitudes will have less influence on the intention to enroll for those with higher levels of the belief in God as healer.

1.8 Summary

Using a sample of African American cancer patients recruited as part of a culturally relevant narrative-based video intervention, four attitudinal barriers will be examined for the degree to which they affect overall intention to participate in a clinical trial. This study will focus on how these barriers are moderated by two important cultural constructs for African Americans – racial identity and the specific religious belief of God as healer.

The dissertation research employs a cross-sectional, quantitative methodology based on a pretest in which data will be collected immediately prior to a video intervention.

1.9 Definition of Terms

African American: The terms **Black** or **Afri**can American** are used interchangeably throughout this study to refer to individuals of African, Caribbean or West-Indian descent, or otherwise self identifying as Black.

Culture: Culture is the core, fundamental, dynamic, responsive, adaptive, and relatively coherent organizing system of life designed to ensure the survival and well-being of its members. A system which comprises beliefs, values, and lifestyles (Kagawa-Singer et al., 2010).

Cancer Health Disparity: The National Cancer Institute defines a 'cancer health disparity' as any difference in the incidence, prevalence, mortality, and burden of cancer and related adverse health conditions that exist among specific population groups in the United States.

Enrollment Fraction: The number of individuals enrolled in a clinical trial divided by the number of patients diagnosed with cancer

Ethnicity: Ethnicity is one's sense of identity as a member of a cultural group within a power structure of a multicultural society and as identified by others as a member of that group on the basis of socio-historical context (Kagawa-Singer et al., 2010). For this study ethnicity will refer to the individual's shared history, ancestry, language and geographic origin.

Race: Race has been said to refer to biological differences between groups of people (Dein, 2004). Race as a construct, developed from the belief that races represent subspecies of *Homo sapiens*, and, therefore, one's phenotype was believed to be indicative of one's genotype and potential for moral character (Kagawa-Singer et al., 2010). Thus, in this study, race refers to the original biological categories, derived from physical characteristics, recognizing that there are more similarities than differences between racial groups and more differences than similarities within these groups (Littlefield, Lieberman and Reynolds, 1982).

Racial Identity: As defined by Sellers (1998), racial identity is the part of the person's self-concept that is related to her/his membership within a race. It is concerned with both the significance the individual places on race in defining him/herself and the individual's interpretations of what it means to be Black. For this study this is a social construction, which refers to a sense of group or collective identity based on an individual's perception that they share a common heritage or experience with a particular racial group (Helms, 1993).

Religion: Definitions of religion and spirituality are used inconsistently throughout the literature. For this study, they will be used synonymously to refer all factors related to an organized system of beliefs, practices, rituals, and symbols (Thoreson, 1998).

Therapeutic Clinical Trials: Therapeutic clinical trials are rigorously controlled research studies designed to test new treatments or new ways of using existing treatments and how well they work in people. These are done to answer questions about the safety and efficacy of new therapies in patients with disease.

CHAPTER TWO: REVIEW OF THE LITERATURE

This chapter presents a summary of the literature about factors affecting clinical trial participation among African Americans. It describes common attitudinal barriers to participation and presents an overview of literature on the proposed role of the cultural and psychological constructs of religious beliefs and racial identity.

2.1 Introduction

When compared with non-participants, clinical trial participants are more likely to be younger, have higher education, be of higher socioeconomic status and are overwhelmingly more likely to be white and male (Adams-Campbell et al., 2004; McCaskill-Stevens et al., 1999). The current literature is replete with established barriers to trial enrollment for Black patients and tangible factors that impede even a willing patient's participation in clinical trials (Adams-Campbell et al., 2004; Baquet et al., 2008; Corbie-Smith, 1999; Mouton et al., 1997; Ford et al., 2008). Factors that frequently prevent African American cancer patients from enrolling in clinical trials include personal beliefs, attitudes and socio-cultural factors. They also encompass factors outside of the individual's locus of control such as trial design and eligibility criteria (Advani et al., 2003; Townsley et al., 2005; Branson et al., 2007). Despite the identification of some barriers, there needs to be a better understanding of modifiable factors that contribute to differences that exist in the participation of Blacks compared with all other groups in order to address health disparities in clinical trial enrollment.

2.2 Barriers to African American Trial Participation

Eligibility

Eligibility for therapeutic clinical trials is based on relatively stringent entry criteria. The presence of co-morbid conditions is often a major exclusion criterion built into trial designs (Adams-Campbell et al., 2004). Comorbidity alone accounts for the design factor most frequently responsible for the exclusion of minorities, regardless of their attitudes or willingness to participate (Adams-Campbell et al., 2004; Stewart et al., 2007). Specifically, the existence of comorbid cardiovascular, cerebrovascular diseases and diabetes tend to be the most common exclusion criteria for cancer clinical trials (Van Spall et al., 2007; Morris et al., 2010). These very diseases are also most prevalent among African Americans (Adams-Campbell et al., 2004; Adams-Campbell et al., 2004; American Cancer Society, 2010).

A large study of breast cancer patients at a National Cancer Institute (NCI) comprehensive cancer center reported that eligibility was a more important factor for Black patients than white patients (Simon et al., 2004). Black patients were more likely to be ineligible than white patients because of poor disease performance status and inadequate organ function. According to this study, unwillingness was much more important than ineligibility; 12% of the failed enrollment was attributed to ineligibility, while 88% was due to patient refusal.

In an examination of rate-limiting factors for cancer patients being served by a historically Black medical institution, another study determined overall eligibility for clinical trials to be at only 8.5% (Adams-Campbell et al., 2004). Approximately 17% of participants were deemed ineligible to enroll in a clinical trial due to the presence of co-

morbid conditions¸ another 25% were unable to enroll because no suitable trials were open, and 10% were ineligible due to advanced disease stage. The remaining participants were ineligible due to disease specific factors. Despite the low proportion ultimately eligible, almost two thirds of those who were eligible actually enrolled in a trial (Adams-Campbell et al., 2004). This is much higher than the proportion suggested by national statistics, which ranges from 3% to 20% for eligible minorities (Stewart et al., 2007; Adams-Campbell et al., 2004). Despite the obvious benefits of changing eligibility requirements, a relaxation of stringent eligibility criteria may compromise the integrity of any findings on therapeutic trials and reduce the usefulness of the results (Comis et al., 2003). It is therefore not considered as a useful intervention strategy. For African American cancer patients, the issue of eligibility may be as important as a willingness to participate; however, understanding willingness to enroll among those eligible may offer the greater avenue for decreasing disparities in participation.

Lack of Knowledge and Awareness of Clinical Trials

A basic knowledge about clinical trials and general awareness of their purpose, expected risks and benefits is often necessary before a patient considers one as a cancer treatment option. Several studies report that lack of knowledge and general misperceptions about clinical trials remains one of the major barriers to intention to enroll among African Americans (Shavers-Hornaday et al., 1997; Braunstein et al., 2008; Fenton et al., 2009). Patients faced with this decision-making might obtain information about trials and how to participate, from a variety of sources including their physician, friends, the internet or other media sources (Freimuth et al., 2001; Braunstein et al., 2008). The source of information is shown to have a direct impact on a patient's

likelihood to participate as certain sources are deemed more trustworthy than others; Fenton et al., 2009).

A 2006 study investigated the differences in attitudes of female cancer clinical trials participants and non-participants (Madsen et al., 2007). Madsen and colleagues found that most of the patients they studied stated the media was a major source of their knowledge about and attitudes toward trials, however, they also judged the media to be untrustworthy(Madsen et al., 2007). Since this was a Dutch study, the attitudes may not be representative of African Americans. It did suggest that media representation and normative beliefs may be an important consideration.

A 2009 US-based study of the role of the physician in health-decision making relative to cancer clinical trials reported that the majority of patients are made aware of a clinical trial by their physician (Comis et al., 2003). The study showed that cancer survivors and the public alike depend primarily on their physicians as their most important source of health information, including clinical trials. Advani's 2003 study found that the influence of a physician's advice on the likelihood of participating was ranked lower for African American patients than white patients relative to all other factors influencing the decision to participate. Communication between a patient, their physician and their families is an important factor in awareness and knowledge about clinical trials and influences their intention to participate (Albrecht et al., 2008).

In a study of racial differences among cancer patients in a radiation oncology clinic, Wood and colleagues (2006) found no difference between white and non-white patients in their interest in learning about clinical trials or the rate of previous or current enrollment. They did, however, find differences in expectations of clinical trials.

Compared with white patients, more non-white cancer patients reported they would likely enroll in a clinical trial only if there was a greater than 50% chance of them benefiting from the trial (Wood et al., 2006). Freimuth and colleagues (2001) established, through qualitative inquiry that there was a lack of accurate knowledge about clinical research among African Americans including adequate knowledge of the informed consent process (Freimuth et al., 2001).Given that knowledge and awareness are known to be necessary, but not sufficient for behavior change, improving knowledge, alone does not present an effective intervention strategy.

Provider Level Barriers

Low enrollment of African Americans has also been attributed to provider-level factors. These center around the fact that eligible patients may not be referred to clinical trials by their physician (McCaskill-Stevens et al., 1999). In 2008 Albrecht and colleagues confirmed that when offered a trial, most eligible patients do in fact enroll. Simon and colleagues (2004) showed that over two thirds of women in their study were not even offered participation in a clinical trial (Simon et al., 2004). Sub-optimal patient-physician interactions seem to contribute to low clinical trial participation for African Americans (Stewart et al., 2007; Hutchins et al., 1999). This includes the inability of physicians to adequately explain clinical trials to the level at which a patient fully understands. It also includes the inability of some physicians to make the patient feel comfortable, respected and not pressured nor intimidated. The underrepresentation of African American oncologists may also have a negative impact on African American patient accrual to clinical trials (Stewart et al., 2007; Cohen et al., 2002).

Non-Changeable Individual Factors: SES, Race, Gender

Brown and Topcu (2003) focused on African Americans aged 50 years and older. In their study sample of 222 whites and 216 African Americans, gender and age were significant predictors of intention to enroll. They were unable to show any race-based difference in willingness to participate and intention to enroll; however, willingness to participate was significantly higher among males than females and persons of younger age compared to older individuals (Brown & Topcu, 2003).

Similarly, in their study of enrollment in NCI-sponsored cooperative group trials, Murphy and colleagues (2004) also found age to predict enrollment, with younger patients much more likely to enroll than those over 65. Although the majority of incident cancers are diagnosed in older adults (Comis et al., 2003), the more aggressive tend to be diagnosed in younger populations (Cancer Facts and Figures, 2010). Therefore, since these studies did not control for the aggressiveness of the cancer, it is unclear exactly why younger participants are more likely to enroll.

A 2003 study reported significant interactions between race and age, as well as race and income, in predicting enrollment (Brown & Topcu, 2003). Factors such as knowledge about Tuskegee and fatalistic attitudes did not result in a decreased likelihood to participate when African Americans were compared with whites, for this older population. This study concludes a view that intervention strategies would be best targeted to racial differences in factors related to age and income level, rather than attitudes and knowledge (Brown & Topcu, 2003).

BeLue and colleagues (2006) examined gender differences in both the perceptions of risks and benefits of trial participation, and the perceived barriers and motivators to

participation through a series of focus groups. They found that men and women expressed different beliefs and expressed different barriers. For example, being treated respectfully as an individual and not as a study subject was more important to women than men. Knowing the source of research funding was more important to men than women. Their findings suggested that there were different factors that ultimately contributed to intention to enroll in clinical research for males compared with females (BeLue et al., 2006).

When African American cancer trial participants are compared with white participants, education and income emerge as two factors that differ significantly between them (Advani et al., 2003). African American patients who were not willing to participate were more likely to be lower income and have less education than those who did participate (Advani et al., 2003). Race is often confounded with socioeconomic status (SES), and racial differences in willingness to participate in clinical trials may be more attributable to SES than race, though few investigators have studied this. Advani and colleagues (2003) found that being African American versus White was not as strong a predictor of willingness to enroll, as being poor and lacking education. In comparing African-American with white patients' beliefs about cancer, clinical trials and their overall willingness to participate, Advani and colleagues (2003) found no differences by race in the percentage of patients who had heard of a clinical trial, knew what a clinical trial was, or had been asked to participate in one (Advani et al., 2003).

In Wei Du and colleagues' 2009 follow-up study of breast cancer patients the racial difference in enrollment rate found were thought to in part be explained by the race-driven differences in perceptions of clinical trials. They recommended this should

guide educational interventions such that specific barriers pertinent to population subgroups are addressed. They also stated since their study was done in breast cancer patients, the generalization to other types of cancer should be done with caution.

Thus, addressing individual level barriers to African American participation may help increase accrual to clinical trials (Advani et al., 2003; Wood et al., 2006). However, since factors such as gender, age and race are not amenable to change, focusing on factors that are likely more changeable could prove a more viable focus point for intervention.

Access/Cost-Related Barriers

It is unclear whether the disparities in enrollment would still exist in an equal-access system (Stewart et al., 2007). The US Department of Veteran's affairs (VA) is one such system, and the findings of a study (Shavers et al., 2001a) of VA patients show no racial differences in decision to enroll in a clinical trial. They suggest that systemic factors, such as access and cost, are responsible for the apparent underrepresentation and not patient-centered factors.

An Australian study similarly concluded that the underlying issues leading to disparities in cancer outcome are complex and multi-factorial. The authors agreed that timely access to high-quality care for all would decrease the disparity in cancer outcome; however, when they compared public and private patients, where ready access to a comparable level of medical care was available, differences in outcome were still apparent. Factors including differential stage at diagnoses, mode of presentation, completion of care, acceptance of treatment recommendations and co-morbidities, also seemed to contribute to disparities (Moore et al., 2010).

Other Factors Affecting Trial Participation

The reasons a cancer patient may refuse to participate in a clinical trial are complex. It is challenging to fully assess the contribution of each factor. In a qualitative study of African Americans recruited from churches, Linden and colleagues (2007) showed that 80% of their participants reported being willing to enroll in a clinical trial. In particular, they were more likely to participate if they felt the cause was personally meaningful to them. Similarly, in attempting to understand the decision to enroll in a clinical trial, prior experience with a research study or clinical trial may be influential.

There is also evidence to suggest that associations between clinical trial participation differ by types of cancer. In the Du et al. study (2009) a multivariable logistic model found race and stage of disease to be significantly related to trial enrollment where African American patients were less likely to enroll compared with white patients. Thus cancer type and stage of disease should be considered in any explanatory model of clinical trial participation.

2.3 Attitudinal Barriers to African American Trial Participation

An appreciation of the beliefs, values, attitudes, and preferences of the African American community is essential to understanding their fears and barriers (Branson et al., 2007). This requires an awareness of the root of these attitudes as African Americans have a particularly strained relationship with scientific research in the United States (Gamble, 1997). Studies show significant differences in attitudes towards clinical trials between white patients and non-white patients (Wood et al., 2006). Many of the specific cultural and attitudinal factors which exist are the legacy of a sordid past of slavery and unfair/unethical treatment (Gamble, 1997).

A randomized study in a large urban Comprehensive Cancer Center tested a patient education video as a tool to increase clinical trials enrollment among breast cancer patients (Du et al., 2009). They aimed to determine if there were race-based differences in attitudes towards clinical trials and to show a change in these individual attitudes. The sample of almost 200 breast cancer patients showed a small increase in enrollment in therapeutic trials for the group randomized to the educational intervention. This change was not statistically significant but it offered preliminary evidence that changing attitudes may increase enrollment. The study clearly showed not only a lower enrollment rate among African American patients, but also significantly more negative scores on three out five attitudinal scales (Du et al., 2009)

Corbie-Smith and colleagues (1999) documented the most commonly cited reasons for the attitudes African Americans have towards participation in clinical trials. These included: 1) mistrust of doctors, scientists, and the government; 2) concern about the ethical conduct of investigators; and 3) believing that investigators would treat poor or minority patients unfairly. Others have confirmed these, as well as the fear of loss of autonomy after signing a research informed consent (Sood et al., 2009; Verheggen et al., 1998). They are considered here in more detail as the main attitudes under study for this dissertation.

Fear and Distrust of the Medical Establishment

A fear and distrust of doctors, scientists and the government is frequently cited as one of the most pervasive attitudinal barriers to clinical trial participation for African Americans, linked to both individual experiences with discrimination, as well as a cultural memory of victimization and exploitation (Rajakumar et al., 2009; Boulware et

al., 2003; Shavers et al., 2001b; Swanson & Ward, 1995; Mouton et al., 1997; Sood et al., 2009; Gamble, 1997).

A 2008 study of 717 patients from Maryland outpatient cardiology and general medicine clinics found African Americans expressed a significantly lower willingness to participate in a cardiovascular drug trial, compared with white participants (Braunstein et al., 2008). African Americans scored significantly higher than whites on mean distrust scales, and believed that doctors had previously experimented on them without their consent. Significantly more African American patients than whites reported that their physicians would not fully explain participating in research to them, and they believed doctors would prescribe medication as a way of experimenting on them. They also more frequently reported that they believed their doctors would ask them to participate in research even if it may harm them (Braunstein et al., 2008).

A series of focus groups held in Los Angeles, Chicago, Washington DC, and Atlanta in 1997 found that accurate knowledge about clinical research was limited and that a general understanding and trust of informed consent procedures was pervasive. Participants expressed a distrust of researchers as a significant barrier to recruitment to clinical trials (Freimuth et al., 2001). Rajakumar and colleagues (2009) also found that distrust of medicine and research was significantly greater among African Americans even when education was controlled for, as education was associated with having significantly greater distrust (Rajakumar et al., 2009).

While numerous others have found distrust to be an important predictor of enrollment in clinical trials (Corbie-Smith, 1999; Corbie-Smith et al., 2002; Rajakumar et al., 2009; Gamble, 1997; Katz et al., 2008a; McCallum et al., 2006), Advani and

colleagues (2003) did not find distrust of the medical profession or medical research to be a significant barrier to participation in their study (Advani et al., 2003). Thus more research is necessary to understand the role of distrust in decisions about clinical trial participation.

It is suspected that the trust issues stem from the historical treatment of African Americans in research. The critically low participation of African Americans in clinical trials and other medical procedures, such as organ donation, has been linked to this legacy (Gamble, 1997; Swanson & Ward, 1995). The Tuskegee syphilis Study conducted by the US Public Health Service from 1932 to 1972 is a very specific example of unethical treatment of Black people throughout the history of the United States. Gamble (1997) writes that the legacy of Tuskegee symbolizes racism in medicine, misconduct in human research, the arrogance of physicians and government abuse of Black people. Gamble (1997) further asserts that this mistrust between African Americans and whites in fact predates Tuskegee and it is limiting to consider one event as the single cause of such complex attitudes (Gamble, 1997).

Crawley (2001) details multiple dimensions of trust as they impact decision-making for clinical trials to include 1) trusting in the fiduciary relationship 2) trust as confidence in competence; and 3) perceptions of trustworthiness. This consideration suggests how multifaceted attitudes towards clinical trials, which are rooted in racially based trust issues, truly are.

Worry that Investigators Will Treat Poor or Black Patients Unfairly

Some African Americans fear that clinical trials will leave them vulnerable to exploitation because of their status as a minority group or their lack of income. This

vulnerability, in the context of research, refers to an inability on the part of study participants to protect their own interests (Grady et al., 2006). While this attitude can be linked to historical abuse, it also relates to the fact that minority patients are more likely to have lower incomes, be younger, less educated, and underinsured or uninsured (Macklin, 2003). Community leaders and ethicists have expressed concern that regardless of the risks involved, those with limited access to health care will enroll in research studies to obtain the basic health care services that would otherwise be unavailable to them (Grady et al., 2006). Patients fear that they are then even more likely to be treated unfairly by researchers or healthcare workers if they are visible minorities (Kennedy et al., 2007). In the radiation oncology patients studied by Wood and Colleagues (2006), this attitude was pervasive whereby more non-White patients believed that they had been treated on clinical trials without their knowledge (Wood et al., 2006). Kennedy, Mathis, and Woods (2007) also confirm that there continues to be an underlying element of mistrust and fear of being treated unfairly between the poor populations and minority populations that may be subjects of research and the research establishment.

Concern About the Ethical Conduct of Researchers

Studies of patient populations and the public alike, reveal a concern that researchers and clinical research in general is not conducted in an ethical manner when it comes to African American participants (Gamble, 1997; Corbie-Smith, 1999; Comis et al., 2003). Corbie-Smith and colleagues conducted focus group interviews of 33 African American patients in an urban public hospital outpatient setting in 1997. They reported participants expressed concern about unethical treatment of poor or minority patients.

This in turn fed into their general mistrust of the medical establishment. One study showed only 28% of the African American women surveyed about perceptions of women in clinical trials felt that the research was ethical (Mouton et al., 1997).

The unethical treatment of African Americans in the Tuskegee Syphilis study is thought to fuel continued concern about the present day ethical conduct of researchers. There are, however, polarized views as to whether or not there really are long lasting effects and differential knowledge about Tuskegee to the effect it has impact on enrollment in clinical trials or any other aspect of the patient experience. Shavers and Colleagues (2008) suggest that awareness of historical and ethical misconduct in biomedical research and the knowledge of Tuskegee must be taken into account when recruiting into clinical trials. Differences in awareness of the study have been shown. Out of 179 African American and white Detroit residents, 88% of African Americans had heard of the Tuskegee study, compared with 28% of whites. Further, 51% of African Americans reported less trust of researchers due to knowledge of Tuskegee, compared with 34% of whites. 49% of African Americans stated they would not be willing to participate in a research study due to this knowledge, compared to 17% of whites. Katz and colleagues (2008), however challenge this purview, reporting that the widely acknowledged "legacy" was not statistically associated with the willingness to participate in biomedical studies (Katz et al., 2008b; Katz et al., 2007; Katz et al., 2009). They confirmed that their studies did not assess the broader question of whether and how historical events influence people's willingness to participate in research (Katz et al., 2008a).

Fear of Loss of Autonomy After Signing an Informed Consent Document

Several studies have reported on the general misunderstanding and lack of understanding of the research informed consent process (Corbie-Smith, 1999; Verheggen et al., 1998). For example, Corbie-Smith reported that patients did not understand the goal of the consent process and instead saw signing the document as akin to relinquishing their rights (Corbie-Smith, 1999). They further reported that participants understood an informed consent form to be a means of legal protection for physicians (Corbie-Smith, 1999; Corbie-Smith et al., 1999). The extent of a research participant's understanding of the informed consent process has been debated for general clinical research populations (Joffe et al., 2001) and this may pose an even greater barrier for African Americans.

2.4 Racial Identity and Trial Participation

As described previously, trust is a major impediment to the willingness of African Americans to enroll in clinical trials and has been linked to the legacy of Tuskegee (Tejeda et al., 1996; Braunstein et al., 2008)). Personal experiences with racism have also been found to foster a mistrust of the medical system. Terrell and Terrell (1981) define a construct known as cultural mistrust, which refers to African American's mistrust of Whites and the White American establishment (e.g., government, law enforcement, schools). This is reactive to racism and mistreatment by mainstream society and is characterized by suspicion of the motives of others and a general lack of trust of White Americans. This construct has been examined in studies of educational and occupational expectations of Black adolescents (Terrell et al., 1993). Conceptually, this appears directly pertinent to how Blacks may view doctors, the healthcare establishment and subsequently clinical trials.

Considering the link between cultural mistrust and experiences with racism the range of factors that may influence African American's mistrustful attitudes should be further explored. Given that African Americans are skeptical of clinical research due to the historical treatment of blacks, it is conceivable that feeling vulnerable and liable to be exploited depends on the extent to which they also identify as a part of the mistreated group. According to Helms (1990) a person's interpretation of information and their response to their environment is strongly influenced by their racial identity. Sellers and colleagues (1998) define racial identity as the significance and qualitative meaning one attributes to being black in their conceptualizations of self. Thus one's racial or ethnic identity can be examined in the context of decision-making for clinical trials. Racial identity has rarely been studied in the context of attitudes towards clinical trials, but may be a relevant factor.

Sellers and colleagues (1998) have done a considerable amount of work to identify the components of racial identity. They propose four dimensions of racial identity: racial salience, the centrality of identity, the regard in which a person holds the group associated with the identity and the ideology associated with the identity (Sellers et al., 1998a). Their work suggests identities are situationally influenced, as well as being stable properties of the person. That is, racial identity in African Americans has both dynamic (susceptible to conceptual cues) and stable properties, which influence behavior accordingly at the level of the specific event (Sellers et al., 1998a). The current study focused only on centrality, which refers to the significance that an individual attaches to race in defining themselves and is thought to be relatively stable across situations (Sellers et al., 1998a). Their work also suggests that an individual's perception of their racial

identity is the most valid indicator of their identity. Individuals have a number of different identities, which are hierarchically ordered, thus focusing on the importance that an individual places on race in their definition of self (Sellers et al., 1998a).

Williams-Brown and colleagues (2008) proposed that more work should be done to establish how cultural and racial/ethnic profiles impacted individual health attitudes and behaviors. They conducted a series of individual interviews with U.S.-born and Jamaican-born Black men living in the metropolitan Atlanta area. Participants were asked to talk about their sense of self, their ethnicity, their culture and their health-related attitudes. The study found that both U.S-born and Jamaican-born Black men who conveyed a sense of strong ethnic identity were more likely to have positive health attitudes compared with men who did not convey a strong sense of ethnic identity. Overall ethnic identity was positively associated with health related attitudes. Considered as a health-related behavior, the attitudes towards enrolling in a clinical trial may be similarly impacted by a level of racial or ethnic identity for African Americans.

The concept of racial identity has not been extensively considered in the context of health decision-making, especially when it comes to clinical trials participation. There is literature that suggests racial/ethnic minority groups have shown that greater identification with one's race/ethnicity or culture of origin may have a protective effect on health and may buffer the negative influence of unfair treatment and racial/ethnic discrimination (Chae et al., 2008). Chae and colleagues found that high levels of ethnic identification were associated with lower odds of being a current smoker compared with low levels of identity. Given that clinical trials decision-making has been linked with issues of trust and racial discrimination in the past, perhaps racial identity ought to be

similarly explored for its potential buffering or enhancing effect on this decision for African Americans. In a separate study of 1216 African American men from the National Survey of American Life, a significant interaction was found between reported discrimination and internalized negative racial group attitudes (a related identity measure) in predicting cardiovascular disease (Chae et al., 2010). Agreeing with negative beliefs about Blacks was positively associated with cardiovascular disease history and moderated the effect of racial discrimination. This study suggested overall that a group identity was a moderating factor in assessing and predicting cardiovascular health among African American men.

The psychological health and well-being of African Americans has also been linked to racial identity (Bediako et al., 2007; Sellers et al., 1998b; Carter et al., 1997; Rivas-Drake, 2010). Literature substantiates the claim that African Americans with a strong racial identity tend to have better mental health status than those who have less positive or weaker racial identity (Helms, 1990; Butler, 1975). In a study of 555 youth (Sellers et al., 2003), racial identity and race-related stress accounted for more of the variance in mental health among African American college students than any other predictors. Further, there is evidence of a direct relationship between racial centrality and psychological distress (Sellers et al., 2003). Of note, racial centrality was found to be a risk factor for experiencing discrimination and a protective factor in buffering the negative impact of discrimination on psychological distress. Centrality is thus likely to be relevant to the decision to participate in a clinical trial due to the fact that African Americans who define themselves more strongly as African Americans or Black are more likely to feel a sense of cultural commitment, which in turn may lead to an increased

willingness to participate in a clinical trial. It is conceivable that those with stronger racial identity might be more willing to participate in clinical trials since they may feel a stronger connection to other African Americans and may recognize that their participation may have benefits for the larger group. Thus, there may be an interaction between racial identity and mistrust because of the history of African Americans and research in the United States.

Other studies show that an African American's strong self identity relates directly to health outcomes including stress management and dietary control (Bediako et al., 2007); Chambers, 2000). Applied to his study on racial identity and sickle cell disease management, Bediako proposes a termed *salutogenic,* or health-enhancing effect, of racial identity in certain circumstances (Bediako et al., 2007). He suggests a generalizability to other health behaviors.

Emerging research explores the role of a social identity, like racial and ethnic identity in consumer behavior and health (Oyserman et al., 2007; Oyserman, 2008). Oyserman's work focuses on how the self-concept, which includes racial identity, functions to influence judgment, decision-making and real world behavior (Oyserman et al., 2007). Oyserman (2007) proposes a mechanism of identity-based motivation, whereby individuals make choices based on how they see themselves or identify as part of a group. This work considers an individual's membership as a particular racial or ethnic group, influential of beliefs about how the group fits into a broader society, what they should believe in, and how they should act in ways that are congruent with beliefs about group membership. This is thought to motivate the types of decisions individuals make and thus influence their health beliefs and health decisions. Extending this

argument, perhaps individual decisions to enroll in clinical trials are influenced by whether one believes the choice to be congruent with their in-group's (i.e., African Americans or other Blacks) choice.

Oyserman and colleagues' (2007) identity-based motivation model has been used to understand barriers to engaging in health promotion among racial-ethnic minorities and low-SES Americans; positing that they are more likely to perceive health promotion as an out-group characteristic rather than an in-group characteristic. Thus thinking of oneself as a minority in-group member dampens health promotion efficacy (i.e., "that is not a thing that we do"), and increases health fatalism (i.e., "there is nothing we can do about it") (Altschul et al., 2006). They reported a significant moderating effect related to in-group identity.

Oyserman and colleagues (2007) showed that white American and racial-ethnic minority group participants differ in their beliefs about health promotion and that racial-ethnic minority group participants are more likely to encode health promotion activities as middle class and White. Thus it is conceivable that participating in a clinical trial is something that African Americans, particularly those with a strong racial identity, do not see as congruent with in-group behavior and thus their willingness to enroll may be modified by this perspective. A 2007 study illustrates this point referencing a study in which women who self-identified as "African American" were more likely to seek mammography screening than those who self-identified as "Black" (Bowen et al., 1997a). The author's rationale was that perhaps women who self identified as African American felt less at odds with the dominant culture than those who self-identified as Black (Bowen et al., 1997b; Oyserman et al., 2007). While the intricacies of differentiating between

Black and African American are not the focus of this dissertation, this finding does suggest a role for racial identity worthy of exploring in the context of clinical trials decision-making. Further, it alludes to the need to establish whether a strong racial identity is more likely to promote enrollment, as consistent with the concept of altruism and doing something to benefit the group, as discussed earlier; or if it has the opposite effect whereby participating in clinical trials is not seen as in-group behavior for African Americans thus would dissuade one from participating. The latter would be consistent with Oyserman's observations where minority focus group participants did not see health promotion as in-group defining but rather described behaviors such as exercising, eating salad and dieting as "White" behaviors (Oyserman et al., 2007).

2.5 Religion and Trial Participation

It is conceivable that racial differences in trial participation may also be attributable to cultural factors such as religion; however, the role of religion or religious beliefs in the intention to enroll in cancer clinical trial has rarely (if at all) been examined. Advani et al., (2003) found that a belief in God was a significant predictor of a decreased willingness to participate in research. In this study, 95% of African-American patients (compared with 78% of white patients) reported strongly believing that God would determine their prognosis and whether they would be cured or die from their disease. Interactions were not tested to determine potential moderating effects of covariates, however the overall results of this study are important to consider since religion, education, income were more important barriers to willingness to participate than race (Advani et al., 2003).

The connection between religion and health has been shown for decades. In a survey of community health center in Glasgow, the prevalence of symptoms was found to relate to religious allegiance (Hannay, 1980). People who actively participated in their religion, rather than having a purely passive allegiance, had significantly fewer physical, mental or social symptoms. Greater religious observance was found among minority groups and acted as a stabilizing factor (Hannay, 1980).

The connection between religion and health has been further demonstrated by several, more recent studies (Levin et al., 2005; Blumenthal et al., 2007; Contrada et al., 2004c; Hannay, 1980; Ellison & Levin, 1998c; Contrada et al., 2004b; Contrada et al., 2004a; Holt et al., 2005; Ingersoll-Dayton et al., 2002; Johnson et al., 2005a). The extant literature, using various definitions of spirituality or religiosity, tends to focus on the role of religion in recovering from acute conditions such as myocardial infarctions (Blumenthal et al., 2007). Current studies have examined the positive effects of religion and religious involvement (Blumenthal et al., 2007) both in general populations, as well as specifically African American populations (Levin et al., 2005) on health. These studies find a direct relationship between religious involvement and having a belief in God, and better disease outcomes and increased rates of recovery. An association has also been found with more frequent church attendance and better self-rated health (Krause, 2010). Further there are lower rates of morbidity and cause-specific mortality among those with religious affiliations that make strict behavioral demands compared to religions with more liberal guidelines (Levin et al., 2005).

In research on religious beliefs and general medical treatment, Matthews, Sellergren and Manfredi (2002) found various factors to affect medical information

seeking, treatment engagement and emotional adjustment among African American cancer patients. They cited religious beliefs among their focus group participants, as a key cultural factor which played an important role in the behavior of African American cancer patients (Matthews et al., 2002).

The literature that does address religion and health decision-making among African Americans pertains mainly to screening decisions and health seeking behavior (Gullate, 2006; Figueroa et al., 2006; Dessio et al., 2004). For example religiousness and self-directed problem solving were significantly associated with prostate cancer screening attitudes (Abernethy et al., 2009). Interviews with a convenience sample of 129 women between 30 and 84 who self-reported finding a breast symptom before their breast cancer diagnosis were conducted. Women who reported talking to God only about their breast change were significantly more likely to delay seeking medical care than those who reported telling another person (Gullatte et al., 2010).

However, not all studies have found an association between religion and health. For example, Blumenthal found little evidence that self-reported spirituality, frequency of church attendance and frequency of prayer were associated with cardiac morbidity or all cause mortality after an acute myocardial infarction (Blumenthal et al., 2007).

The existing body of research does not adequately examine how specific religious beliefs may factor into complex health decision-making for African Americans and is worth exploring. Linden and colleagues' qualitative research revealed that participants expressed a mistrust in recruitment into clinical trials, and they believed that culturally sensitive recruitment efforts would be more effective in recruiting African American patients (Linden et al., 2007). Specifically participants in the study stated a higher

likelihood of participating if the church was somehow involved in their decision, stating they would feel more trusting and more likely view the clinical trial as more legitimate if someone from the church presented it. This suggests that where a negative attitude towards participation exists, religious factors may have a moderating effect. In this study, women also discussed the importance of 'praying" over medical interventions and how in particular, Southern Blacks consider God the ultimate healer, and they did not go to doctors (Linden et al., 2007). This again suggests there may be utility in further exploring how religious beliefs influence enrollment and exactly how they may modify prevalent attitudes towards clinical trials.

2.6 Theoretical Considerations

There is a paucity of research on clinical trial recruitment of minorities that is driven by a solid theoretical model. Several studies make mention of a theory used; however, they do not discuss the manner in which the theory was used nor do they directly connect any constructs to a theoretical basis. For example, Du and colleagues in their study of the impact of the NCI video on recruitment of lung cancer patients, state their hypothesis is based on Andersen's health behavior model(Du et al., 2008). However they do not to elaborate beyond this nor do they mention how exactly the theory connects their aims and hypotheses.

Also used in some research on clinical trial participation is the Theory of Reasoned Action (Azjen & Fishbein, 1980). This model considers predisposing and enabling factors that differentially predict willingness to participate in a clinical treatment trial (Brown & Topcu, 2003). Considering race as one of the *predisposing factors* in the framework, the study posits that race will lead to a differential effect in willingness to

participate. However the main criticism of the TRA is it does not account for behaviors that are under volitional control, and participation in clinical trials is behavior under volitional control.

Yang et al. (2009) employ the Risk Information Seeking and Processing framework (RISP), which they suggest is an antecedent to the Theory of Planned Behavior. The RISP model (2009) proposes a way in which cancer patients deal with information about clinical trial enrollment. They postulate information processing styles influence the attitudes toward clinical trials and in turn how this relates to behavioral intentions to participate (Janet Yang et al., 2010). They also test how this works in terms of motivations for participation, under the premise that attitudes are formed relative to how information is processed. The findings of this study point towards an overall role for information processing and attitudes toward clinical trials, however not to the intent to participate (Yang et al, 2009). They are among the first to provide evidence in support of the TPB proposition that attitudes toward clinical trials will lead to intention to enroll in clinical trials. Further, they provide strong justification that communication and justification about clinical trial enrollment should move beyond simply increasing awareness. That addressing and changing attitudes towards clinical trials is key. Specifically, the authors proposed finding means to cancer patients' cognitive and affective evaluations of potential risks involved in the research process (Yang et al., 2010). This highlights the fact that any theoretical basis should look more towards the intention to participate (as for example suggested by the TPB) and factors that have a direct theoretical link to the intention construct.

Use of the TPB may be particularly relevant when investigating clinical trial participation since work has shown that intention to engage in a specific behavior does predict actual behavior, in this case enrollment (Andrykowski et al., 2006). As articulated by the theory, intention is the cognitive representation of a person's readiness to perform a given behavior, and it is considered to be the immediate antecedent of behavior (Ajzen, 1985). The TPB posits that intention to engage in a specific behavior is a strong proximal indicator of the subsequent and actual performance of said behavior (Andrykowski et al., 2006; Ajzen, 1985). As stated by Godin and Kok (1996) the correlation between measures of intention and subsequent health behavior ranges from 0.25 to 0.72 and on average is 0.47. In the context of the dissertation, the variables under study relate to each of the key cognitive variables that determine intention. That is ***attitudes*** regarding that behavior (attitudinal barriers towards clinical trial participation); ***subjective norms*** regarding the behavior (as determined by ones ethnic identity and how they define themselves or identify with other black people); and *perceived behavioral control* (the extent of an individual's belief in God as a healer of their cancer). While the study variables are not exhaustive representations of the TPB constructs, the theory seems to be a reasonable guide for better understanding how these factors impact the intention to enroll.

Du et al.'s assessment of impact of their educational video in lung cancer patients showed a significant impact on attitudes towards clinical trials and they found that the reported likelihood to enroll was correlated with actual trial enrollment (2008). The connection between attitudes, intention to enroll and actual enrollment is consistent with the TPB even though this study did not explicitly use this theoretical guidance. Studies

that have examined and applied the TPB to understanding of behavioral intentions have shown that the collection of TPB constructs accounted for up to 53% of variance in behavioral intentions beyond that which could be accounted for by clinical and demographic variables (Andrykowski et al., 2006) . Further, of these constructs in the TPB it was consistently behavioral attitude that was most consistently associated with behavioral intentions and subjective norms the least so (Andrykowski et al., 2006).

Andrykowski and colleagues applied the TPB to a study of intentions to engage in physical and psychosocial health behaviors after cancer diagnosis(Andrykowski et al., 2006). The TPB helped to facilitate understanding of how 130 adults with a cancer diagnosis were currently performing and their future intentions based on a collection of physical and psychosocial health behaviors. They found the TPB constructs explained an added 25% of the variance in intentions over and above that explained by demographic and clinical variables (Andrykowski et al., 2006). Behavioral attitude was most consistently associated with intention. Andrykowski and colleagues (2006) affirm that TPB serves as a comprehensive model for understanding change in psychosocial and physical health behaviors alike following a cancer diagnosis. The TPB also would permit a consideration of variables which relate to ones normative beliefs and attitudes such as religious beliefs and racial identity, making it a good guiding theory for understanding factors affecting intention to enroll in clinical trials.

Many models of racial identity are based on the explicit assumption that race is a very central identity in a normally functioning African American(Sellers et al., 1998b). There are several theoretical models in racial identity literature, many of which are modeled on Cross's Model of Racial Identity (Ponterotto & Pederson, 1993). These

models however were not specifically designed for use in a health decision-making context; however, they provide some context and guidance for health-based interventions.

2.7 Summary

In consideration of culturally competent interventions, integration of social and historical context of a population is essential (Kagawa-Singer et al., 2010). While there is no shortage of literature that details some of the barriers to participation in trials identified among African Americans, some critical constructs, such as racial identity and religiosity, have rarely been examined. Previous multidisciplinary work suggests these two constructs may moderate the attitudes of African American patients towards many health behaviors, thus understanding how they may impact clinical trial decision-making could prove especially valuable.

There are further gaps in the literature in terms of methods to impact these barriers as most work has been atheoretical. There appears to be no reason why the TPB cannot be used as a suitable framework to understand the relationship between these constructs and the intention to participate in clinical trials. Attitudes, norms and perceived behavior control are all characteristics of human behavior that are modifiable (Andrykowski et al., 2006). Thus the ability to understand and demonstrate the level of influence exerted by socio-cultural factors may provide better guidance than currently exists for designing interventions to impact the intention of African American cancer patients to participate in a clinical trial.

CHAPTER THREE: METHODS

This chapter includes a description of the study sample, conceptual model, study design, measures and instrumentation. The data analysis plan is also presented.

3.1 Study Overview

In current health disparities research, a call to action for researchers suggests a focus on the impact of cultural variables shaping individual attitudes toward disease and treatment. There is, however, limited research examining these relationships among Black cancer patients and cultural factors surrounding their attitudes toward and intentions to enroll in clinical trials. Subsequently there are few culturally targeted interventions, which are focused on impacting these attitudes in order to increase the likelihood of trial participation among African Americans with cancer. Therefore, this study specifically examines two cultural constructs recognized as important in Black culture, and their relationship with attitudinal barriers to trial participation. Findings may inform new areas of focus for targeting interventions and designing educational materials to address the underrepresentation of African Americans in therapeutic clinical trials.

3.2 Study Site

The Washington Hospital Center (WHC) is an acute care teaching and research hospital, the largest non-profit hospital in the District of Columbia (DC) metropolitan region. Washington Cancer Institute (WCI) at WHC sees African American patients of diverse backgrounds and is DC's largest provider of cancer care, treating more of DC's cancer patients than any other program. Based on a 2007 annual report from the Cancer Institute, 38.7 percent of patients coming to WCI lived in the District of Columbia, 49.9 percent in Maryland, 7.8 percent in Virginia and 3.6 percent were from other states and

countries. Further, 54.5 percent of the patients were female; 59.2 percent were African-American, 34.3 percent non-Hispanic white, 3.0 percent Hispanic white and 3.7 percent had designated race as "other". WCI thus provided a diverse pool of patients from which to draw for this study. The cancer institute was funded by the National Center on Minority Health and Health Disparities for a two-year project targeting African American cancer patients. The overall goal was to design and implement an intervention that will help to increase minority participation in cancer clinical trials. This dissertation made use of the same study population.

3.3 Study Sample

Sampling and Eligibility

The sample for the dissertation study was a non-probability, purposive convenience sample of patients at WCI and dictated by the parent study described later in the section. Eligible participants:

- Self-identified as Black or African-American
- Were age 21 years or older
- Able to communicate verbally in English
- Had a confirmed cancer diagnosis
- Anticipated cancer treatment to be given at Washington Hospital Center

Patients who met any of the following criteria were ineligible:

- Had previously expressed an interest in participating in a clinical trial
- Had ever participated in any research study (including those unrelated to cancer), as manifested by having ever signed a research informed consent

- Had apparent physical distress or altered mental status precluding ability to give informed consent and/or complete study procedures

Recruitment

Potentially eligible participants were identified by their medical oncologist or nurse navigator either during their consultation visit or the day prior through the electronic scheduling system. This recruitment method initially resulted in an overrepresentation of female breast cancer patients as this was the main source of study referrals by physicians and staff. A deliberate effort was then made to recruit participants from other specialty oncology clinics within the hospital center, which resulted in an increase in male participants and the diversity of primary cancer sites represented within the sample. Ultimately, enrollments in the study were the result of a number of recruitment mechanisms which varied depending on the care provider they were referred by and the manner in which the study was initially presented to them. For instance some patients were given an overview of the study by their provider, before being asked to participate. Others were approached directly, while in the waiting room and waiting to see their provider, thus presented the study and asked to participate directly by me. Further, due to recruitment from several specialty clinics, participants were at various stages of treatment and at different points post-diagnosis.

Sample Description

The final study sample consisted of 111 participants; the majority of whom were female (76%). The mean age was 60 with the youngest participant 31 years of age and the oldest 87 years of age. Eighty-two percent of the participants were older than age 50. Patients self-identified as *African-American* (41%), *Black* (46%), *African* (4%),

Caribbean (4%) or *Other* (5%). The latter category included participants who were of mixed parentage/ethnicity or who considered themselves bi-racial. Eighty-eight percent of participants were US born nationals, while 12% were foreign-born/immigrants. More than half of the US-born sample were born on the East-Coast (58%), 29% were born in the Southern United States; 2% and 3% respectively, were born in the Midwestern/Central US and on the west coast. Approximately one third of the sample (37%) had a total annual household income over $75,000. Overall this was a relatively educated sample with fewer than 10% of participants having not completed high school. Seventy-one percent reported a family history of cancer, 42% were married and 82% had at least one child. All but 3% of the sample reported being Christian; the majority self-identified as Baptist (48%). Forty-seven percent reported attending church at least once a week, and 22.5% reported no active church attendance. Details are shown in Table 1.

Table 1: Summary Statistics: Socio-Demographic Variables

N= 111		Mean	Range
Age		60.1	(31-87)
		N	**Percent**
Gender	Female	84	76
	Male	27	24
Self Identified Race/Ethnicity	African-American	46	41
	Black	51	46
	African Ancestry	4	4
	Caribbean or West Indian Ancestry	4	4
	Other	6	5
Participant Born in US	Yes	98	89
	No	13	12
Region of US born	West Coast	3	3
	East Coast	64	58
	South	29	26
	Midwest/Central/Southwest	2	2
Annual Household Income	< $8000	13	12
	$8000- $11999	3	3
	$12000 –$15999	7	6
	$16000 – $19999	3	3
	$20000 - $29999	6	5
	$30000 – $39999	9	8
	$40000 –$49999	8	7
	$50000 - $74999	21	19
	>$ 75000	41	37
Family History of Cancer	No	32	29
	Yes	79	71
Marital Status	Never Married	26	23
	Married	47	42
	Marriage Equivalent	1	1
	Widowed	13	12
	Separated/Divorced	24	22
Number of Children	None	20	18
	1 or More	91	82
Highest Level of Education	< High School	11	10
	High School Graduate or GED	29	26
	Some college or technical school	33	30
	College Graduate	38	34
Church Attendance per Week	None	25	23
	1-3 Times	34	31
	4 or more	52	47
Ever Experienced Racism	Not at All	17	15
	Not Much	37	33
	Not Sure	15	14
	Somewhat	31	28
	Extremely	11	10

3.4 Study Design

Data for this dissertation were collected from participants of the parent study aimed to assess the impact of a narrative based video on cultural attitudes towards clinical trials among African American cancer patients. The dissertation was a non-experimental cross-sectional quantitative study testing a conceptual model that incorporated four of the attitudes from the parent study, with two cultural constructs measured solely for the dissertation work.

The parent study evaluated whether a 15-minute video with targeted information for African American cancer patients impacted six dimensions of attitude and affected their willingness to enroll in therapeutic clinical trials. I conducted a thorough informed consent process and obtained signed consent from the participants prior to any study activities and data collection. All key terms in both the consent form and items in the structured interview were explained to the participant as they appeared, to ensure a basic level of understanding. For clarity, participants were also told that the terms clinical trial, clinical research study and therapeutic trial were used interchangeably throughout the study and these words were also clearly defined. Participants completed a structured interview pre-test assessing their attitudes on six barriers, racial identity, religious belief and intention to enroll, immediately before viewing the intervention video for the parent study. Participants completed the same items related to the six dimensions of attitude and a single item of self-reported likelihood of enrollment in a clinical trial, immediately following the video.

I verbally administered each interview reading each question and all possible response options to the participant. Responses were recorded on a paper version of the questionnaire and later double-keyed into a secure database. The study design did not include a control group, thus all participants viewed the same video.

3.4.1. Pilot Work and Video Description

The parent study developed and tested the impact of a culturally targeted video on the six previously cited patient-level barriers to clinical trial participation among African Americans. Through the use of compelling patient, physician and ethicist narratives, the video addressed each barrier in turn and showed how each patient went from a place of fear after receiving their diagnosis, to overcoming that aspect of their fear of participating in a clinical trial. The physician and ethicists' interviews served to provide factual context for each barrier. The 15-minute video made use of progress messaging via narrative communication, shown to be particularly effective with communicating disparity based information and impacting behavioral intention among the study population (Nicholson et al., 2008).

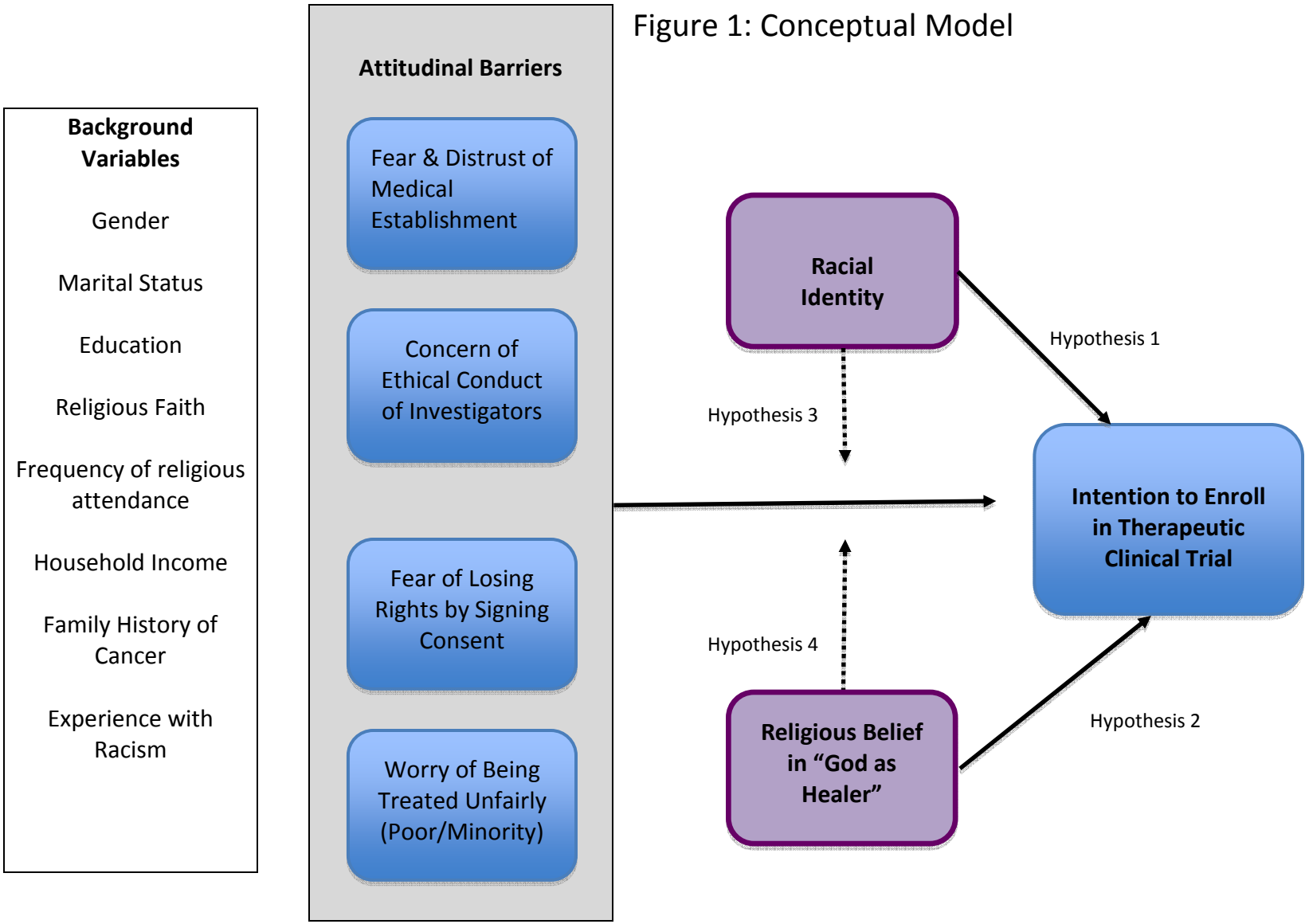
A series of patient interviews were conducted to develop the content for the video. These interviews served also to inform potential areas of focus for the dissertation study. I conducted 27 semi-structured interviews with cancer survivors, together with the producer of the patient education video. The patients were identified by research coordinators, nurse navigators and physicians in the Washington Cancer Institute. They had previously participated in a clinical trial, or consulted with an oncologist at WCI following their diagnosis. The patients discussed their experience from receiving their cancer diagnosis through considering their treatment options which included a clinical

trial. They were asked directly about their experience as it pertained to each of the attitudinal study barriers. Themes, quotes and key points from these interviews were used to identify further areas of inquiry for the dissertation study.

3.4 Conceptual Framework/Model

The framework (figure 1) depicts the explanatory variables studied in this dissertation investigating the impact of four dimensions of attitude along with racial identity and religious beliefs on the intention to enroll in a clinical trial.

Figure 1: Conceptual Model



3.5 Data Collection

3.5.1 Data Time-points

Demographic data were collected at pre-test. To minimize issues of health literacy the survey was verbally administered, which enabled participants to ask questions for clarification and ensured the completeness of the data. The pre-test consisted of a two-page survey taking approximately 20 minutes or less to complete. A post-test was administered in a similar fashion; however, the dissertation utilized data collected at pre-test only. I personally conducted all interviews to ensure uniform delivery to all participants.

3.5.2 Measures and Instrumentation

Dependent Variable: Intention to Enroll in a Therapeutic Clinical Trial

Participant's intention to enroll in a clinical trial was the main study outcome. A single item question on the survey was used to assess the participant's hypothetical willingness to participate in a clinical trial on a likert-type response scale. Scores on this item were 5 = Very likely; 4 = Somewhat likely; 3 = Not Sure; 2 = Somewhat unlikely; 1= Very unlikely. A high score indicated a greater intention to enroll.

To account for the proportion of the sample responding "Not Sure" (16.2%), the same question was asked of the study sample a second time, however only providing a 'Yes' or 'No' response option. This resulting binary intention variable was used as the main study outcome/dependent variable. In some cases the analysis used the binary intention variable, and this was noted in each section as appropriate. Table 2 shows the distribution of responses to these two items in the sample.

Table 2: Dependent Variable Item Responses

Likert-type Assessment:	Very Unlikely	Somewhat Unlikely	Neither/ Not Sure	Somewhat Likely	Very Likely
At this moment, is it likely that you would sign up to participate in a therapeutic clinical trial	18 (16.2%)	39 (35.1%)	18 (16.2%)	15 (13.5%)	21 (18.9%)

Binary Assessment:	Yes	No
At this moment, is it likely that you would sign up to participate in a therapeutic clinical trial	50 (45%)	61 (55%)

Independent Variables: Attitudinal Barriers

Each of the independent variables represented attitudinal barriers to trial participation documented in the literature. Six dimensions of attitude were measured for the parent study, four of which were used for the dissertation study and are detailed here. As there was no previously validated instrument to measure the exact attitudes identified for study a new one was developed for this purpose and was pilot tested and validated in this population for the dissertation study. These items were all adapted from existing scales, which measured concepts similar, but not identical to those assessed in this study. Constructs were assessed using a 5-item scale with likert-type responses scored 1 = Strongly Disagree; 2= Somewhat Disagree; 3 = Not sure/Neither; 4 = Somewhat Agree; 5= Strongly Agree. The responses for each item were summed to produce a composite or total score for each attitude dimension with a possible range from 5 to 25. Some items were reverse scored as required such that a high score indicated higher influence.

The four attitudinal scales, items, and their response frequencies are shown in tables 3 through 6 followed by the two scales for the moderator variables and their items (tables 7 and 8).

1. Fear and distrust of the medical establishment scale assessed fear and distrust of doctors, scientists and the government. It included five statements. Responses were given on a 5-point scale. For items 1 and 2, the lead in question was: "On a scale from 'very much' to 'not at all', how much would each of the following affect your decision whether or not to participate in a clinical trial?" For items 3 and 4, the lead in question asked, "How much do you 'agree' or 'disagree' with the following statement?"

Table 3: Distribution of Responses on Fear and Distrust of the Medical Establishment Scale: Frequencies and Percents

	Not at All	Not Much	Not Sure	Somewhat	Very Much
1. Trust in the doctor who offers you the trial	6 (5.4%)	4 (3.6%)	5 (4.5%)	11 (9.9%)	85 (76.6%)
2. The reputation of the treatment center where the trial is done	6 (5.4%)	2 (1.8%)	4 (3.6%)	14 (11.7%)	86 (77.5%)
	Strongly Disagree	Somewhat Disagree	Neither/ Not Sure	Somewhat Agree	Strongly Agree
3. I can not trust health care workers	50 (45.0%)	29 (26.1%)	4 (3.6%)	23 (20.7%)	5 (4.5%)
4. I am suspicious of clinical trials	22 (19.8%)	19 (17.1%)	13 (11.7%)	43 (38.7%)	14 (12.6%)
5. I am suspicious of information I receive from researchers	21 (18.9%)	30 (27.0%)	13 (11.7%)	34 (30.6%)	13 (11.7%)

2. Concern about the ethical conduct of investigators scale included five statements. The lead in questions for this scale were as follows: "How much do you 'agree' or 'disagree' with the following statements" (items 6 - 9). "From 'very likely' to very unlikely" (item 10)

Table 4: Distribution of Responses on Concern about the ethical conduct of investigators scale: Frequencies and Percents

	Strongly Disagree	Somewhat Disagree	Neither/ Not Sure	Somewhat Agree	Strongly Agree
6. Most clinical research is ethical	27 (24.3%)	56(50.5%)	12 (10.8%)	9 (8.1%)	7 (6.3%)
7. Researchers do not care about me or my well being	32 (28.8%)	36 (32.4%)	12 (10.8%)	20 (18.0%)	11 (9.9%)
8. My doctor would not ask me to participate in a clinical trial if he or she thought it would hurt me	66 (59.5%)	25 (22.5%)	3 (2.7%)	10 (9.0%)	7 (6.3%)
9. I am confident the group of people who approve clinical trials make sure all participants are treated fairly	46 (41.4%)	43 (38.7%)	10 (9.0%)	8 (7.2%)	4 (3.6%)
	Very Unlikely	Somewhat Unlikely	Neither/ Not Sure	Somewhat Likely	Very Likely
10. How likely do you think it is that you might be used as a guinea pig if you were in a clinical trial?	14 (12.6%)	22 (19.8%)	20 (18.0%)	28 (25.2%)	27 (24.3%)

3. Fear of losing one's rights by signing a research informed consent document scale was a five item likert-type response set. The lead in question for all items was: "If I were to sign an informed consent for a clinical trial…"

Table 5: Distribution of Responses on Fear of losing one's rights by signing a research informed consent document scale: Frequencies and Percents

	Strongly Disagree	Somewhat Disagree	Neither/ Not Sure	Somewhat Agree	Strongly Agree
11. I could still ask my doctors any questions that I want to	94 (84.7%)	14(12.6%)	1 (0.9%)	2 (1.8%)	0 (0%)
12. If doctors took my blood they could do tests on it they have not told me about	19 (17.1%)	13 (11.7%)	9 (8.1%)	35 (31.5%)	35 (31.5%)
13. I would only be agreeing to do what is explained to me in the consent form	68 (61.3%)	32 (28.8%)	6 (5.4%)	1 (0.9%)	4 (3.6%)
14. I could still change my mind about participating at any time	84 (75.7%)	23 (20.7%)	1 (0.9%)	2 (1.8%)	1 (0.9%)
15. The researchers would only do what is stated in the consent form	42 (37.8%)	49 (44.1%)	5 (4.5%)	7 (6.3%)	8 (7.2%)

4. Worry that investigators will treat poor or Black patients unfairly

The lead in question for items 16 through 19 was: "How much do you 'agree' or 'disagree' with the following statements". For item 20 it was "From 'very often', to 'never..'

Table 6: Distribution of Responses Worry That Investigators will treat poor or Black patients Unfairly Scale: Frequencies and Percents

	Strongly Disagree	Somewhat Disagree	Neither/ Not Sure	Somewhat Agree	Strongly Agree
16. Black people in clinical trials receive the same care from doctors and health care workers as people of other races and ethnicities	16 (14.4%)	40(36.0%)	12 (10.8%)	21 (18.9%)	22(19.8%)
17. If I were to enroll in a clinical trial my doctors would treat me with dignity and respect	56 (50.5%)	39 (35.1%)	9 (8.1%)	7 (6.3%)	0 (0%)
18. Compared with others, poor people are used more in research without their permission	14 (12.6%)	17 (15.3%)	25 (22.5%)	25 (22.5%)	30 (27.0%)
19. Black people are used more in research with their knowledge or permission than other races and ethnicities	18 (16.2%)	15 (13.5%)	25 (22.5%)	27 (24.3%)	26 (23.4%)
	Never	Rarely	Do Not Know	Fairly Often	Very Often
20. How often, if ever, do you think doctors prescribe medication as a way of experimenting on Black patients without their knowledge or permission	12 (10.8%)	20 (18.0%)	38 (34.2%)	26 (23.4%)	15 (13.5%)

Moderator Variable 1*:* Centrality

Racial identity was measured using the *Multidimensional Inventory of Black Identity*, 8-item *Seller's Centrality Scale* (Sellers, Smith et al, 1998). The Centrality dimension in Seller's Identity Scale (1997) has established construct validity and displayed moderate internal consistency when used in a study of African American students (Cronbach's α = 0.78). Rowley et al. (1998) reported similar measures of reliability with α = 0.73 in a study of college students, and α = 0.73 in a population of high school students. Mean scores were found to range from 5.20 (SD 1.14) for African American students at a predominantly white university, to 5.28 (SD =0.98) for African American students at an African American university. Items 1, 4 and 8 were modified slightly to create positively phrased statements rather than the reversed coded items in the original scale. Possible range for the composite score was 8 to 40. The stem of the questions was: "To what extent do you agree or disagree with the following statements."

Table 7: Distribution of Responses on Seller's Centrality scale: Frequencies and Percents

	Strongly Disagree	Somewhat Disagree	Neither/ Not Sure	Somewhat Agree	Strongly Agree
1. Overall, being Black has a lot to do with how I feel about myself.	39 (35.1%)	8(7.2%)	6 (5.4%)	15 (13.5%)	43 (38.7%)
2. God and only God can heal cancer	15 (13.5%)	6 (5.4%)	6 (5.4%)	16 (14.4%)	68 (61.3%)
3. My destiny is tied to the destiny of other Black people.	41 (36.9%)	16 (14.4%)	4 (3.6%)	19 (17.1%)	31 (27.9%)
4. Being Black is important to my sense of what kind of person I am.	22 (19.8%)	9 (8.1%)	9 (8.1%)	23 (20.7%)	48 (43.2%)
5. I have a strong sense of belonging to Black people.	11 (9.9%)	11 (9.9%)	8 (7.2%)	25 (22.5%)	56 (50.5%)
6. I have a strong attachment to other Black people	7 (6.3%)	12 (10.8%)	8 (7.2%)	26 (23.4%)	58 (52.3%)
7. Being Black is an important reflection of who I am	56 (50.5%)	20 (18.0%)	5 (4.5%)	14 (12.6%)	16 (14.4%)
8. Being Black is a major factor in my social relationships	28 (25.2%)	17 (15.3%)	5 (4.5%)	20 (18.0%)	41 (36.9%)

Moderator Variable 2: Belief in God as Healer

The aspect of religious beliefs measured was the perception of 'God as a healer' as measured by an established scale (Holt et al., 2009). This construct assessed an individual's belief that God acts as a healer in the event they have cancer, either directly or indirectly through physicians. This is a two dimensional construct. The scale had high internal reliability with Cronbach's α = 0.86 (Holt et al., 2009). Total score for the construct ranges from 9 to 45. The scale consists of 9-items as follows and Table 8 details the response frequencies within the sample:

Table 8: Distribution of Responses on Belief in God as Healer scale: Frequencies and Percents

	Strongly Disagree	Somewhat Disagree	Neither/ Not Sure	Somewhat Agree	Strongly Agree
God works through the doctors to heal cancer	3 (2.7%)	3(2.7%)	5 (4.5%)	20 (18.0%)	80 (72.1%)
God and only God can heal cancer	16 (14.4%)	18 (16.2%)	9 (8.1%)	9 (8.1%)	59 (53.2%)
My experience with cancer has made me realize that God is the ultimate healer	3 (2.7%)	6 (5.4%)	8 (7.2%)	10 (9.0%)	84 (75.7%)
I believe that if one is healed of cancer, it is God's will	4 (3.6%)	7 (6.3%)	4 (3.6%)	16 (14.4%)	80 (72.1%)
I believe that God gives the doctors/nurses the ability to heal cancer	2 (1.8%)	7 (6.3%)	7 (6.3%)	16 (14.4%)	79 (71.2%)
I believe that if you ask God for healing, He will heal you	6 (5.4%)	7 (6.3%)	9 (8.1%)	23 (20.7%)	66 (59.5%)
I believe that having a close relationship with God will lead to cancer recovery	7 (6.3%)	7 (6.3%)	5 (4.5%)	30 (27.0%)	62 (55.9%)
Healing can only occur from God, not from medicine or doctors	28 (25.2%)	28 (25.2%)	8 (7.2%)	12 (10.8%)	35 (31.5%)
Doctors give the cancer treatment, but God does the actual healing	9 (8.1%)	6 (5.4%)	7 (6.3%)	17 (15.3%)	72 (64.9%)

Contextual Variables

To assess the influence of various other characteristics, several contextual variables were assessed directly or by proxy measure. These are described below and shown in Table 1.

Acculturation: On the demographic survey, country of birth (United States versus other) was assessed. For foreign-born respondents (n = 13), the length of time they have been living in the U.S. was assessed. Also, generation was assessed by asking whether or not their parents were born in the United States. The primary language spoken at home was also assessed. These responses were translated to a proxy measure of high (46.2%), medium (38.0%), and low acculturation (15.8%) based on generation, length of time in the US and English primarily spoken at home.

Racism:

Experiences of racism were thought to be important in considering responses to questions about racial centrality and potentially any questions related to an intention to enroll in a clinical trial. As such the decision was made to assess whether personal experiences with racism may relate to the individual attitudes under study. Due to limited time and space on the demographic questionnaire a single item was added to assess study participant's personal experience with racism. This asked: "Overall, during your lifetime, how much have you personally experience racism?" Response options and corresponding scores were: 1= Not at all (15.3%); 2= Not much (33.3%); 3 = Not sure (13.5%); 4 = Somewhat (27.9%); 5 = Very Much (9.9%).

Socioeconomic Status was measured by average household income, and split into categories as High, medium and low

Dichotomous Variables

Dichotomous versions of the independent variables were created and also tested in separate models in addition to the likert-type variables. For each variable a mean split was used to classify each participant as either 'high' or 'low' for that category depending upon their total score being above or below the mean.

God as Healer: The mean score on this scale was 37.29 and anyone scoring above this (59.5% of the sample) was considered High, and below this (40.5% of the sample) was considered low belief. Due to the distribution of responses on this scale, only the continuous version of this variable was entered into the multivariate models.

Centrality: The mean score was 24.86 and participants were categorized as having high centrality if their scores were greater than this (56.8% of the sample) and low centrality below this (43.2%). Due to the distribution of responses on this scale, only the continuous version of this variable was entered into the multivariate models.

Distrust of the medical establishment: The mean score was 8.09 and anyone scoring above this (54.1% of the sample) was considered High on the distrust scale, and below this (45.9% of the sample) was considered low on the distrust scale.

Concern about ethical conduct of investigators: The mean score on this scale was 11.71 and anyone scoring above this (46.8% of the sample) was considered High, and below this (53.2% of the sample) was considered low belief.

Fear of losing rights after signing research informed consent: The mean score was 9.58 and anyone scoring above this (45.0% of the sample) was considered high belief, and below this (55.0% of the sample) was considered low belief.

Worry about being treated unfairly: The mean score on this scale was 14.36 and anyone scoring above this (49.5% of the sample) was considered High, and below this (50.5% of the sample) was considered low belief

3.6 Data Analysis Plan

SPSS v. 18.0 was used for all analyses. First, the reliability and validity of scales were examined. Next, bivariate associations were assessed. Finally multivariate associations and interactions were estimated. An alpha level of .05 was assumed for all analyses.

3.6.1 Scales Construction and Reliability

A principal components analysis for the items for each of the four attitudinal scales was performed using SPSS to establish the basic psychometric properties. Principle components analysis, using PROMAX oblique rotation explored the factor structure of these four scales. In addition, the two validated scales used for Racial Identity and Belief in God as Healer were assessed for internal reliability in this study population.

3.6.2 Bivariate Analysis

Correlation analyses examined the relationships between the attitude scales and the likert outcome of the dependent variable. Chi-square analyses were the primary technique to assess relationships with the binary dependent variable. Bivariate associations using analyses of variance assessed relationships between all scales (i.e., the attitudinal scales, the moderators and the dependent variable likert scale) with demographic variables. The latter are included for reference as Appendix I.

3.6.3. Regression Analyses

Logistic regression analysis was chosen as the primary multivariate analytic method based on the binary main study outcome variable (Intention to enroll: Yes/No). Due to the exploratory nature of this study, a forced entry method was used as it does not rely on some level of 'a priori' theoretical knowledge of the basic relationships between the variables. There is very scant literature to date that has looked at either racial centrality or belief in God as a healer in this context, thus there was otherwise limited theoretical guidance for this decision.

A baseline regression model was established to determine necessary covariates to include. There were no statistically significant differences in intention to enroll based on

different levels of the socio-demographic variables in the sample, as such four covariates were retained due to their conceptual relevance to clinical trial participation. Age, gender, marital status and experience of racism were all controlled for in each model. Unadjusted models for each of the attitudes and the moderators were first tested, followed by adjusted models for each. Next, each interaction was tested: attitude 1 by centrality; attitude 2 by centrality; attitude 3 by centrality; and attitude 4 by centrality. This was then repeated with the corresponding interactions using the belief in God as healer variable.

Finally racial centrality and religious belief were stratified to explore whether the predictive value of these models was modified at different levels of the proposed moderator variables. As described earlier, the mean split in each variable was used to classify participants as either high or low for each of centrality and level of religious belief.

3.6.4 Missing Data

As the survey instruments was interviewer administered, this ensured that complete answers for each survey item were obtained. Thus, no missing data occurred.

3.6.5 Power Analysis

Based on analysis of the study hypotheses and assuming a 5% attrition rate, and 80% power, recruitment of 114 participants was the target of the parent study. WCI planned to recruit this sample of 114 African American cancer patients potentially eligible for therapeutic trials over an 11-month period. Three patients were ultimately ineligible thus the final sample size was 111.

Since the dissertation used data from the parent study, a final power analysis was conducted using G*Power, (Faul et al., 2009) to determine the actual power achieved for these analyses. Based on a sample size of 111, alpha of 0.05 and the set of predictors selected for the final multivariate models and their distribution, the actual power achieved for this study and the primary outcomes was 68%.

3.7 Human Subjects Concerns

This proposal was submitted and approved by the University of Maryland, College Park Institutional Review Board (IRB) and the Georgetown University/Medstar Health IRB through a joint agreement (See Appendix B).

Prior to administration of any study instruments or viewing of the video, I executed a thorough informed consent with each study participant (See Appendix C for consent form). After completing the pre-test, watching the video and completing the post-test, all participants received a $25 gift card to Target as acknowledgment for their participation and appreciation of their time. Since the study site required all visitors and patients to pay for parking, those who drove to the site were given a parking voucher to cover the cost of their parking.

An additional consent form was also signed for those participants agreeing to do a qualitative follow-up study via telephone interview, which is beyond the scope of this dissertation (Appendix D). They were all provided a copy of their consent forms.

Participants were informed there were no major risks to participating in the study; however, that there was a possibility that they may feel uncomfortable discussing some of the study topics, particularly surrounding race, their religious beliefs and cancer. Further, there was a possibility that some participants would feel distress discussing treatment

options, especially if they were unsure at the time of their course of action. Caution was taken to administer each interview with compassion to minimize distress and allow the participant to stop or take a break as needed. In the instance where participants expressed a desire to further discuss participating in a clinical trial, they were referred to speak with their oncologist about trials for which they may be eligible. If they expressed any other issues, they were referred to the patient liaison in WCI's patient support services center to help them identify resources and provide guidance. The patient support services is a resource for patients and their families, providing access to licensed social workers, educational programs, counselors, spiritual support, complementary therapies and ethics advisors.

CHAPTER FOUR: RESULTS

4.1 Introduction

This chapter describes the results of the current study of the role of racial identity and religious beliefs in the attitudes of African American cancer patients' intention to enroll in therapeutic clinical trials. These results describe how the proposed moderators relate to four attitudinal barriers and subsequently to trial participation intention among the study population. Also described is the relative contribution of the attitudinal barriers and demographic characteristics to the intention to enroll in a clinical trial among the study population. The chapter concludes with a summary of the overall findings.

4.2 Independent Variables: Attitudinal Barrier

The first step in the analysis was to examine and establish the independent variables, the four attitudinal barriers. Thus, a correlation matrix of all items was examined. Next reliability coefficients for each of the four scales were examined. Finally, factor analyses were conducted.

4.2.1 Reliability Analysis of Scales

Cronbach's alpha was established for the four attitudinal scales. This statistic measures how well the items in a scale correlate with the sum of the other items, measuring the consistency between these individual items. Cronbach's alpha, item means and standard deviations, as well as total scale means and variances are summarized in Table 9. For general interpretation of the Cronbach's alpha for each scale, the following rules of thumb provided by George and Mallery (2003) were used. Greater than 0.9 is considered excellent, greater than 0.8 is considered good, greater than 0.7 is acceptable, greater than 0.6 is questionable, greater than 0.5 is Poor, and below 0.5 is unacceptable.

1. Fear & Distrust of Medical Establishment

The Cronbach's alpha for the fear and distrust of the medical establishment scale was 0.586 for the original 5-items, which is considered relatively low, or 'questionable'. The removal of two items increased the alpha to 0.746 which is considered "good" per George and Mallery (2003). The resulting final scale had 3 items, with a total scale mean of 8.10 (possible range 5 to 15) and variance of 10.73. These 3 items included: "I can not trust health care workers", "I am suspicious of clinical trials" and "I am suspicious of information I receive from researchers"

2. Concern about Ethical Conduct of Investigators

The original alpha for the concern about ethical conduct of investigators scale of five items was low at 0.528 (considered 'poor') and an analysis of the item-total statistics did not suggest any improvement with the removal of items from this scale. The final scale mean was 11.71 (in a possible range of 5 through 25). Standard deviation was 3.607.

3. Fear of Losing Rights by Signing Informed Consent

Cronbach's alpha was 0.602 for the five-item scale measuring the extent to which participants were fearful of losing their rights after signing an informed consent form for a clinical trial. This represents an acceptable alpha for this scale, so all 5 items were retained and the mean score on this scale was 9.58 where 5 was the minimum and 25 the maximum total score.

4. Worry About Being Treated Unfairly (Poor/Minority)

Cronbach's alpha was 0.636 for the full five-item scale of worry about being treated unfairly, which again was considered acceptable and no items were removed. The mean score on this scale was 14.36 where 5 was the minimum and 25 the maximum.

Table 9: Reliability and Descriptives for Study Variables

Scale	Cronbach's Alpha	# of Items	Item Means	Item Variance	Scale Mean	Scale Variance	Scale sd
Fear and Distrust (original)	0.59	5	3.43	1.54	17.13	14.49	3.81
Fear and Distrust (Final)	0.75	3	2.70	1.80	8.10	10.73	3.23
Ethical Conduct	0.53	5	2.34	1.50	11.71	13.01	3.61
Fear of Losing Rights	0.60	5	1.92	1.02	9.58	9.81	3.13
Worry about Being Treated Unfairly	0.64	5	2.87	1.70	14.36	15.96	4.00
Centrality (original)	0.68	8	3.39	0.42	27.09	47.06	6.86
Centrality (Final)	0.84	7	3.55	2.42	24.86	60.61	7.79
God as Healer	0.84	9	4.14	1.50	37.29	52.83	7.27

4.2.2 Correlation of Individual Items on Attitudes Scales

Pearson product-moment correlation coefficients were calculated to assess the strength of association between each individual item on the attitudes scales. Correlation of the items with each other and with the single response item to the intention to enroll outcome were examined. The correlation matrix in table 10 shows the relationship between the twenty items comprising the attitudes scales. The individual items as listed in the matrix by number are:

1. Trust in the doctor who offers you the trial
2. The reputation of the treatment center where the trial is done
3. I can not trust health care workers
4. I am suspicious of clinical trials
5. I am suspicious of information I receive from researchers
6. Most clinical research is ethical
7. Researchers do not care about me or my well being
8. My doctor would not ask me to participate in a clinical trial if he or she thought it would hurt me
9. I am confident the group of people who approve clinical trials make sure all participants are treated fairly
10. How likely do you think it is that you might be used as a guinea pig if you were in a clinical trial?
11. I could still ask my doctors any questions that I want to
12. If doctors took my blood they could do tests on it they have not told me about
13. I would only be agreeing to do what is explained to me in the consent form
14. I could still change my mind about participating at any time
15. The researchers would only do what is stated in the consent form
16. Black people in clinical trials receive the same care from doctors and health care workers as people of other races or ethnicities on clinical trials
17. If I were to enroll in a clinical trial my doctors would treat me with dignity and respect
18. Compared with others, poor people are used more in research without their permission
19. How often, if ever, do you think doctors prescribe medication as a way of experimenting on Black patients without their knowledge or permission?
20. Black people are used more in research without their knowledge or permission than others races and ethnicities

Y. At this moment, is it likely that you would sign up to participate in a therapeutic clinical trial

Seven of the 20 attitude items were significantly correlated with the intention item. At the $p = 0.01$ level, significant correlations with the intention item were found for item 4 (r

= - 0.29); item 5 (r = - 0.34); item 18 (r = - 0.353); and item 19 (r = - 0.22). At the p = 0.05 level, item 7 (r = - 0.196); item 19 (r = - 0.234); and item 20 (r = 0.223) were correlated with the intention item. As depicted in table 10 many of the individual items were significantly correlated with each other. For example item 4: "I am suspicious of clinical trials" was strongly correlated with 12 of the other items. Item 7: "Researchers do not care about me or my well being", was significantly correlated with 10 of the other items. Items 1 and 2 were the only items having significant correlations only with each other and no other items on the attitudes scales. These two items asked "How much would the following affect your decision whether or not to participate in a trial": Item 1: "Trust in the doctor who offered you the trial", and item 2: "The reputation of the treatment center where the trial is done" (r = 0.623)

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	Y
1	1	**.623****	.017	-.011	.048	-.133	.007	-.015	.023	-.106	-.011	-.097	-.122	.085	-.039	-.027	-.066	.034	.050	.008	-.011
2		1	.079	-.079	-.042	-.032	.009	-.064	.019	-.053	-.047	-.143	-.076	.027	-.019	.011	-.002	-.023	.144	-.013	.053
3			1	**.431****	**.380****	**.194***	**.351****	.152	.171	**.242***	**.207***	.140	.071	**.198***	.077	.114	.091	**.314****	.126	**.302****	-.129
4				1	**.668****	.117	.457**	.149	**.261****	.179	**.216***	**.304****	**.198***	**.232***	**.368****	**.223***	**.294****	**.441****	**.227***	**.456****	**-.292****
5					1	**.194***	**.453****	-.008	**.275****	**.260****	**.219***	**.243***	.065	**.219***	**.252****	**.264****	.104	**.409****	**.254****	**.376****	**-.335****
6						1	**.207***	.005	.131	.091	.158	-.038	-.024	.091	-.059	.182	**.201***	.112	.143	.137	-.132
7							1	**.206***	**.261****	**.307****	.133	**.199***	**.220***	.164	**.349****	**.299****	.107	**.368****	**.220***	**.375****	**-.196***
8								1	.142	.121	**.266****	.119	.172	.109	.129	.146	.106	.140	.096	**.205***	-.088
9									1	**.335****	**.201***	.151	**.201***	-.044	**.372****	**.293****	.174	**.353****	**.283****	**.341****	-.180
10										1	.058	**.210***	.049	-.100	.165	**.230***	.096	**.262****	**.190***	**.245****	**-.234***
11											1	.084	**.451****	**.379****	**.320****	.175	-.009	.101	.182	.152	-.106
12												1	**.224***	.174	**.217***	**.224***	.079	**.302****	**.237***	**.417****	-.161
13													1	**.280****	**.533****	.142	.031	.162	.094	.165	.070
14														1	**.195***	**.196***	-.102	.123	.128	.167	.062
15															1	**.221***	**.202***	**.304****	.126	**.345****	-.035
16																1	**.270****	**.267****	.121	**.202***	-.147
17																	1	.068	-.039	.093	-.127
18																		1	**.367****	**.622****	**-.353****
19																			1	**.446****	**-.292****
20																				1	**-.223***
Y																					1

Table 10: Pearsons Correlation of Individual Items on Attitudes Scale and Intention Item

**Correlation is significant at the 0.01 level (2-tailed).

*Correlation is significant at the 0.05 level (2-tailed).

4.2.3 Principle Components Analysis

A factor analysis was conducted in order to determine if the underlying structure of the attitudinal measures analytically corresponded to the conceptual scales. As this was the first use of the attitudinal items, a principle components analysis (PCA) was conducted for an examination of the full set of 20 items used to measure the four attitudinal constructs.

As there was known correlation between some of the attitudinal variables (see Table 12), an oblique rotation (PROMAX) of the correlation matrices was selected. The resulting Kaiser-Meyer-Olkin (KMO) statistic measuring sampling adequacy was .753, indicating PCA was appropriate for these data. The Bartlett's test of sphericity was also calculated to test the null hypothesis that the variables were uncorrelated. It was found to be statistically significant (Chi-square= 606.60; 190 df; $p < 0.01$). This also suggested the appropriateness of a factor analysis for these data (Field et al., 2003).

Conducting an exploratory factor analysis, results suggested a six factor solution for the 20 items assessing attitudes. This was determined by examination of the scree plot, Eigen values, and factor loadings. Items loading with at least .55 were considered. For the fear and distrust of the medical establishment scale, two components were extracted. Similarly for the worry of being treated unfairly scale, two factors were extracted. Concern of ethical conduct and fear of losing rights scales both had one factor each extracted.

Next, the PCA was conducted forcing a 4-factor solution to determine how these items loaded on each factor. With a forced 4-factor solution, the solution resulted in a 48.1% total item variance explained (compared with 60.2% of total item with the 6 factor solution). There was some overlap in how the items loaded on the four factors (See Appendix H), yet the decision was made to maintain the original four scales for conceptual reasons.

4.3 Moderator Variables

4.3.1 Racial Identity: Seller's Centrality Scale

Initially, the 8-item Seller's Centrality Scale was examined. With all original items retained, the internal consistency was lower than previously reported values in the literature (alpha = 0.675). An examination of item-statistics suggested the removal of one item: *"Being black is an important reflection of who I am."* Removal of this item resulted in the 7-item final scale which was used for the study, raising the overall alpha to 0.841 which is considered good reliability and is higher than that reported for previous uses of this scale in other populations (see Table 9). PCA of the centrality scale in this population revealed a uni-dimensional structure with all items loading on just one factor. Table 10 shows these factor loadings for the centrality scale.

Table 11: Factor Loadings for Centrality Scale

Being Black is important to my sense of what kind of person I am.	0.811
Being Black is a major factor in my social relationships.	0.775
I have a strong sense of belonging to Black people.	0.738
I have a strong attachment to other Black people.	0.715
In general, being Black is an important part of my self-image.	0.708
My destiny is tied to the destiny of other Black people.	0.670
Overall, being Black has a lot to do with how I feel about myself.	0.619

4.3.2 Belief in God as Healer

Table 9 includes the descriptive statistics associated with the God as Healer scale which assessed levels of the proposed moderator variable among the study population. Mean scores and variances were computed for each item in the scale and all summary statistics are presented.

The reliability for the God as Healer scale was good with an alpha of 0.837 in this population. This is consistent with the Cronbach's alpha previously reported by the researchers who developed and validated this scale (0.86) (Holt et. al, 2009).

Factor loadings for the God as Healer scale (shown in Table 12) revealed two distinct dimensions for the scale, which is also consistent with previous use in the literature (Holt et. al, 2009). Seven items loaded onto the first dimension, God as direct healer, and the remaining two items loaded onto the second dimension for God as indirect healer through medicine and doctors.

Table 12: Factor Loadings for God as Healer Scale

Factor 1: God as Healer- Directly	
God and only God can heal cancer	0.831
Doctors give the cancer treatment, but God does the actual healing	0.804
Healing can only occur from God, not from medicine or doctors	0.751
I believe that if one is healed of cancer, it is God's will	0.740
I believe that if you ask God for healing, He will heal you	0.736
My experience with cancer has made me realize that God is the ultimate healer	0.651
I believe that having a close relationship with God will lead to cancer recovery	0.649
Factor 2: God as Healer through Medicine, and Doctors	
God works through the doctors to heal cancer	0.781
I believe that God gives the doctors/nurses the ability to heal cancer	0.778

4.7 Correlation Analysis

Pearson product-moment correlation coefficients were calculated to assess the strength of association between the composite score variables on each of the four attitudinal scales, the two moderator scales and the Likert form of the intention to enroll variable (See Table 13). The correlation between the two proposed moderators God as healer and racial centrality was 0.23 and was significant at the 0.05 level (2-tailed). Total belief in God as healer was also significantly correlated with distrust at 0.05 level (r =0.21). Eleven of the remaining correlations

were significant at the 0.01 level. Specifically, concern about the ethical conduct of investigators was positively and significantly correlated with distrust of the medical establishment scale (r = 0.49) and worry of being treated unfairly due to being poor or minority scale (r = 0.58). It was also significantly negatively correlated with intention to enroll (r = -0.28). Distrust of the medical establishment scale was significantly correlated with a fear of losing one's rights by signing a research informed consent scale (r =0.38) and worry of being treated unfairly due to being poor or minority scale (r =0.53). Finally it had a statistically significantly negative correlation with intention to enroll (r = -0.31). Worry of being treated unfairly due to being poor or minority was significantly associated with a concern about losing one's rights after signing a consent form (r = 0.47); and statistically significantly negatively associated with intention to enroll (r = -0.36). A fear of losing one's rights after signing a consent form was significantly associated with a belief in God as healer (r =0.25), worry of being treated unfairly (r =0.47) and concern about ethical conduct of investigators (r =0.35).

Correlational Research Questions

Examination of these correlations provides some evidence of the support of the first two study hypotheses. Hypotheses 1 and 2 investigate the relationship between racial identity and intention to enroll, and belief in God as healer and intention to enroll, respectively. Power analysis using G*Power revealed that with the sample size of n=111, and alpha set to 0.05 (two-tailed bi-directional test), a correlation coefficient of 0.30 or larger would be significant in either a positive or negative direction Power (1- β) = 0.907.

Hypothesis 1 suggests that participants with higher levels of racial identity will be more likely to express intention to enroll in a therapeutic clinical trial: proposing a positive correlation between the two. Table 12 reveals this relationship is not statistically significant (r = -0.05,

p=.592). The direction of the correlation is negative implying a higher level of racial identity correlates with a decreased intention to enroll in a clinical trial, yet it is close to zero and not statistically significant. Thus there is no evidence to support hypothesis 1 through correlation analysis.

Hypothesis 2 proposes that participants with stronger belief in the notion of God as healer will be less likely to express an intention to enroll in a therapeutic clinical trial, suggestive of a negative correlation between the two variables. Although the association is in the hypothesized direction, showing that the stronger the belief in God as healer the less likely a participant has intention to enroll, the correlation is weak and not statistically significant (r = -0.027, p =0.78). Thus the correlational analyses do not support Hypothesis 2.

Table 13: Pearson Correlations of Attitudes, Moderators and Intention Variables

	Distrust	Ethics	Rights	Worry	Centrality	God as Healer	Intention
Distrust	1	**0.49****	**0.38****	**0.53****	0.11	**0.21***	**- 0.31****
Ethics		1	**0.35****	**0.58****	0.03	0.10	**- 0.28****
Rights			1	**0.47****	-0.07	**0.25****	- 0.07
Worry				1	0.03	0.06	**- 0.36****
Centrality					1	**0.23****	-0.05
God as Healer						1	- 0.03
Intention							1

**Correlation is significant at the 0.01 level (2-tailed).

*Correlation is significant at the 0.05 level (2-tailed).

4.8 Binary Dependent Variable Analyses

Next, the binary version of the dependent variable was considered. Overall intention to enroll in a clinical trial (yes versus no/not sure) was examined to first identify if there were any differences in intention based on the distribution of demographic variables within the sample. Chi-square tests of independence were performed to examine the relationship between this binary intention to enroll variable and all background variables shown in Table 14.

While there were some differences in the percentage of each group expressing intention to enroll, none of these were statistically significant at $\alpha = 0.05$. For instance, within this sample a greater proportion of men (55.6%) expressed intention to enroll than did women (41.7%) at baseline. Similarly a greater proportion of foreign-born participants (53.8%) expressed intention to enroll than did the corresponding proportion for US-born nationals (43.9%). It should be noted however that the limited sample size within some of these groups made it challenging to detect a difference.

Table 14: Proportion of Intention to enroll by Demographic Variable

		Intention To Enroll N (%)		
		Yes	Chi-Sq	*p-value*
Gender	Male	15 (55.6%)		
	Female	35 (41.7%)	1.591	0.207
Age	30-39	4 (57.1%)		
	40-49	5 (41.7%)		
	50-59	18 (50.0%)		
	60-69	15 (45.5%)		
	70-89	8 (34.8%)	1.807	0.771
Marital Status	Married or Equivalent	19 (39.6%)		
	Not Married	31(49.2%)	1.019	0.313
US vs Foreign Born	US Born	43 (43.9%)		
	Foreign Born	7 (53.8%)	0.461	0.497
SES	Low	16 (50.0%)		
	Middle	15 (39.5%)		
	High	19 (46.3%)	0.822	0.663
Education Level	< High School	3 (27.3%)		
	High School grad or GED	15 (51.7%)		
	Some College or Technical School	17 (51.5%)		
	College Graduate	15 (39.5%)	2.961	0.398
Number of Children	None	12 (60.0%)		
	1 or more	38 (41.8%)	2.204	0.138
Experience of Racism	Not At All	8 (47.1%)		
	Not Much	15 (40.5%)		
	Not Sure	6 (40.0%)		
	Somewhat	15 (48.4%)		
	Very Much	6 (54.5%)	1.026	0.906
Number of Times Attending Church per month	None	14 (56.0%)		
	1-3 Times	14 (41.2%)		
	4 or more	22 (42.3%)	1.575	0.455
Family History of Cancer	Yes	34 (43.0%)		
	No	16 (50.0)	0.446	0.534
Belief in God as Healer	High	26 (39.4%)		
	Low	24 (53.3%)	2.100	0.147
Racial Centrality	High	28 (44.4%)		
	Low	22 (45.8%)	0.021	0.884

4.10 Regression Analysis

Multivariate logistic regression was conducted to assess the role of each predictor in the study population's intention to enroll in a clinical trial. These relationships are summarized beginning with model 1 in Table 15.

Model 1

Model 1 assessed Hypothesis 1 by regressing the intention to enroll variable on the centrality scale. In an unadjusted model, using the continuous form of the centrality variable (model 1a), the relationship was not statistically significant (OR = 1.002, p = 0.926). Regressing intention to enroll on the binary form of the centrality variable (model 1b) the relationship was also not statistically significant (OR = 1.058, p = .884). Thus, again Hypothesis 1 seems unsupported.

Table 15: Unadjusted Regression Model: Racial Centrality

			95% CI for exp b		
Model	**Variable**	**OR**	**Lower**	**Upper**	***p*-value**
1a	Racial Centrality (Likert)	1.002	0.955	1.052	.926
1b	Racial Centrality (Binary)	1.058	0.884	2.249	.497

Model 2

Model 2 assessed Hypothesis 2 (Table 16). Three unadjusted models (2a, 2b and 2c) were used to test the direct ability of a belief in God as healer to predict a participant's intention to enroll, using the binary version of the intention variable. As noted in Chapter 3, the two dimensions of the God as healer scale were parsed out and therefore model 2a tested the full scale (OR = 0.972, p = 0.277), model 2b tested God as direct healer subscale (OR = 0.962, p = 0.752) and model 2c tested subscale God as healer through doctors and medicine (OR = 0.969, p = 0.269). None of these models achieved statistical significance.

The unadjusted model (2b) was run a second time using the binary measure of belief in God as healer (full scale), and this also was not found to be statistically significant (OR = 0.569. p =0.149)

Table 16: Unadjusted Regression Model: God as Healer

Model	Variable	OR	95% CI for exp b		*p*-value
			Lower	Upper	
2a	God as healer (full scale- Likert)	0.972	0.922	1.023	.277
2b	God as direct healer dimension	0.962	0.752	1.230	.758
2c	God as indirect healer dimension	0.969	0.916	1.025	.269
2d	God as healer (full scale- Binary)	0.569	0.264	1.223	.149

Model 3

In order to inform interaction analyses, the relationships between the attitudinal scales and the intention outcome variable were next assessed. Table 17 shows unadjusted models assessing the predictive ability of each of the four attitudinal barriers showed that concern about the ethical conduct of investigators scale (OR = 0.840, p = 0.004), distrust of the medical establishment scale (OR = 0.834, p = 0.004), and worry about unfair treatment scale (OR = 0.873, p = 0.009) (Models 3a, 3b and 3c respectively) were significant predictors of intention to enroll when entered into separate models. Specifically, the higher a participant scored on these scales, the less likely they were to express intention to participate in a trial. A concern about loss of rights or autonomy after signing a consent form, fell short of significance in the unadjusted model (Model 3d, OR = 0.941, p = .337)

Table 17: Unadjusted Regression Models by Individual Attitude

Model	Variable	OR	95% CI for exp b		*p*-value
			Lower	Upper	
3a	**Ethics**	**0.840**	**0.746**	**0.945**	**.004**
3b	**Distrust**	**0.834**	**0.736**	**0.945**	**.004**
3c	**Worry**	**0.873**	**0.788**	**0.966**	**.009**
3d	Rights	0.941	0.83	1.07	.337

Model 4

The four attitudinal barriers scale were entered into Model 4 together without any other covariates using a forced entry method. As shown in Table 18 each of the predictors fell short of statistical significance in this model. There was no adjustment for demographic variables in this model and no moderators entered, suggesting that these four variables together in the absence of covariates do not sufficiently predict intention to enroll in a clinical trial. This raised concerns of collinearity because of the significant and moderate correlation between scales (see Table 13), thus all subsequent models were also run separately for each scale. Each model testing hypotheses 3 and 4 was fitted first entering all four attitudinal constructs together in one adjusted model, followed by each attitude separately within each adjusted model to examine how this impacted the predictive value of the variables in each model.

Table 18: Unadjusted Regression Models With all Four Attitudes

Model	Variable	OR	95% CI for exp b		*p*-value
			Lower	Upper	
4	Ethics	0.898	0.779	1.034	.135
	Distrust	0.893	0.769	1.038	.141
	Worry	0.942	0.822	1.079	.385
	Rights	1.059	0.911	1.231	.454

Model 5

Demographic variables identified as potentially influential from the bivariate analyses or determined to be theoretically important were entered into Model 5. These analyses adjust for the effects of SES, gender, age, marital status and having ever experienced racism. Age was entered into all models as a continuous variable; SES (high, medium, low), gender, marital status (married, not married) and experience with racism (some/very much versus not much/none) were all entered as categorical variables (shown in Table 19). Reference categories in each case are indicated by '1' values.

Demographic variables among the study population were entered in the second block following the four attitudinal barriers entered in block 1. Results showed that ethical conduct of investigators was the only statistically significant attitudinal variable in this adjusted model. Participants with greater concern about ethical conduct were less likely to express intention to enroll (OR = 0.85; p =0.04) in the multivariate model.

Each attitudinal variable was then tested separately. Model 5a tested concern about the ethical conduct of investigators scale in a model with the demographic covariates. Again an increase in concern about ethical conduct scale was significantly associated with a decreased likelihood of enrollment (OR = 0.810, p = 0.01). Model 5b tested only distrust of the medical establishment scale in the adjusted model. An increase in distrust was a significant predictor of a decreased intention to enroll (OR = 0.822, p = 0.04). Model 5c included the scale, Worry of being treated unfairly due to being poor or minority, and this was a significant predictor of a decreased odds of intention to enroll (OR = 0.877, p = 0.02). Model 5d included the concern about losing rights scale, which was not a significant predictor of intention to enroll (OR = 0.944, p = 0.38).

Table 19: Adjusted Regression Model for All Four Attitudes

Model	Variable	OR	95% CI for exp b Lower	Upper	*p*-value
5	**Ethics**	**0.850**	**0.726**	**0.995**	**.043**
	Distrust	0.889	0.758	1.043	.150
	Worry	0.976	0.844	1.129	.744
With all 4	Rights	0.889	0.758	1.043	.451
attitudes	Age	0.97**0**	0.934	1.008	.126
	Male (reference)	1			
	Female	0.481	0.174	1.329	.158
	Married or Equivalent (reference)	1			
	Not Married	0.561	0.210	1.495	.248
	High SES (reference)	1			
	Middle SES	0.781	0.261	2.334	.658
	Low SES	1.318	0.372	4.662	.669
	Racism (some to very much) (reference)	1			
	Racism (not much to none)	1.011	0.411	2.483	.982

Table 20: Adjusted Regression Models for Individual Attitudes

Model	Variable	OR	95% CI for exp b Lower	Upper	p-value
5a	**Ethics**	**0.810**	**0.713**	**0.920**	**.001**
Only Ethics	Age	0.972	0.936	1.008	.127
	Male	1			
	Female	0.419	0.157	1.124	.084
	Married or Equivalent (reference)	1			
	Not Married	0.528	0.206	1.350	.182
	High SES (reference)	1			
	Middle SES	0.681	0.243	1.907	.464
	Low SES	1.112	0.342	3.617	.860
	Racism (some to very much, ref)	1			
	Racism (not much to none)	1.060	0.447	2.516	.895
5b	**Distrust**	**0.822**	**0.720**	**0.939**	**.004**
Only Distrust	Age	0.974	0.939	1.011	.164
	Male	1			
	Female	0.603	0.233	1.558	.296
	Married or Equivalent	1			
	Not Married	0.680	0.268	1.728	.418
	High SES	1			
	Middle SES	0.890	0.310	2.554	.829
	Low SES	1.583	0.472	5.313	.457
	Racism (some to very much)	1			
	Racism (not much to none)	0.855	0.365	2.003	.719

Model	Variable	OR	95% CI for exp b		p-value
			Lower	Upper	
5c	**Worry**	**0.877**	**0.789**	**0.975**	**.015**
Only Worry	Age	0.984	0.950	1.019	.371
	Male	1			
	Female	0.591	0.271	1.509	.271
	Married or Equivalent	1			
	Not Married	0.627	0.252	1.560	.316
	High SES	1			
	Middle SES	0.762	.274	2.115	.601
	Low SES	1.154	0.360	3.695	.810
	Racism (some to very much)	1			
	Racism (not much to none)	0.862	0.372	1.997	.728
5d	Rights	0.944	0.829	1.075	.384
Only Rights	Age	0.981	0.947	1.016	.276
	Male	1			
	Female	0.553	0.223	1.372	.223
	Married or Equivalent	1			
	Not Married	0.646	0.264	1.581	.339
	High SES	1			
	Middle SES	0.688	0.249	1.900	.470
	Low SES	1.121	0.356	3.536	.845
	Racism (some to very much)	1			
	Racism (not much to none)	0.878	0.372	1.994	.755

4.10.1 Moderation Effects

Model 6: Racial Centrality as a Moderator

The first proposed moderation model had each of the four attitudinal barrier scales entered simultaneously, and racial centrality entered as an interaction term with each of the four attitudes. None of the interaction terms were statistically significant in this adjusted model nor were the main effects, when all four attitudes were entered into the same model as shown in Table 21.

Table 21: Centrality Interaction Models with All Four Attitudes

Model	Variable	OR	95% CI for exp b		*p*-value
			Lower	Upper	
6	Ethics	0.737	0.399	1.359	.328
	Distrust	0.809	0.390	1.681	.571
	Worry	0.890	0.513	1.546	.680
	Rights	1.237	0.662	2.309	.505
	Centrality	0.947	0.735	1.220	.673
	Age	0.967	0.929	1.007	.101
	Male (reference)	1			
	Female	0.477	0.170	1.338	.159
	Married or Equivalent (reference)	1			
	Not Married	0.595	0.218	1.626	.312
	High SES (reference)	1			
	Middle SES	.817	0.268	2.494	.723
	Low SES	1.587	0.422	5.972	.494
	Racism (some to very much) (ref)	1			
	Racism (not much to none)	0.955	0.363	2.508	.925
	Centrality*Distrust	1.003	0.978	1.029	.806
	Centrality*Ethics	1.005	0.984	1.027	.628
	Centrality*Rights	0.994	0.969	1.019	.633
	Centrality*Worry	1.004	0.983	1.024	.729

Again, due to concerns of multicollinearity each moderation model was then fit with only one attitudinal barrier at a time. Model 6a first tested a moderation model as in Model 6, however it focused only on the ethics scale interaction with racial centrality. There were no significant interactions between centrality and the attitudinal barrier, nor were there any significant main effects, as shown in Table 22.

Table 22: Centrality Interaction Model for Ethics

			95% CI for exp b		
Model	**Variable**	**OR**	**Lower**	**Upper**	***p*-value**
6a	Ethics	0.679	0.427	1.082	.103
	Centrality	0.941	0.793	1.116	.483
	Age	0.969	0.932	1.007	.104
	Male (reference)	1			
Ethics	Female	0.409	0.152	1.102	.137
	Married or Equivalent (reference)	1			
	Not Married	0.549	0.213	1.418	.223
	High SES (reference)	1			
	Middle SES	0.704	0.249	1.987	.507
	Low SES	1.248	0.369	4.219	.721
	Racism (some to very much) (ref)	1			
	Racism (not much to none)	0.861	0.348	2.128	.916
	Centrality*Ethics	1.007	0.990	1.023	.434

Model 6b included the distrust scale, and this main effect was not a significant predictor of intention to enroll and none of the interaction effects were statistically significant. Similarly, Model 6c and 6d tested the worry scale and the rights scale, respectively. As shown in table 23 none of the main nor interaction effects were statistically significant.

When initially examining each of the models involving centrality, an interaction term for centrality*racism was also tested. Despite its apparent conceptual relevance, this interaction was never found to be significant thus was left out of these models for the sake of parsimony.

Table 23: Centrality Interaction Models by Individual Attitudes

			95% CI for exp b		
Model	**Variable**	**OR**	**Lower**	**Upper**	***p*-value**
	Distrust	0.775	0.488	1.231	.280
6b	Centrality	0.997	0.859	1.157	.966
	Age	0.974	0.938	1.011	.162
	Male	1			
	Female	0.600	0.232	1.553	.292
Distrust	Married or Equivalent	1			
	Not Married	0.690	0.269	1.766	.439
	High SES	1			
	Middle SES	0.911	0.316	2.627	.863
	Low SES	1.643	0.483	5.584	.426
	Racism (some to very much) (ref)	1			
	Racism (not much to none)	1.187	0.501	2.812	.698
	Centrality*Distrust	1.002	0.985	1.020	.810
	Worry	0.758	0.504	1.139	.182
6c	Centrality	0.927	0.743	1.156	.499
	Age	0.983	0.948	1.019	.350
Worry	Male	1			
	Female	0.577	0.224	1.490	.256
	Married or Equivalent	1			
	Not Married	0.634	0.255	1.581	.329
	High SES	1			
	Middle SES	0.759	0.273	2.112	.598
	Low SES	1.227	0.378	3.988	.733
	Racism (some to very much)	1			
	Racism (not much to none)	1.102	0.466	2.607	.826
	Centrality*Worry	1.006	0.991	1.021	.463
6d	Rights	1.019	0.640	1.621	.938
	Centrality	1.031	0.860	1.235	.744
	Age	0.981	0.947	1.016	.285
Rights	Male	1			
	Female	0.559	0.225	1.390	.211
	Married or Equivalent	1			
	Not Married	0.645	0.263	1.578	.336
	High SES	1			
	Middle SES	0.685	0.247	1.900	.468
	Low SES	1.119	0.355	3.527	.848
	Racism (some to very much)	1			
	Racism (not much to none)	1.175	0.507	2.724	.707
	Centrality*Rights	0.997	0.979	1.015	.739

Model 7 Belief in God as Healer as a Moderator

To test hypothesis 4 the full model included all of the attitudinal variables with religious belief in God as a healer entered in an interaction with each of the attitudinal barriers. Table 24 shows there were no statistically significant interaction effects seen with all the individual attitudes together in the adjusted model, nor were there any statistically significant main effects.

Table 24: God as Healer Interaction Model with all Four Attitudes

Model	Variable	OR	95% CI for exp b		*p*-value
			Lower	Upper	
7	Ethics	1.287	0.501	3.308	.601
	Distrust	1.692	0.534	5.356	.371
	Worry	0.687	0.315	1.498	.346
	Rights	0.773	0.309	1.930	.581
	Religious Belief	1.052	0.824	1.344	.684
	Age	0.968	0.931	1.008	.112
	Male (reference)	1			
	Female	0.539	0.186	1.558	.254
	Married or Equivalent (reference)	1			
	Not Married	0.483	0.177	1.317	.155
	High SES (reference)	1			
	Middle SES	0.779	0.258	2.348	.657
	Low SES	1.348	0.365	4.982	.654
	Racism (some to very much)	1			
	Racism (not much to none)	0.903	0.358	2.275	.829
	Religious Belief*Distrust	0.983	0.955	1.013	.263
	Religious Belief*Ethics	0.988	0.963	1.014	.358
	Religious Belief*Rights	1.009	0.986	1.033	.457
	Religious Belief*Worry	1.009	0.989	1.030	.392

When the attitudinal barriers were entered into this model individually, there were similarly no significant main effects or interaction effects detected (Table 25). Specifically, Model 7a tested the ethics scale by itself in an interaction with belief in God as healer. There were no significant interaction or main effects. Model 7b tested distrust of the medical establishment as an interaction with belief in God as a healer. None of these effects reached statistical significance.

Table 25: God as Healer Interaction Models for Ethics and Distrust

			95% CI for exp b		
Model	**Variable**	**OR**	**Lower**	**Upper**	***p*-value**
7a	Ethics	1.114	0.605	2.051	.730
	Religious Belief	1.094	0.897	1.336	.375
	Age	0.971	0.935	1.008	.122
	Male (reference)	1			
Ethics	Female	0.429	0.157	1.168	.098
	Married or Equivalent (reference)	1			
	Not Married	0.496	0.192	1.281	.147
	High SES (reference)	1			
	Middle SES	0.663	0.235	1.871	.437
	Low SES	1.050	0.319	3.458	.936
	Racism (some to very much) (ref)	1			
	Racism (not much to none)	0.925	0.387	2.212	.861
	Religious Belief*Ethics	0.991	0.974	1.008	.305
7b	Distrust	1.026	0.507	2.075	.943
	Religious Belief	1.044	0.893	1.220	.591
	Age	0.974	0.939	1.011	.168
	Male (reference)	1			
Distrust	Female	0.629	0.239	1.656	.347
	Married or Equivalent (reference)	1			
	Not Married	0.644	0.249	1.666	.364
	High SES (reference)	1			
	Middle SES	0.866	0.300	2.505	.791
	Low SES	1.543	0.459	5.192	.483
	Racism (some to very much) (ref)	1			
	Racism (not much to none)	1.160	0.495	2.722	.733
	Religious Belief*Distrust	0.994	0.976	1.013	.535

In Table 26, Model 7c entered the worry about being treated unfairly scale into the model while Model 7d tested the concern about losing rights scale and found neither of them reached statistical significance with interaction or main effects.

Table 26: God as Healer Interaction Models for Worry and Rights

			95% CI for exp b		
Model	**Variable**	**OR**	**Lower**	**Upper**	***p*-value**
7c	Worry	0.831	0.491	1.404	.488
	Religious Belief	0.961	0.778	1.186	.709
	Age	0.984	0.950	1.020	.378
	Male (reference)	1			
Worry	Female	0.624	0.241	1.621	.333
	Married or Equivalent (reference)	1			
	Not Married	0.645	0.257	1.623	.352
	High SES (reference)	1			
	Middle SES	0.795	0.283	2.233	.664
	Low SES	1.178	0.363	3.820	.785
	Racism (some to very much) (ref)	1			
	Racism (not much to none)	1.162	0.501	2.695	.727
	Religious Belief*Worry	1.001	0.988	1.016	.835
7d	Rights	0.880	0.823	1.142	.710
	Religious Belief	0.969	0.429	1.802	.726
	Age	0.981	0.947	1.016	.287
	Male (reference)	1			
Rights	Female	0.570	0.225	1.446	.237
	Married or Equivalent (reference)	1			
	Not Married	0.654	0.266	1.606	.354
	High SES (reference)	1			
	Middle SES	0.704	0.253	1.959	.501
	Low SES	1.130	0.355	3.599	.837
	Racism (some to very much) (ref)	1			
	Racism (not much to none)	1.126	0.494	2.563	.778
	Religious Belief*Rights	1.002	0.984	1.020	.826

4.10.2 Stratified Analysis

Finally, as a means to further explore the moderation hypotheses given the concern about collinearity between the attitudinal variables, a stratified analysis was conducted to explore the effects on different levels of the proposed moderator variables, racial centrality and religious belief. Cases were split based on the mean to create high

and low levels of centrality and belief in God as a healer. Adjusted regression models were then fit using these levels of stratification.

These results are shown in Table 27 as a presentation of model 8 (which includes all four attitudinal variables with covariates), followed by models 8a through 8d (individual attitudinal variables one at a time, with covariates). This is displayed first for the low centrality stratum followed by the corresponding models for the high centrality stratum (models 9 and 9a through 9h).

Model 8: Low Centrality Model 8 shows for participants with low centrality there were no statistically significant predictors in an adjusted model of all four attitudinal variables

Table 27: Stratified Analysis Low Centrality- Full Model

Low Centrality			95% CI for exp b		
Model	**Variable**	**OR**	**Lower**	**Upper**	**p-value**
8	Ethics	0.918	0.710	1.186	.512
	Distrust	0.869	0.672	1.123	.283
	Worry	0.870	0.664	1.140	.312
	Rights	1.156	0.929	1.438	.193
	Age	0.989	0.935	1.046	.693
	Male	1			
	Female	1.109	0.314	7.433	.693
Low centrality	Married or Equivalent	1			
	Not Married	1.109	0.232	5.295	.897
	High SES	1			
	Middle SES	0.581	0.111	3.023	.518
	Low SES	2.234	0.277	18.046	.441
	Racism (some to very much)	1			
	Racism (not much to none)	0.561	0.128	2.450	.441

Similarly when each adjusted model was fit with one attitudinal variable at a time in Table 28 (Models 8a through 8d)

Table 28: Stratified Analysis Low Centrality- Ethics and Distrust

Low Centrality		95% CI for exp b			
Model	**Variable**	**OR**	**Lower**	**Upper**	**p-value**
8a	Ethics	0.834	0.678	1.026	.087
	Age	0.989	0.939	1.042	.680
	Male	1			
	Female	1.068	0.265	4.305	.927
Low centrality					
	Married or Equivalent	1			
	Not Married	0.9240	0.228	3.743	.912
	High SES	1			
	Middle SES	0.505	0.105	2.418	.392
	Low SES	1.375	0.226	8.361	.729
	Racism (some to very much)	1			
	Racism (not much to none)	0.753	0.187	3.023	.228
8b	Distrust	0.827	0.664	1.028	.087
	Age	0.989	0.938	1.042	.669
	Male	1			
	Female	1.653	0.405	6.743	.483
Low centrality					
	Married or Equivalent	1			
	Not Married	1.368	0.319	5.860	.673
	High SES	1			
	Middle SES	0.24	0.127	3.062	.561
	Low SES	2.154	0.308	15.073	.439
	Racism (some to very much)	1			
	Racism (not much to none)	0.530	0.142	1.978	.345

Table 29: Stratified Analysis Low Centrality- Worry and Rights

Low Centrality			95% CI for exp b		
Model	**Variable**	**OR**	**Lower**	**Upper**	**p-value**
8c	Worry	0.842	0.689	1.029	.092
	Age	0.997	0.947	1.050	.917
	Male	1			
	Female	1.509	0.358	6.355	.575
low centrality	Married or Equivalent	1			
	Not Married	1.178	0.291	4.775	.818
	High SES	1			
	Middle SES	0.526	0.110	2.523	.422
	Low SES	2.003	0.295	13.622	.477
	Racism (some to very much)	1			
	Racism (not much to none)	0.506	.133	1.920	.317
8d	Rights	1.040	0.860	1.259	.684
	Age	1.0030	0.955	1.053	.915
	Male	1			
	Female	1.287	0.338	4.899	.712
	Married or Equivalent	1			
low centrality	Not Married	0.895	0.227	3.534	.874
	High SES	1			
	Middle SES	0.375	0.078	1.806	.222
	Low SES	0.982	0.163	5.932	.984
	Racism (some to very much)	1			
	Racism (not much to none)	0.469	0.129	1.708	.251

Model 9: High Centrality:

In Table 30, Model 9 shows an adjusted model of all four attitudinal variables entered simultaneously. Gender was found to be a statistically significant predictor of intention to enroll in high centrality models. Females with high centrality were significantly less likely to express intention to enroll compared with their male counterparts in this full model (OR = 0.125, p = 0.019). This gender effect was seen in

each of Models 8a (OR = 0.134, p = 0.016), 8b (OR = 0.163, p = 0.026) and 8c (OR = 0.190, p = 0.029) and 8d (OR = 0.125, p = 0.043).

Table 30: Stratified Analysis High Centrality- Full Model

Model	High Centrality Variable	OR	95% CI for exp b Lower	Upper	*p*-value
High centrality 9	Ethics	0.842	0.668	1.060	.143
	Distrust	0.836	0.655	1.067	.151
	Worry	1.041	0.848	1.277	.701
	Rights	0.975	0.722	1.316	.867
	Age	0.935	0.868	1.006	.071
	Male	1			
	Female	**0.125**	**0.022**	**0.715**	**.019**
	Married or Equivalent	1			
	Not Married	0.251	.056	1.128	.071
	High SES	1			
	Middle SES	0.787	0.148	4.181	.779
	Low SES	1.603	0.257	9.981	.613
	Racism (some to very much)	1			
	Racism (not much to none)	1.642	0.399	6.751	.492

Two marginally significant main effects were seen for marital status and age among participants with high centrality, although falling short of the 0.05 significance level. The corresponding variables in the low centrality subset of the sample did not reach statistical significance and had odds ratios in the opposite direction. This is further suggestive of a moderation effect of centrality, however on the demographic variables rather than the attitudinal variables. The ethics scale was significant in Model 9a; however, the coefficient and direction for the ethics scale were quite similar for Model 8a (low centrality), suggesting only a main effect not an interaction.

Table31: Stratified Analysis High Centrality- Ethics, Distrust, Rights, Worry

	High Centrality		95% CI for exp b		
Model	**Variable**	**OR**	**Lower**	**Upper**	**p-value**
9a	**Ethics**	**0.797**	**0.663**	**0.959**	**.016**
	Age	0.942	0.882	1.006	.075
High centrality	Male	1			
	Female	**0.134**	**0.026**	**0.688**	**.016**
	Married or Equivalent	1			
	Not Married	0.259	.062	1.084	.075
	High SES	1			
	Middle SES	0.636	0.138	2.930	.562
	Low SES	1.121	0.212	5.925	.893
	Racism (some to very much)	1			
	Racism (not much to none)	1.698	0.456	6.317	.430
	Distrust	**0.784**	**0.644**	**0.955**	**.015**
	Age	0.943	0.882	1.007	.081
9b	Male	1			
	Female	**0.163**	**0.033**	**0.803**	**.026**
High centrality	Married or Equivalent	1			
	Not Married	0.283	.068	1.178	.083
	High SES	1			
	Middle SES	0.818	0.171	3.926	.802
	Low SES	1.616	0.292	8.932	.582
	Racism (some to very much)	1			
	Racism (not much to none)	1.633	0.432	6.170	.469
	Rights	0.854	0.671	1.086	.198
	Age	0.953	0.896	1.013	.122
	Male	1			
	Female	**0.190**	**0.043**	**0.844**	**.029**
9c	Married or Equivalent	1			
High centrality	Not Married	0.362	.091	1.444	.071
	High SES	1			
	Middle SES	0.777	0.159	3.786	.754
	Low SES	1.248	0.241	6.470	.792
	Racism (some to very much)	1			
	Racism (not much to none)	1.451	0.386	5.454	.582
	Worry	0.887	0.771	1.020	.093
	Age	0.960	0.903	1.020	.190
9d	Male	1			
	Female	**0.125**	**0.022**	**0.715**	**.043**
High centrality	Married or Equivalent	1			
	Not Married	0.313	.079	1.237	.098
	High SES	1			
	Middle SES	0.741	0.160	4.879	.702
	Low SES	0.949	0.185	4.879	.950
	Racism (some to very much)	1			
	Racism (not much to none)	1.642	0.443	5.952	.465

Model 10: Low Belief in God as Healer

In Table 32, Model 10 examines the predictive value of all four attitudinal variables entered together with covariates, followed by models 10a through 10d (individual attitudinal variables analyzed one at a time, with covariates) for the low belief in God as a healer stratum.

Model 10 was an adjusted model including all four attitudinal variables for those with a low level of belief in God as a healer. In this full model, ethics was a statistically significant predictor of decreased intention to enroll (OR = 0.743, p = 0.026) but none of the other three attitudes were significant.

Table 32: Stratified Analysis Low Belief in God as Healer- Full Model

	Low Belief in God as Healer		95% CI for exp b		
Model	**Variable**	**OR**	**Lower**	**Upper**	**p-value**
10	**Ethics**	**0.743**	**0.573**	**0.965**	**.026**
	Distrust	0.873	0.704	1.082	.215
Low Belief	Worry	0.971	0.792	1.190	.774
	Rights	1.210	0.973	1.505	.087
	Age	1.008	0.954	1.065	.765
	Male	1			
	Female	0.530	0.113	2.493	.421
	Married or Equivalent	1			
	Not Married	0.322	0.077	1.350	.121
	High SES	1			
	Middle SES	0.509	0.121	2.138	.356
	Low SES	0.375	0.057	2.482	.309
	Racism (some to very much)	1			
	Racism (not much to none)	1.454	0.387	5.459	.579

Separate models were run with each of the attitudinal barriers at a time. These models suggest that at low level of belief in God as healer, it was demographic factors,

which proved to be significant predictors of enrollment intention (Models 10a through 10d). Specifically, (Model 10a) when ethics was the only attitude in the model, it was no longer significant as a main effect (OR = 0.849, p = 0.085), however age was a significant predictor of decreased odds of intended enrollment. Specifically**,** with increasing age, there was decreased likelihood of intention to enroll, for those with low belief in God as a healer (OR = 0.901, *p* = 0. 009).

Table 33: Stratified Analysis Low Belief in God as Healer- Ethics

	Low Belief in God as Healer		95% CI for exp b		
Model	**Variable**	**OR**	**Lower**	**Upper**	**p-value**
	Ethics	0.849	0.7051	1.023	.085
10a Low Belief	**Age**	**0.901**	**0.833**	**0.975**	**.009**
	Male	1			
	Female	0.470	0.090	2.450	.370
	Married or Equivalent	1			
	Not Married	0.716	0.154	3.334	.671
	High SES	1			
	Middle SES	1.887	0.275	12.962	.519
	Low SES	6.811	0.787	58.934	.081
	Racism (some to very much)	1			
	Racism (not much to none)	1.104	0.244	4.987	.898

When distrust was the only attitudinal variable included in the adjusted model, age and SES became significant predictors of intention. With increasing age, participants were significantly less likely to express intention to enroll (OR = 0.893, *p* = 0.010). Participants of low SES were significantly more likely to express intention to enroll (OR = 10.157, *p* = 0.049) compared with participants of high SES within the same group.

Table 34: Stratified Analysis Low Belief in God as Healer- Distrust

	Low Belief in God as Healer		95% CI for exp b		
Model	**Variable**	**OR**	**Lower**	**Upper**	**p-value**
10b	Distrust	0.795	0.609	1.038	.092
	Age	**0.893**	**0.820**	**0.973**	**.010**
	Male	1			
Low Belief	Female	0.487	0.090	2.642	.404
	Married or Equivalent	1			
	Not Married	0.879	0.177	4.376	.875
	High SES	1			
	Middle SES	2.251	0.294	17.253	.435
	Low SES	**10.157**	**1.011**	**102.061**	**.049**
	Racism (some to very much)	1			
	Racism (not much to none)	0.901	0.192	4.220	.895

When worry of being treated unfairly was the only attitude introduced into the adjusted model (10c), age again was a significant predictor of intention to enroll such that increasing age was associated with a decreased likelihood of intention to enroll (OR = 0.909, p = 0.016). The same age effect was seen for model 10d with fear of losing one's rights variable (OR = 0.907, p = 0.013).

Table 35: Stratified Analysis Low Belief in God as Healer- Worry and Rights

Low Belief in God as Healer			95% CI for exp b		
Model	**Variable**	**OR**	**Lower**	**Upper**	**p-value**
10c	Worry	0.845	0.703	1.016	.073
	Age	**0.909**	**0.842**	**0.982**	**.016**
Low Belief	Male	1			
	Female	0.654	0.124	3.460	.617
	Married or Equivalent	1			
	Not Married	0.824	0.170	3.994	.810
	High SES	1			
	Middle SES	2.346	0.332	16.595	.393
	Low SES	9.231	0.962	88.534	.054
	Racism (some to very much)	1			
	Racism (not much to none)	0.792	0.174	3.614	.763
	Rights	0.876	0.667	1.151	.342
	Age	**0.907**	**0.839**	**0.980**	**.013**
10d	Male	1			
	Female	0.483	0.096	2.436	.378
Low belief	Married or Equivalent	1			
	Not Married	0.708	0.151	3.322	.662
	High SES	1			
	Middle SES	1.882	0.276	12.804	.518
	Low SES	7.236	0.785	66.723	.081
	Racism (some to very much)	1			
	Racism (not much to none)	0.946	0.217	4.136	.942

Model 11: High Belief in God as Healer

For those with a high level of belief in God as healer, a full adjusted model including all four attitudinal variables, suggested that age (OR = 0.895, p = 0.015) was significant predictor of decreased odds of intention to enroll. Being in a low SES group compared with the high SES group was predictive of a greater odds of enrolling (OR = 11.06, p = 0.052).

In models 11a and 11b, a high belief in God as healer revealed a statistically significant reduction in odds of intention to enroll for those who had high concern about

ethics and high levels of distrust of medicine and doctors. Specifically in Model 11a where ethics was the only attitudinal barrier entered there was a significant decrease in odds of intention to enroll (OR = 0.762, p = 0.011) with increased concern. In Model 11b where distrust was the only attitudinal barrier entered, increasing distrust was associated with a statistically significant decrease in odds of intention to enroll (OR = 0.832, p = 0.043).

Table 36: Stratified Analysis High Belief in God as Healer- Full Model, Ethics and Distrust

	High Belief in God as Healer				
Model	**Variable**	**OR**	**Lower**	**Upper**	**p-value**
11	Ethics	0.916	0.729	1.150	.449
High belief	Distrust	0.909	0.633	1.305	.603
	Worry	0.942	0.714	1.242	.670
	Rights	0.940	0.690	1.282	.698
	Age	**0.895**	**0.818**	**0.978**	**.015**
	Male	1			
	Female	0.497	0.082	3.005	.447
	Married or Equivalent	1			
	Not Married	0.937	0.183	4.809	.938
	High SES	1			
	Middle SES	2.540	0.316	20.401	.381
	Low SES	11.063	0.979	125.075	.052
	Racism (some to very much)	1			
	Racism (not much to none)	0.961	0.196	4.719	.961
	Ethics	**0.762**	**0.618**	**0.939**	**.011**
11a	Age	1.009	0.958	1.063	.735
	Male	1			
	Female	0.535	0.119	2.396	.414
	Married or Equivalent	1			
	Not Married	0.413	0.108	1.582	.197
High belief	High SES	1			
	Middle SES	0.514	0.134	1.966	.331
	Low SES	0.393	0.072	2.150	.281
	Racism (some to very much)	1			
	Racism (not much to none)	1.193	0.351	4.058	.778

	High Belief in God as Healer				
Model	**Variable**	**OR**	**Lower**	**Upper**	**p-value**
	Distrust	**0.832**	**0.695**	**0.994**	**.043**
	Age	1.016	0.966	1.069	.530
11b	Male	1			
	Female	0.921	0.225	3.776	.130
High belief	Married or Equivalent	1			
	Not Married	0.640	0.183	2.233	.484
	High SES	1			
	Middle SES	0.661	0.172	2.537	.547
	Low SES	0.560	0.106	2.964	.495
	Racism (some to very much)	1			
	Racism (not much to none)	0.894	0.281	2.850	.850

Models 11c and 11d suggested no statistically significant predictors of intention to enroll for participants with a high belief in God as healer.

Table 37: Stratified Analysis High Belief in God as Healer- Worry and Rights

	High Belief in God as Healer				
Model	**Variable**	**OR**	**Lower**	**Upper**	**p-value**
	Worry	0.884	0.762	1.026	.105
	Age	1.027	0.978	1.080	.286
High belief	Male	1			
11c	Female	0.909	0.225	3.673	.893
	Married or Equivalent	1			
	Not Married	0.592	0.169	2.078	.413
	High SES	1			
	Middle SES	0.568	0.153	2.107	.398
	Low SES	0.369	0.072	1.885	.231
	Racism (some to very much)	1			
	Racism (not much to none)	0.956	0.305	2.999	.938
	Rights	0.997	0.846	1.151	.970
11d	Age	1.025	0.976	1.076	.330
	Male	1			
	Female	0.940	0.246	3.584	.928
	Married or Equivalent	1			
	Not Married	0.695	0.205	2.357	.559
High belief	High SES	1			
	Middle SES	0.492	0.133	1,821	.288
	Low SES	0.365	0.071	1.868	.227
	Racism (some to very much)	1			
	Racism (not much to none)	0.933	0.300	2.895	.904

4.12 Summary Findings

The analyses in this chapter yielded no significant findings based on the original study hypotheses 1 and 2. They did however partially support hypotheses 3 and 4. Table 18 summarizes the findings.

Table 38: Summary Findings and Decisions

	Decision	Findings
Hypothesis 1 Participants with higher levels of racial identity will be more likely to express intention to enroll once attitudinal barriers and demographic controls are taken into account.	Unsupported	- Correlation analysis: Direction of association is consistent with hypothesis. The correlation is negative implying a higher level of racial identity correlates with a decreased odds of intention to enroll in a clinical trials - Correlation is weak and not statistically significant - Unadjusted regression model shows no significant relationship with intention to enroll
Hypothesis 2 Participants with stronger belief in the notion of God as healer will be less likely to express an intention to enroll in a therapeutic clinical trial once attitudinal barriers and demographic controls are taken into account.	Unsupported	- Correlation analysis: Direction of association is consistent with hypothesis. Correlation is negative implying stronger belief in God as healer correlates with decreased odds of intention to enroll - Correlation is not statistically significant - Unadjusted regression models show no significant relationship with intention to enroll

Hypothesis 3 The attitudinal barriers will be moderated by racial identity (centrality) such that there will be less influence on the intention to enroll for those with higher levels of racial identity	Unsupported	- No moderation effect on attitudinal barriers - Potential moderation effect of racial centrality on gender and intention to participate. Males with high centrality have significantly increased likelihood of intending to enroll in clinical trials compared with females
Hypothesis 4 The attitudinal barriers will be moderated by belief in God as healer such that there will be less influence on the intention to enroll for those with higher levels of belief.	Partially supported	- Participants with low levels of belief in God as a healer increasing age significantly lowers the likelihood of intending to participate (but not for those with high levels of belief) - - Belief in God as a Healer moderates the effect of a 'Concern about ethical conduct of investigators' scale as a predictor of intention to enroll as well as the distrust of medical establishment scale - For participants with low levels of belief, being in the low SES group significantly increased the odds of intention to enroll compared with high SES group

CHAPTER FIVE: DISCUSSION

5.1 Introduction

This chapter is a summary and discussion of the results of the study as presented by the findings for each study hypothesis. These findings are discussed in the context of the study population and with respect to the larger population of African American cancer patients and the place of this research in the existing literature. It also includes a discussion of the inevitable limitations of the study, as well as implications for theory, practice and future interventions and research.

5.2 Study Findings

The dissertation study was part of a larger intervention aimed to assess the effectiveness of a culturally targeted video. The video was designed to specifically address the attitudinal barriers, which serve as independent variables in this dissertation study. The four specific attitudinal barriers considered were, 1) fear and distrust of the medical establishment (doctors, scientists and the government); 2) concern about the ethical conduct of investigators; 3) fear of losing one's rights by signing a research informed consent; and 4) worry that investigators will treat poor Black patients, in particular, unfairly (e.g. the patient becomes a guinea pig because of their race or SES). In this study population three of the four attitudes were related to intention to enroll. The attitudinal barrier, fear of losing one's rights by signing a consent form, did not prove to be significantly associated with intention. Of the three attitudes that were related to intention, concern about ethical conduct of investigators appeared to be most important in the study population as evidenced by its significant relationship with the intention outcome in both adjusted and unadjusted models.

The ethical misconduct of scientists and researchers especially relative to African American populations in the US appears to resonate and be particularly salient to this study population. The US Public Health Services Study is not the only example of ethical misconduct and exploitation of African Americans in biomedical research. There is, however, discourse surrounding how relevant it still is to African Americans today, and the role it plays in their attitudes towards participation in clinical research. These data suggest that occurrences such as the Tuskegee study are still highly relevant, particularly for this population. Further, these data implore a full consideration of the role this and other such incidents may still play in the decision of African Americans cancer patients to consider a therapeutic clinical trial. Where the tendency today may be for some providers to want to avoid bringing up Tuskegee and other historical abuses of human subjects, these data suggest that it is in fact a subject that needs to be broached. For African American patients in particular, fostering an environment where such issues can be openly addressed may prove beneficial.

While each of the four attitudinal scales were proposed as distinctly related to intention to enroll, this study revealed that the associations were not clear cut. All of the items were highly correlated, causing some overlap in the scales. While each scale measured different dimensions of attitude and addressed different elements of a patients concern, some of the differences in the constructs were subtle. The initial correlation analysis revealed significant correlations between the scales such that one might caution against their use analytically in this manner. However it should be noted that the exploratory nature of this study necessitated such an examination. In the absence of a literature base to otherwise establish an acceptable level of correlation between these

variables, the nature of their interrelationships was important to understand in order to guide further study.

5.2.1 Relationship between attitudinal barriers and intention to enroll

Hypothesis 1 suggested that participants with higher levels of racial identity are more likely to express intention to enroll once attitudinal barriers and demographic controls are taken into account. In the unadjusted logistic model racial centrality was not significant, thus the first hypothesis was unsupported.

Hypothesis 2 suggested that participants with stronger belief in the notion of God as healer will be less likely to express an intention to enroll in a therapeutic clinical trial once attitudinal barriers and demographic controls are taken into account. Results did not support this second hypothesis.

Two scales were central to Hypotheses 1 and 2. While they did not seem to be important predictors of intention to enroll in a therapeutic clinical trial in this sample, this study was able to validate the centrality scale and the God as healer scale for the first time in this study population. This is important because it shows the distribution of these scales in a sample of newly diagnosed urban African American cancer patients, providing information on the utility of these instruments with diverse populations.

The data collected on religious denominations represented by the participants and their frequency of church attendance demonstrated the high religiosity of the sample. Thus, it is possible that there may not have been enough variability in the measure for religious belief to significantly detect an association with intention to enroll in a therapeutic trial with the sample size of 111. In Holt and colleagues' (2006) original

scale validation and development study, the population consisted of cancer patients along the "Bible belt", with past cancer diagnoses. The current study population consisted of relatively recently diagnosed patients, mostly in active treatment. Item means for the dissertation study population were higher on each of the 8 items on the instrument, when compared with the original population. Further, the overall mean score on the God as healer scale was relatively high for the study population: 37.29 (7.27) and certainly higher than the original population with 32.23 (3.96). Thus, if religiosity and belief in God as healer is high among all study participants, it may not be useful in distinguishing between those who were willing to enroll in a clinical trial and those who were not.

Similarly, responses on the Seller's centrality scale resulted in participants who were either highly central, or who had low centrality and not as many participants in between or with neutral responses. The total mean score was 52.83 (7.27) in this study population, which was in the range of previous studies. What resulted in this case was a population with a somewhat bimodal distribution on this variable and means, which clustered at the midpoint of the scales for several items. The item mean score was 3.39 (0.42), compared with estimates in other populations ranging from 5.20 (1.14) for African American students at a predominantly white university, to 5.28 (0.98) for African American students at an African American university. There is value in validating such a scale in a population of African American cancer patients as ethnic identity variables such as centrality have been shown for example to buffer certain protective risk factors, while enhancing protective factors to drug use (Brook & Pahl, 2005). Perhaps there may be value in exploring ways in which centrality might similarly work in such a unique

population as the cancer patients in this study relative to their attitudes and behavior towards clinical trials.

It is plausible that centrality could have an enhancement effect on intention in cancer patients who are highly central: in such a way as to enhance the altruistic appeal of trial participation. Alternately it may actually have a buffering effect, whereby participants who are more highly central may have more anti-establishment views and increasing levels of distrust research as they may identify more with experiences of racism and historical mistreatment of African Americans. This would result in a decreased intention to enroll. The responses on the centrality scale within this population suggest there could conceivably be two types of centrality operating within this population. Perhaps one of which deals with the connectedness participants feel to other Blacks (which is potentially more likely to lead to an enhancing effect on intention to enroll). Conversely there may be the dimension of centrality which addresses the extent to which being Black is a part of how they view themselves- and perhaps this dimension may be more related to a decreased intention to enroll or a buffering effect.

5.2.2 Moderation Effect

According to Cohen, Cohen and Aiken (2003) an interaction is thought of as an interplay among predictors that produces an effect on the outcome that is different from the sum of the effects of the individual predictors. As such when two predictors interact with one another, the regression of Y on one of the predictors is conditional on the value of the other predictor (Aiken and Aiken, 2003). This study hypothesized a role for racial identity (specifically racial centrality) and a specific belief in God as a healer, in the patient's expressed intention to enroll in a therapeutic clinical trial. It further

hypothesized a conditional relationship between the outcome variable of intention to enroll in a therapeutic clinical trial, and four attitudinal barriers to participation. The relationship between these independent variables and the outcome was proposed as conditional on two contextual variables, racial centrality and a belief in God as a healer. This conditional relationship referred specifically to a moderation effect, whereby the strength and direction of the relationship between the independent variable and dependent variable may be reduced as the value of the moderating variable increases, or vice versa. According to Baron and Kenny (1986) a moderator effect may also be said to occur where the direction of the correlation changes in the presence of another variable (Baron and Kenny, 1986).

Hypothesis 3 proposed that the attitudinal barriers will be moderated by racial identity such that there will be less influence on the intention to enroll for those with higher levels of racial identity. This hypothesis was only partially supported. There was a potential moderation effect of racial centrality on gender and intention to participate but no moderation effect on the attitudinal barriers as hypothesized. Females with high centrality had significantly lower odds of intention to enroll in clinical trials than did males. This was a surprising finding as the literature shows women are more likely to participate in clinical trials than men under most conditions. In this case it could be that the altruism factor actually does play a role for Black men of high centrality, as previously note. Whereas females with high racial centrality could perhaps be more impacted by the fear of exploitation that may come with clinical trials participation.

An anecdotal qualitative response by one male study participant stated " There is such a thing as machismo for Black men too, you know….maybe even more so than for

Hispanics even though everyone thinks that it's more important for them. I'd argue it's more important for Black men…we have to do things to preserve the race…."

Hypothesis 4 suggested that attitudinal barriers will be moderated by belief in God as healer such that there will be less influence on the intention to enroll for those with higher levels of belief. This hypothesis was partially supported. A clear and direct moderation effect was not seen as hypothesized however the stratified analyses and the significance of interaction terms in the adjusted models suggested there is some level of effect modification occurring. This effect however was difficult to isolate potentially due to the correlation between the four attitudinal variables.

A belief in God as a Healer appeared to consistently moderate the effect of 'Concern about ethical conduct of investigators' as a predictor of intention to enroll but no other attitudinal barriers. Specifically, for those with a stronger belief in God as healer, lower scores on the ethics scale predicted a greater intention to enroll than those with higher scores on the ethics scale. The relationship was weaker for those with less strong belief in God as healer, but still remained in the same direction. It may be that if one believes that God is ultimately the healer and has strong concerns about investigators conducting their research in an ethical manner, there may be no impetus to enroll in a trial or to consider something experimental.

In the stratified analyses, among participants with low levels of belief in God as a healer there was evidence that increasing age lowered the odds of intention to enroll in a clinical trial. This may be a true age effect, consistent with the literature that shows that on the average, clinical trial participants tend to be younger. Within the dissertation study population, clinical trial participation may decrease in likelihood with age due to

the distrust of clinical research that is consistent with older participants having more fears and concerns of trials for historical reasons.

Further, low levels of belief in God as a healer also showed that being in the low SES group significantly increased the odds of intention to enroll compared with the high SES group by over 10-fold, though this association was marginal due to large confidence intervals. This would be consistent with a theory of disenfranchisement for those of lower SES. It could be argued, for instance, that individuals in a higher SES may feel more empowered in their health decision-making and are more apt to make decisions of their own volition, where members of a lower SES group may make that same decision out of a feeling of vulnerability. That is, compared with those in a high SES, the lower SES group may include individuals who feel they have less control over their health outcomes and therefore be more likely to 'subject themselves' to research, or "the system" if they feel they have no choice. This also could be consistent with study findings that show that lower income populations are more likely to participate in research due to a lack of other treatment options. These individuals elect to enroll in clinical trials to access the basic health care they lack.

5.3 Implications of Findings

Both religious belief in God as healer and racial centrality represent two variables which may help to capture variability among African American populations that can then be the focus for affecting health outcomes, in this case intentions to enroll in clinical trials.

There is limited research examining the relationships of socio-cultural factors among Black cancer patients and factors surrounding their attitudes toward and intentions to

enroll in clinical trials. Subsequently there are few culturally targeted interventions, which are focused on impacting these attitudes in order to increase the likelihood of trial participation for this subgroup.

While studies have certainly found positive associations with factors of religious involvement acting as mediators and moderators of health outcomes, the literature is also replete with negative or null associations. The Belief in God as healer scale and measuring this aspect of religious influence on health outcome looks at an aspect of the religion-health connection which arguably stands separate from that usually associated with social support (Holt et. al, 2009). Where proposed mechanisms for the religion-health connection tend to address intrapersonal factors (e.g. coping mechanisms) and interpersonal factors (e.g. social support and social influence), this concept seems to address what are referred to as faith based factors (Holt, Lewellyn et al, 2005). That is, factors that enable individuals to attach meaning to their illness and most important in this context, factors related to their spiritual health locus of control (Holt, Lewellyn et al, 2005).

A belief in God as healer may be consistent with a cancer patient feeling they are "giving the problem to God" (Holt and McClure, 2006). The findings of this study perhaps highlight this aspect of coping with cancer and suggest the role of an individual's control beliefs in the clinical trials decision-making process; one which is perhaps mediated by a belief in God as a healer. It could be that the extent to which a patient believes they are in control of their disease directly relates to their likelihood to participate in a trial.

In the US, the focus on eliminating health disparities has translated into an increased focus of research on race-specific or targeted messaging. Funding continues to be channeled and earmarked for 'culturally appropriate and specific' interventions. Thus issues of race, and racial identity are inextricably linked to the approach taken in designing and even evaluating such interventions. Race, gender and SES represent un-modifiable variables that are related to trial participation in this study.

What this dissertation study and others have suggested is that given the relative importance of un-modifiable demographic factors such as gender perhaps an alternative approach to intervention is a focus on variables which are, at least conceptually related to these. The two constructs - belief in God as healer and racial centrality - have been shown to moderate the relationship between gender, race and income (SES) and their ability to influence the intention to enroll. This may posit an alternative target for intervention and an indirect way to impact the demographic factors which make a difference in outcome.

Consideration of moderators in intervention design

Linden and colleagues' qualitative research revealed that participants in their study expressed a mistrust in recruitment into clinical trials, and they believed that culturally sensitive recruitment efforts would be more effective in recruiting African American patients (Linden, Hannah M. M. et al., 2007a). Participants in the study stated a higher likelihood of participating if the church was somehow involved in their decision, affirming they would feel more trusting and more likely view the clinical trial as more legitimate if someone from the church presented it. This suggests that where a negative attitude towards participation exists, religious factors may have a moderating effect.

Intervention designs tend to focus on a set of changeable characteristics in the target population and administer a treatment, the effect of which is intended to shift the target characteristic in the same direction for everyone. However this dissertation shows that the impact may differ for different subgroups based on different levels of factors such as religion or racial identity. That is, to establish a moderation of intervention response-determining characteristics of those who respond and those who do not. It also implies that targeting interventions for trial accrual based on two characteristics or social constructs which are thought to be particularly salient for African American populations may not be as cost effective unless a measure of the strength of belief or strength of identity can first be established. Further, together with the literature, this seems to make the case that down the line it is more efficient to focus on religious belief through use of the church or religious figures as a way to impact race and income based differences.

Studies across disciplines recognize that oftentimes when health interventions fail to show a significant impact on an individual level or community level, this can be attributed to a failure to acknowledge cultural norms and a lack of cultural specificity. Understanding the key cultural constructs and the manner in which they operate within a population and a focus on cultural congruency are both essential in designing cost-effective interventions.

5.5 Implications for theory

The Theory of Planned Behavior was used to inform the theoretical framework for this study. As postulated by the theory, behavior is mediated directly by intention, and indirectly through normative beliefs and attitudes, which impact intention (Azjen & Fishbein, 1975). The cross-sectional nature of this study renders it impossible to assess

whether an intention to enroll in a trial ever translates into actual trial enrollment, thus utility of the theoretical framework in this context is limited. It is through the TPB that a sense of directionality in the proposed relationships between the constructs was inferred such that attitudes preceded the intention, which hypothetically leads to engaging in the desired behavior, enrolling in a therapeutic trial. It should be noted that among this study population, intentions may be less tied to behavior (actual trial enrollment) due to the serious nature of the illness, which may make it difficult to make decisions. This study also highlights a need for further theory development, with a focus on culturally relevant health behavior theory that accounts for important moderating variables among population subgroups.

5.6 Limitations

One limitation of this study is the selection bias inherent in the study population and the sampling methodology. Potential participants were targeted in a purposive manner and the study sample consisted of patients who self-selected to participate in this study. This represents a somewhat biased sample given these individuals were likely overall less resistant to research as indicated by their willingness to participate in this study. Thus the true relationship between the attitudes, the mediators and the intention to enroll may be obscured by the biased sample.

Further, all of the participants in this study were cancer patients; therefore, it is likely their attitudes towards therapeutic trials were somewhat skewed given the nature of their illness. Individuals faced with a terminal illness have more fatalistic attitudes or are more aware of their own mortality and consequently their responses to the questions about religion may represent a very skewed sample. Asking people who are already sick

how they feel about what is essentially another treatment option makes it challenging to tease out the true nature of the relationships between these attitudes and intention.

Another limitation in this study was the validity of the instrument used to assess attitudes. While each of the scales by definition had at a minimum, an 'acceptable' alpha reliability, the instrument could certainly be more refined. It may be that these alphas were in fact too low and contribute in part to the muted effect size in the study. However, the argument can be made that for newly emerging constructs such as those under study, alphas upward of .8 may be unrealistic. The items are brief and tested with a unique population. Further, the concepts are emergent and still under development; they measure concepts that are not as concrete as some psychological constructs which may more appropriately be held to these rigorous standards of scale reliability.

When the final regression models are considered, the study was only able to achieve moderate power (68%). For this reason it is possible that some of the analyses were underpowered and thus the conclusions drawn citing a lack of relationship between hypothesized variables should be considered in light of this constraint (i.e Type 2 Error).

Also worth noting is the questionable validity of the item assessing the attitudinal barrier that is the concern about losing one's autonomy after signing a consent form. Assessing issues related to consent problems, when one has to actually consent the participants in order to ask them about consent presents a unique challenge. Responses to the items on the concern about losing autonomy after signing a research consent, scale ought to be interpreted with caution. Prior to administering the study questionnaire, I conducted a full informed consent process for the study, as required. As these questions were administered, it was not uncommon for participants to preface their response with

"well, I now know coz [sic] you said earlier, that I can stop at any time I want to". Thus it is difficult to know the extent to which these responses were actually due to their level of knowledge versus what they understood from the study consent process.

5.7 Threats to Validity

Being a non-experimental design, this dissertation uses cross-sectional data which limits the ability to determine the direction of the relationships hypothesized. Those seen in this sample can only determine that there is an association. It is difficult to determine whether intention to enroll influences attitudes, racial identity, and religious beliefs or whether the predictor variables affect intention to enroll. However the results can provide support for potential causal associations and direct future research.

There are likely multiple other factors that play into the formation of attitudes towards clinical trials that cannot be measured, but may become evident in qualitative interviews. There is the potential that other plausible or alternative explanations exist, presenting a threat to the internal validity of this study. In the absence of an experimental design for this study, the results of this study have to be interpreted with caution and with an understanding that they may simply inform future research. Further, it is expected that there was a level of measurement error in assessing the study variables within the population particularly on the newly developed scales.

It is also important to note that these results may not be generalizeable to African American populations in other locales within the United States based on the unique diversity among African Americans in the District of Columbia metro area. These results may generalize to metropolitan areas with similar diversity among the Black population

however, the unique demographic of the area in which this study was conducted should be noted.

In addition, patients enrolled were at various stages of treatment and yet this study asked questions dealing specifically with the intention to enroll on a therapeutic trial. It is therefore important to note that results and attitudes might vary depending on the type of clinical trial in question.

Given the nature of the questions asked in the structured interview, there may be a social desirability bias which may result in the participant not fully disclosing their true feelings on a response, or alternately may exaggerate it. Finally, as noted by Rajakumar (2009), a challenge of studying trust and attitudes surrounding mistrust, is that those with high levels of distrust may not participate (Rajakumar, 2009), rendering the range of trust assessed, potentially more limited than in the general population (Rajakumar, 2009).

When the final collection of variables in the regression models were considered, the relationships may not have been strong enough to detect the originally calculated effect sizes in such a small population. The result of this would be an actual power that was lower than that originally calculated.

Finally, in assessing the role of racial identity among this population, there are additional items that would have added some valuable data to for context . For instance, more data should have been collected on the survey instrument to assess the extent to which individuals had experienced racism or perceived racism.

5.8 Future Research Directions

The most obvious and immediate direction for future research is to address the limitations outlined in the previous section. A refinement of the instruments to be used to

assess the attitudinal barriers will be the first step as an accurate measurement will allow for more sound conclusions to be drawn from the study. This may in effect be easily achieved by adding more items to the existing instruments as their brevity impacts the reliability. The ability to further pilot test the instrument and then take the assessments in a separate but similar population would aid in refining the initial findings from this population.

Further, it would seem that this line of inquiry could benefit from further qualitative analysis and the exploration of a traditional mixed methods approach to this study. Either using the quantitative findings to inform further qualitative inquiry or using qualitative findings to inform additional quantitative methodology. For this study, I followed up with qualitative interviews on n= 38 participants. My first step will be to analyze the transcripts from interviews that were conducted with participants of this dissertation study. It is likely this might add context to some of the findings and help with further hypothesis development.

The literature does identify other attitudinal barriers thought to affect the willingness of minority patients to participate in research. An assessment of these other attitudes among this population would help to establish their relative importance. It could be that there are some attitudes which are more salient for this population due to its unique make-up. Of note is the lack of an assessment of the role that knowledge and awareness of clinical trials; which was not related to the study hypotheses and so was not considered. It may be informative to assess this and then attempt to adjust for it in an explanatory model.

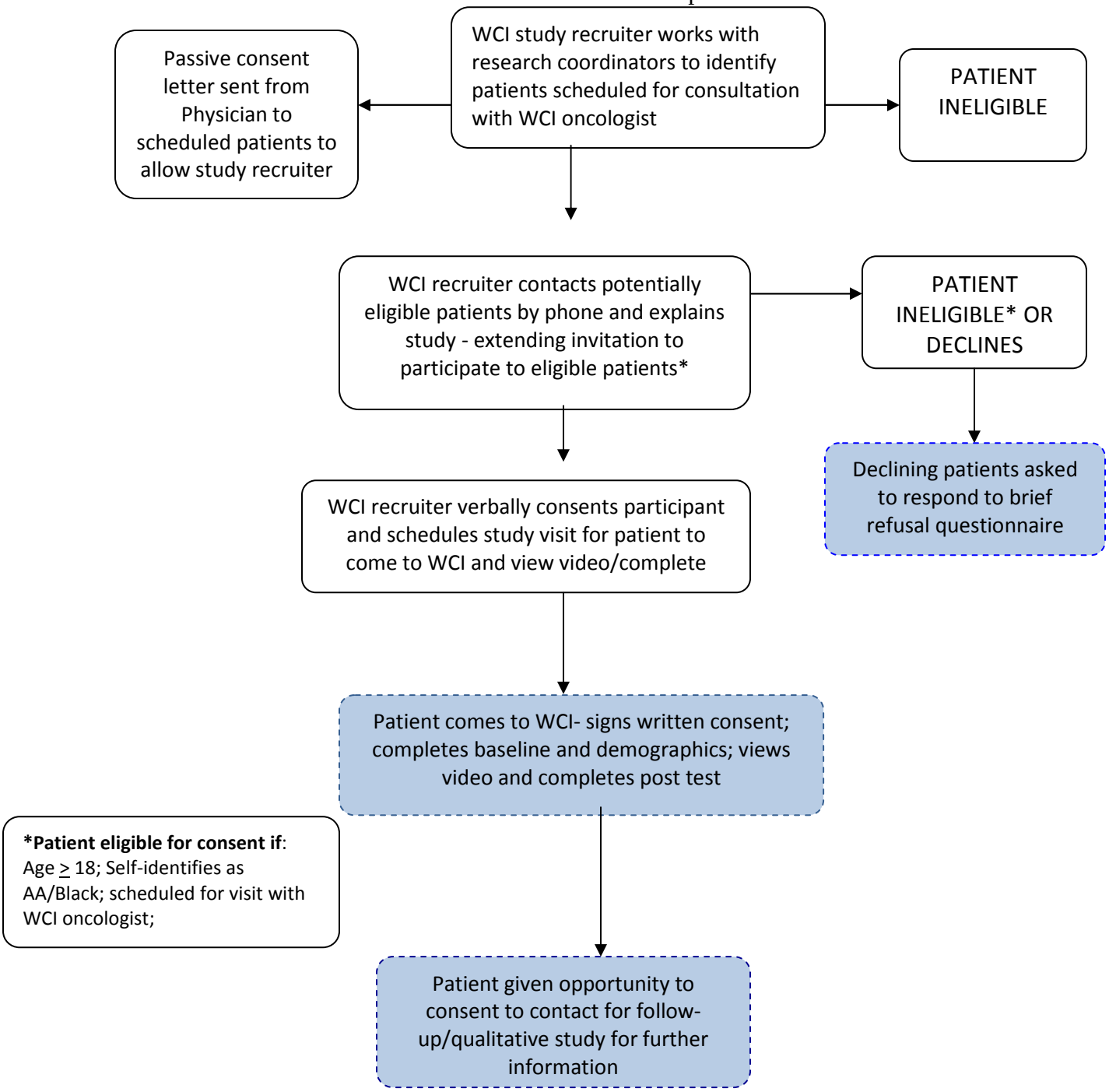
This research provides additional guidance for future inquiry attempting to better characterize minority accrual to clinical trials and development of targeted interventions based on religion and other potentially race-specific constructs. The literature is replete with guidance on how to use or incorporate religion and the push towards cultural competency. What this dissertation suggests is that these social constructs which are frequently the source of focus for many culturally-based interventions should be first characterized fully within the target population.

5.9 Summary

The aim of this study was to understand the relationship between attitudinal factors that present barriers to clinical trial participation and the subsequent intention to enroll in therapeutic clinical trials; and to understand the contribution of racial identity and religious belief to the intention to enroll in therapeutic clinical trials. Data collected from this study population suggested that all of the attitudinal barriers cited in the clinical trials accrual literature may not necessarily apply to this population, rather demographic factors ultimately make more of a difference. The data suggested that the concern about ethical conduct of investigators was the only attitude of the four proposed, which was consistently a significant predictor of intention to enroll in both adjusted and unadjusted models. African American populations in particular have deep-rooted historical reasons that need to be accounted for in the development of any intervention, educational or otherwise (Gamble, V. N., 1997a; Heintzelman, C. A., 2003a). This study seems to suggest that we still need to focus on the role that historical abuses play in influencing the way African American patients feel about clinical research and the extent to which it may influence their attitudes.

Appendix A Flow Chart of Study Activities: Patient Recruitment for Parent Study and Dissertation Study

-Dashed line and filled text box refers to dissertation components



Appendix B WCI IRB Approval

Appendix C Quantitative Study Consent

Informed Consent for Clinical Research

MedStar Research Institute/Georgetown University Medical Center

INSTITUTION: Washington Cancer Institute at Washington Hospital Center

INTRODUCTION

You are invited to consider participating in this study. The study is called "Today's Truth: Research Brings Hope". Please take whatever time you need to discuss the study with your family and friends, or anyone else you wish to. It is important that you read and understand several things that apply to all who take part in our studies:

(a) Taking part in the study is entirely voluntary; the decision to participate, or not to participate, is yours.

(b) Personal benefit to you may or may not result from taking part in the study, but we hope you will benefit from the information it will provide. Knowledge may be gained from your participation that will benefit others.

(c) You may decline to participate or you may withdraw from the study at any time without loss of any benefits to which you are entitled and without jeopardizing your access to care, treatment and health services unrelated to the research.

The purpose and nature of the study, possible benefits, risks, and discomforts, other options, your rights as a participant, and other information about the study are discussed below. Any new information discovered, at any time during the research, which might affect your decision to participate or remain in the study will be provided to you. You are urged to ask any questions you have about this study with the staff members who explain it to you. You are urged to take whatever time you need to discuss the study with your physician, hospital personnel and your family and friends. The decision to participate or not is yours. If you decide to participate, please sign and date where indicated at the end of this form. The investigator (person in charge of this research study) is Sandra M. Swain, MD.

The research is being sponsored by the National Institute of Health. The National Institute of Health is called the sponsor and the MedStar Research Institute, is being paid by the National Institute of Health, to conduct this study with Sandra M. Swain, MD as the primary investigator.

WHY IS THE STUDY BEING DONE?

You are being asked to participate in this study because we would like to learn how you feel about African Americans taking part in cancer treatment research studies, also known as clinical trials.

The purpose of this study is to provide information to African American cancer patients, which may increase their likelihood to participate in a treatment trial. The video designed for use in this study may be shared with other cancer researchers, including National Cancer Institute (NCI) cooperative groups.
This research is being done because there are not enough African Americans who take part in cancer clinical trials. It is important that enough African Americans participate in cancer trials to allow discovery of possible differences of treatment effect by race/ethnicity based on biological, social or cultural factors related to race.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

People in the study are referred to as participants.

About 125participants will be in this study at the Washington Cancer Institute, Washington Hospital Center only.

WHAT IS INVOLVED IN THE STUDY?

If you agree (consent) to participate in this study, a study interviewer will ask you several questions about your attitude about taking part in a clinical trial. Next, you will view a video that was made just for this study, and then the interviewer will ask you the same questions again.

HOW LONG WILL I BE IN THE STUDY?

We think that you will be in the study for about one hour or less. You can stop taking part at any time.

WHAT ARE THE RISKS OF THE STUDY?

There should not be any physical risks as this is not a treatment study; however, talking about attitudes toward clinical research may cause some anxiety for certain people. If you have questions about the study call the investigator at 202-877-8839.

ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may or may not be direct benefit to you.

We cannot promise that you will experience benefits from participating in this study. We do hope that you will benefit from receipt of information in this study. We also hope the information learned from this study will benefit others in the future.

WHAT OTHER OPTIONS ARE THERE?

Instead of being in this study, you have the option not to participate.

WHAT ABOUT CONFIDENTIALITY?

You will not be identified in any reports or publications resulting from this study. In addition to the researchers and research institution(s) conducting this study, organizations that may request to inspect and/or copy your research records for quality assurance, data analysis and other research related and operational or administrative purposes, include groups such as:

The National Institute of Health, MedStar Health Research Institute, MedStar Health Research Institute-Georgetown University Oncology Institutional Review Board (IRB), federal research oversight agencies.

DATA SECURITY

Information about your participation in this study is stored in a research computer that is protected from unauthorized disclosure, tampering, or damage. All data will be stored in a password protected computer that is kept locked. The only individuals allowed to access any data are the investigators associated with this study.

WHAT ARE THE COSTS?

There will be no cost to take part in this study.

PAYMENT FOR PARTICIPATION

Study participants who complete the study will receive a $25 gift card as thanks for their time and participation. They may also receive a pass to cover the cost of parking when they come to the Washington Cancer Institute.

You should not expect anyone to pay you for pain, worry, lost income, or non-medical care costs that occur from taking part in this research study.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part in or leave the study at any time.

We will tell you about new information that may affect your health, welfare, or participation in this study.

By signing this form you do not lose any of your legal rights.

NEW FINDINGS

Throughout the study, we will tell you about new information we receive about treatments that may be appropriate for you, about the experimental treatments under investigation in this study, and any information that may affect your interest in remaining in the study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury, any problems, unexpected physical or psychological discomforts, or if you think that something unusual or unexpected is happening, call Sandra M. Swain, MD at 202-877-8839 or the Oncology fellow on-call at 202-877-6751. Be sure to inform the physician of your participation in this study.

For questions about your rights as a research participant, contact the MedStar Health Research Institute-Georgetown University Oncology Institutional Review Board at:

Address: Georgetown University Medical Center
3900 Reservoir Road, N.W.
SW104 Med-Dent
Washington, D.C. 20057

Telephone: (202) 687-1506

Withdrawal by investigator, physician, or sponsor

The investigators, physicians or sponsors may stop the study or take you out of the study at any time should they judge that it is in your best interest to do so, if you experience a study-related injury, or if you do not comply with the study plan. They may remove you from the study for various other administrative reasons. They can do this without your consent.

After you have completed the study questions, the investigators participate or you may withdraw from the study at any time without loss of any benefits to which you are entitled and without jeopardizing your access to care, treatment and health services unrelated to the research.

The purpose and nature of the study, possible benefits, risks, and discomforts, other options, your rights as a participant, and other information about the study are discussed below. Any new information discovered, at any time during the research, which might affect your decision to participate or remain in the study will be provided to you. You are urged to ask any questions you have about this study with the staff members who explain it to you. You are urged to take whatever time you need to discuss the study with your physician, hospital personnel and your family and friends. The decision to participate or not is yours. If you decide to participate, please sign and date where indicated at the end of this form. The investigator (person in charge of this research study) is Sandra M. Swain, MD.

The research is being sponsored by the National Institute of Health. The National Institute of Health is called the sponsor and the MedStar Research Institute, is being paid by the National Institute of Health, to conduct this study with Sandra M. Swain, MD as the primary investigator.

WHY IS THE STUDY BEING DONE?

You are being asked to participate in this study because we would like to learn how you feel about African Americans taking part in cancer treatment research studies, also known as clinical trials.

The purpose of this study is to provide information to African American cancer patients, which may increase their likelihood to participate in a treatment trial. The video designed for use in this study may be shared with other cancer researchers, including National Cancer Institute (NCI) cooperative groups.
This research is being done because there are not enough African Americans who take part in cancer clinical trials. It is important that enough African Americans participate in cancer trials to allow discovery of possible differences of treatment effect by race/ethnicity based on biological, social or cultural factors related to race.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

People in the study are referred to as participants.

About 125participants will be in this study at the Washington Cancer Institute, Washington Hospital Center only.

WHAT IS INVOLVED IN THE STUDY?

If you agree (consent) to participate in this study, a study interviewer will ask you several questions about your attitude about taking part in a clinical trial. Next, you will view a video that was made just for this study, and then the interviewer will ask you the same questions again.

HOW LONG WILL I BE IN THE STUDY?

We think that you will be in the study for about one hour or less. You can stop taking part at any time.

WHAT ARE THE RISKS OF THE STUDY?

There should not be any physical risks as this is not a treatment study; however, talking about attitudes toward clinical research may cause some anxiety for certain people. If you have questions about the study call the investigator at 202-877-8839.

ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may or may not be direct benefit to you.

We cannot promise that you will experience benefits from participating in this study. We do hope that you will benefit from receipt of information in this study. We also hope the information learned from this study will benefit others in the future.

WHAT OTHER OPTIONS ARE THERE?

Instead of being in this study, you have the option not to participate.

WHAT ABOUT CONFIDENTIALITY?

You will not be identified in any reports or publications resulting from this study. In addition to the researchers and research institution(s) conducting this study, organizations that may request to inspect and/or copy your research records for quality assurance, data analysis and other research related and operational or administrative purposes, include groups such as:

The National Institute of Health, MedStar Health Research Institute, MedStar Health Research Institute-Georgetown University Oncology Institutional Review Board (IRB), federal research oversight agencies.

DATA SECURITY

Information about your participation in this study is stored in a research computer that is protected from unauthorized disclosure, tampering, or damage. All data will be stored in a

password protected computer that is kept locked. The only individuals allowed to access any data are the investigators associated with this study.

WHAT ARE THE COSTS?

There will be no cost to take part in this study.

PAYMENT FOR PARTICIPATION

Study participants who complete the study will receive a $25 gift card as thanks for their time and participation. They may also receive a pass to cover the cost of parking when they come to the Washington Cancer Institute.

You should not expect anyone to pay you for pain, worry, lost income, or non-medical care costs that occur from taking part in this research study.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part in or leave the study at any time.

We will tell you about new information that may affect your health, welfare, or participation in this study.

By signing this form you do not lose any of your legal rights.

NEW FINDINGS

Throughout the study, we will tell you about new information we receive about treatments that may be appropriate for you, about the experimental treatments under investigation in this study, and any information that may affect your interest in remaining in the study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury, any problems, unexpected physical or psychological discomforts, or if you think that something unusual or unexpected is happening, call Sandra M. Swain, MD at 202-877-8839 or the Oncology fellow on-call at 202-877-6751. Be sure to inform the physician of your participation in this study.

For questions about your rights as a research participant, contact the MedStar Health Research Institute-Georgetown University Oncology Institutional Review Board at:

Address: Georgetown University Medical Center Telephone: (202) 687-1506
3900 Reservoir Road, N.W.
SW104 Med-Dent
Washington, D.C. 20057

Withdrawal by investigator, physician, or sponsor

The investigators, physicians or sponsors may stop the study or take you out of the study at any time should they judge that it is in your best interest to do so, if you experience a study-related injury, or if you do not comply with the study plan. They may remove you from the study for various other administrative reasons. They can do this without your consent.

After you have completed the study questions, the investigators want to give you an opportunity to provide them with more information about your thoughts and attitudes towards clinical trials. This will give you a chance to talk in more detail, in a follow-up telephone interview other thoughts that came to mind from the questions you were asked for this study. It will also give the investigators a chance to find out if there is anything additional you want them to know about how African Americans feel about participating in clinical trials.
No matter what you decide to do about this follow-up interview, it will not affect your care or your participation in any other study including this main study. If you have any questions, please talk to the interviewer or investigator, or call the Institutional Review Board at 202-687-1506.

I willingly consent to allow the investigators to contact me for a follow-up study to discuss in more detail the way African Americans think and feel about clinical trials.

↑ **YES** † **NO**

Initials	**Date**

RESEARCHER'S STATEMENT

I have fully explained this study to the subject. As a representative of this study, I have explained the purpose, the procedures, the benefits and risks that are involved in this research study. Any questions that have been raised have been answered to the individual's satisfaction.

_____ _____ _____
Signature of person obtaining the consent Print Name of Person Date

I, the undersigned, have been informed about this study's purpose, procedures, possible benefits and risks, and I have received a copy of this consent. I have been given the opportunity to ask questions before I sign, and I have been told that I can ask other

questions at any time. I voluntarily agree to participate in this study. I am free to withdraw from the study at any time without need to justify my decision. This withdrawal will not in any way affect my future treatment or medical management and I will not lose any benefits to which I am otherwise entitled. I agree to cooperate with Sandra M. Swain, MD and the research staff and to inform them immediately if I experience any unexpected or unusual symptoms.

_____ _____

_____

Signature of Subject Print Name of Subject Date

Appendix D Qualitative Study Consent

Informed Consent for Clinical Research

MedStar Research Institute/Georgetown University Medical Center

INSTITUTION: Washington Cancer Institute at Washington Hospital Center

INTRODUCTION

You are invited to consider participating in this follow-up interview for the study called "Today's Truth: Research Brings Hope". Please take whatever time you need to discuss the study with your family and friends, or anyone else you wish to. It is important that you read and understand several things that apply to all who take part in our studies:

(a) Taking part in the study is entirely voluntary; the decision to participate, or not to participate, is yours.

(b) Personal benefit to you may or may not result from taking part in the study, but we hope you will benefit from the information it will provide. Knowledge may be gained from your participation that will benefit others.

(c) You may decline to participate or you may withdraw from the study at any time without loss of any benefits to which you are entitled and without jeopardizing your access to care, treatment and health services unrelated to the research.

The purpose and nature of the study, possible benefits, risks, and discomforts, other options, your rights as a participant, and other information about the study are discussed below. Any new information discovered, at any time during the research, which might affect your decision to participate or remain in the study will be provided to you. You are urged to ask any questions you have about this study with the staff members who explain it to you. You are urged to take whatever time you need to discuss the study with your physician, hospital personnel and your family and friends. The decision to participate or not is yours. If you decide to participate, please sign and date where indicated at the end of this form. The investigator (person in charge of this research study) is Sandra M. Swain, MD.

The research is being sponsored by the National Institute of Health. The National Institute of Health is called the sponsor and the MedStar Research Institute, is being paid by the National Institute of Health, to conduct this study with Sandra M. Swain, MD as the primary investigator.

WHY IS THE STUDY BEING DONE?

You are being asked to participate in this follow up study because we would like to learn how you feel about African Americans taking part in cancer treatment research studies, also known as clinical trials, now that you have viewed our video about clinical trials.

The purpose of this study is to see how your attitudes toward clinical trials have been affected after watching the video. We also want to know what you think about the role of race, racial identity, and religion in making decisions about cancer treatment. The questions designed for use in this study may be shared with other cancer researchers, including National Cancer Institute (NCI) cooperative groups. None of the information shared along with this will identify you as an individual. This research is being done because there are not enough African Americans who take part in cancer clinical trials. It is important to know other factors that influence the decision to participate or not.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

People in the study are referred to as participants.

About 125participants will be in this study at the Washington Cancer Institute, Washington Hospital Center only.

WHAT IS INVOLVED IN THE STUDY?

If you agree (consent) to participate in this study, a study interviewer will call you at the time you request and ask you several questions about your attitude now about taking part in a clinical trial. Next, you will be asked some questions about how you think race, racial identity, and religion may or may not influence your treatment decisions and those of other African Americans.

HOW LONG WILL I BE IN THE STUDY?

We think that this follow-up study will take about one hour or less. You can talk to the interviewer about your answers for as much time or as little time as you would like. You can stop taking part at any time.

WHAT ARE THE RISKS OF THE STUDY?

There should not be any physical risks as this is not a treatment study; however, talking about attitudes toward clinical research may cause some anxiety for certain people. If you have questions about the study call the investigator at 202-877-8839.

ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this follow-up interview, there may or may not be direct benefit to you.

We cannot promise that you will experience benefits from participating in this interview. We do hope that you will benefit from receipt of information and sharing

your thoughts. We also hope the information learned from this study will benefit others in the future.

WHAT OTHER OPTIONS ARE THERE?

Instead of being in this study and completing this interview, you have the option not to participate.

WHAT ABOUT CONFIDENTIALITY?

You will not be identified in any reports or publications resulting from this study. In addition to the researchers and research institution(s) conducting this study, organizations that may request to inspect and/or copy your research records for quality assurance, data analysis and other research related and operational or administrative purposes, include groups such as:

The National Institute of Health, MedStar Health Research Institute, MedStar Health Research Institute-Georgetown University Oncology Institutional Review Board (IRB), federal research oversight agencies.

DATA SECURITY

Information about your participation in this study is stored in a research computer that is protected from unauthorized disclosure, tampering, or damage. All data will be stored in a password protected computer that is kept locked. The only individuals allowed to access any data are the investigators associated with this study.

WHAT ARE THE COSTS?

There will be no cost to take part in this study.

PAYMENT FOR PARTICIPATION

There will be no payment for participation in this study.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Taking part in this study and completing the interview is voluntary. You may choose not to take part in or stop the interview at any time.
We will tell you about new information that may affect your health, welfare, or participation in this study.
By signing this form you do not lose any of your legal rights.

NEW FINDINGS

Throughout the study, we will tell you about new information we receive about treatments that may be appropriate for you, about the experimental treatments under

investigation in this study, and any information that may affect your interest in remaining in the study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury, any problems, unexpected physical or psychological discomforts, or if you think that something unusual or unexpected is happening, call Sandra M. Swain, MD at 202-877-8839 or the Oncology fellow on-call at 202-877-6751. Be sure to inform the physician of your participation in this study.

For questions about your rights as a research participant, contact the MedStar Health Research Institute-Georgetown University Oncology Institutional Review Board at:

Address: Georgetown University Medical Center
3900 Reservoir Road, N.W.
SW104 Med-Dent
Washington, D.C. 20057

Telephone: (202) 687-1506

Withdrawal by investigator, physician, or sponsor

The investigators, physicians or sponsors may stop the study or take you out of the study at any time should they judge that it is in your best interest to do so, if you experience a study-related injury, or if you do not comply with the study plan. They may remove you from the study for various other administrative reasons. They can do this without your consent.

RESEARCHER'S STATEMENT

I have fully explained this study to the subject. As a representative of this study, I have explained the purpose, the procedures, the benefits and risks that are involved in this research study. Any questions that have been raised have been answered to the individual's satisfaction.

_____	_____	_____
Signature of person obtaining the consent	Print Name of Person	Date

I, the undersigned, have been informed about this study's purpose, procedures, possible benefits and risks, and I have received a copy of this consent. I have been given the opportunity to ask questions before I sign, and I have been told that I can ask other questions at any time. I voluntarily agree to participate in this study. I am free to withdraw from the study at any time without need to justify my decision. This withdrawal will not in any way affect my future treatment or medical management and I will not lose any benefits to which I am otherwise entitled. I agree to cooperate with Sandra M. Swain, MD and the research staff and to inform them immediately if I experience any unexpected or unusual symptoms.

_____ _____

_____

Signature of Subject Print Name of Subject Date

Appendix E Participant Demographic Information

MR#: _____

Last Name: _____

First Name: _____

Middle Initial (if pt doesn't have a MI, then a dash): ____

DOB: _ _/ _ _/ _ _ _ _

Self Identified racial/ethnic background?

1 = African American
2 = Black
3 = African Ancestry
4 = Caribbean or West Indian Ancestry
5 = Other: _____
997 = REF
998 = DK

Were you born in the United States?

1 = YES

If U.S. Region of country at birth:

- West Coast
- East Coast
- South
- Midwest/Central

2 = NO

If Non US born- Country of Birth:

_____

If Non-US, length of time lived in US? _____

Were your parents born in the United States?

1 = YES

If U.S. Region of country at birth:

- West Coast
- East Coast
- South
- Midwest/Central

2 = NO

If Non. US born- Country of Birth:

_____

If Non US born- Main language(s) spoken at home: (if more than one, list all)
_____

Marital Status

- Never Married
- Married
- Marriage equivalent/Living with a partner
- Widowed
- Separated/Divorced

Number of Children

- None
- 1 or more

Education

- < High School
- GED
- High school graduate
- Some college or technical school
- College graduate

Religious Faith

- Baptist/Freewill Baptist
- Catholic
- Episcopalian
- Jehovah's Witness
- Jewish
- Methodist
- Muslim
- Pentecostal/Holiness
- Presbyterian
- Seventh Day Adventist
- Other?

About how many times **a month** do you usually attend religious services?

___ 0 ___ 1-3 ___ 4 or more

Household Income

- <$8,000
- $8,000 - $11,999
- $12,000 - $15,999
- $16,000 - $19,999
- $20,000 - $29,999
- $30,000 - $39,999
- $40,000- $49,999
- $50,000-$74,999
- >$75,000

Family history of any cancer? Y/N

Appendix F Survey of attitudes about clinical trial participation

Barriers and Subscales

1. Fear and distrust of the medical establishment: Questions 1-5
2. Concern about the ethical conduct of investigators: Questions6-10
3. Fear of losing one's rights by signing a research informed consent document Questions 11-15
4. Worry that investigators will treat poor or minority patients unfairly Questions 16- 20
5. Loss of privacy Questions 21-25
6. Lack of knowledge and awareness of clinical trials Questions 26-30
7. Racial Identity Seller's Centrality Scale Questions 31-38
8. Religious beliefs: "God as healer" Questions 40-48

---

1. Fear and distrust of the medical establishment (doctors, scientists and the government).

On a scale from 'very much' to 'not at all', how much would each of the following affect your decision whether or not to participate in a clinical trial*?*

1. Trust in the doctor who offers you the trial
   Very much, somewhat, not sure, not much, not at all
2. The reputation of the treatment center where the clinical trial is done
   Very much, somewhat, not sure, not much, not at all

How much do you agree or disagree with these statements

3. I can not trust health care workers

Strongly agree, somewhat agree, neither agree or disagree, somewhat disagree, very much disagree

4. I am suspicious of clinical trials

Strongly agree, somewhat agree, neither agree or disagree, somewhat disagree, very much disagree

5. I am suspicious of information I receive from researchers

Strongly agree, somewhat agree, neither agree or disagree, somewhat disagree, very much disagree

2. Concern about the ethical conduct of investigators–

How much do you agree or disagree with these statements

6. Most clinical research is ethical

Strongly agree, somewhat agree, neither agree or disagree, somewhat disagree, very much disagree

7. Researchers do not care about me or my well being

Strongly agree, somewhat agree, neither agree or disagree, somewhat disagree, very much disagree

8. My doctor would not ask me to participate in a clinical trial if he or she thought it would hurt me

Strongly agree, somewhat agree, neither agree or disagree, somewhat disagree, very much disagree

9. I am confident the group of people who approve clinical trials make sure all participants are treated fairly

Strongly agree, somewhat agree, neither agree or disagree, somewhat disagree, very much disagree

10. How likely do you think it is that you might be used as a guinea pig if you were in a clinical trial?

Very likely, Somewhat likely, Not Sure, Somewhat unlikely, Not at all likely, not at all likely

3. Fear of losing one's rights by signing a research informed consent document

How much do you agree or disagree with these statements

If I were to sign an informed consent form ***to participate in a clinical trial:***

11. I could still ask my doctors any questions that I want to

Strongly agree, somewhat agree, neither agree or disagree, somewhat disagree, very much disagree

12. If doctors took my blood they could do tests on it they have not told me about

Strongly agree, somewhat agree, neither agree or disagree, somewhat disagree, very much disagree

13. I would only be agreeing to do what is explained to me in the consent form.

Strongly agree, somewhat agree, neither agree or disagree, somewhat disagree, very much disagree

14. I could still change my mind about participating at any time

Strongly agree, somewhat agree, neither agree or disagree, somewhat disagree, very much disagree

15. The researchers would only do what is stated in the consent form

Strongly agree, somewhat agree, neither agree or disagree, somewhat disagree, very much disagree

4. Worry that investigators will treat poor or minority patients unfairly

How much do you agree or disagree with the following statements

16. Black people in clinical trials receive the same care from doctors and health care workers as people of other races or ethnicities on clinical trials

Strongly agree, somewhat agree, neither agree or disagree, somewhat disagree, very much disagree

17. If I were to enroll in a clinical trial my doctors would treat me with dignity and respect

Strongly agree, somewhat agree, neither agree or disagree, somewhat disagree, very much disagree

18. Compared with others, poor people are used more in research without their permission

Strongly agree, somewhat agree, neither agree or disagree, somewhat disagree, very much disagree

19. How often, if ever, do you think doctors prescribe medication as a way of experimenting on Black patients without their knowledge or permission?

very often, fairly often, do not know, rarely, never

20. Black people are used more in research without their knowledge or permission than others races and ethnicities

Strongly agree, somewhat agree, neither agree or disagree, somewhat disagree, very much disagree

5. Loss of privacy

How much do you agree or disagree with the following statements

I believe that if I enroll in a clinical trial:

21. People can access my medical records without my approval.
    Strongly agree, somewhat agree, neither agree or disagree, somewhat disagree, very much disagree
22. My medical records are kept private.
    Strongly agree, somewhat agree, neither agree or disagree, somewhat disagree, very much disagree
23. My privacy is a major concern for the researchers involved
    Strongly agree, somewhat agree, neither agree or disagree, somewhat disagree, very much disagree
24. Personal information like my name, address and phone number will remain confidential
    Strongly agree, somewhat agree, neither agree or disagree, somewhat disagree, very much disagree
25. Any center doing clinical trials has set rules to make sure my records are kept safe

Strongly agree, somewhat agree, neither agree or disagree, somewhat disagree, very much disagree

6. Lack of knowledge and awareness of clinical trials(e.g., what would be done, what would be expected from them and what are the expected risks and benefits of the research presented at participant's comprehension level).

How much do you agree or disagree with the following statements

26. There are always serious side effects related to clinical trials
    Strongly agree, somewhat agree, neither agree or disagree, somewhat disagree, very much disagree
27. If my doctor wanted me to participate in a clinical trial, he or she would fully explain to me everything that is involved
    Strongly agree, somewhat agree, neither agree or disagree, somewhat disagree, very much disagree
28. I can talk to my doctors to find out about participating in clinical trials
    Strongly agree, somewhat agree, neither agree or disagree, somewhat disagree, very much disagree
29. There may be benefits for me if I participate in a clinical trial
    Strongly agree, somewhat agree, neither agree or disagree, somewhat disagree, very much disagree
30. There may be benefits for other people like me if I participate in a clinical trial
    Strongly agree, somewhat agree, neither agree or disagree, somewhat disagree, very much disagree
31. At this moment, is it likely that you would sign up to participate in a therapeutic clinical trial
    Very likely, Somewhat likely, Not sure, Somewhat unlikely, Very unlikely

If you were offered a clinical trial right now would you participate?

YES NO

Interviewer to use a lead-in to this last two set of questions.

Racial Identity (pre-test only)

How much do you agree or disagree with the following statements

32. Overall, being Black has a lot to do with how I feel about myself.
    Strongly agree, somewhat agree, neither agree or disagree, somewhat disagree, very much disagree
33. In general, being Black is an important part of my self-image.
    Strongly agree, somewhat agree, neither agree or disagree, somewhat disagree, very much disagree
34. My destiny is tied to the destiny of other Black people.
    Strongly agree, somewhat agree, neither agree nor disagree, somewhat disagree, very much disagree
35. Being Black is important to my sense of what kind of person I am.
    Strongly agree, somewhat agree, neither agree nor disagree, somewhat disagree, very much disagree
36. I have a strong sense of belonging to Black people.
    Strongly agree, somewhat agree, neither agree nor disagree, somewhat disagree, very much disagree
37. I have a strong attachment to other Black people.
    Strongly agree, somewhat agree, neither agree nor disagree, somewhat disagree, very much disagree
38. Being Black is an important reflection of who I am.
    Strongly agree, somewhat agree, neither agree nor disagree, somewhat disagree, very much disagree
39. Being Black is a major factor in my social relationships.
    Strongly agree, somewhat agree, neither agree or disagree, somewhat disagree, very much disagree

Religious Beliefs: 'God As Healer' (pre-test only)

How much do you agree or disagree with the following statements-

40. God works through the doctors to heal cancer

Strongly agree, somewhat agree, neither agree or disagree, somewhat disagree, very much disagree

41. God and only God can heal cancer

Strongly agree, somewhat agree, neither agree or disagree, somewhat disagree, very much disagree

42. My experience with cancer has made me realize that God is the ultimate healer

Strongly agree, somewhat agree, neither agree or disagree, somewhat disagree, very much disagree

43. I believe that if one is healed of cancer, it is God's will

Strongly agree, somewhat agree, neither agree or disagree, somewhat disagree, very much disagree

44. I believe that God gives the doctors/nurses the ability to heal cancer

Strongly agree, somewhat agree, neither agree or disagree, somewhat disagree, very much disagree

45. I believe that if you ask God for healing, He will heal you

Strongly agree, somewhat agree, neither agree or disagree, somewhat disagree, very much disagree

46. I believe that having a close relationship with God will lead to cancer recovery

Strongly agree, somewhat agree, neither agree or disagree, somewhat disagree, very much disagree

47. Healing can only occur from God, not from medicine or doctors

Strongly agree, somewhat agree, neither agree or disagree, somewhat disagree, very much disagree

48. Doctors give the cancer treatment, but God does the actual healing

Appendix G Qualitative Study Interview Guide

Date _____
Unique Participant ID_____

Pseudonym _____

☐ Introduce yourself
☐ Discuss the purpose of the study
☐ Reaffirm informed consent
☐ Overview structure of the interview (audio recording, taking notes, and use of pseudonym)
☐ Ask if they have any questions
☐ Ensure audio recording equipment is working and remind them they are being taped

ICE BREAKER
Thank you again for participating in the informational study when you came to WCI a few weeks ago. Have you had a chance to think any further about some of the things you saw in the video related to African Americans and clinical trials?
I wanted to just start out by asking you what types of thoughts or words or images now come to mind for you when you hear the term clinical trial?
Would you describe your view as generally positive or generally negative when it comes toward clinical trials?

I am interested in hearing more detail about what you think about some particular topics we want to learn more about in this study. I have four main groups of questions I would like you to share your thoughts on.
I. QUESTIONS ABOUT CLINICAL TRIALS AND RELIGIOUS BELIEFS

1. Do you believe in God or consider yourself a spiritual person?
2. Do you think that religion and a belief in God is more or less important for Black people than others?
    a. Why do you think that?
3. How do you think religion or spirituality relate to health?
    a. Why do you think that?
4. What role does religion play when it comes to clinical trials for treating cancer?
5. Do you think religion affects whether people who have cancer get better or not?
    a. Can you give some examples?
6. For people diagnosed with cancer, do you believe there is hope of finding a better treatment for them through clinical trials if they also believe in God?

II. QUESTIONS ABOUT CLINICAL TRIALS AND RACE/RACIAL IDENTITY

1. Do you think this is a different experience for Black people vs. other?
    a. Why do you think you feel like that?

    b. What sort of things would need to happen to change this?
2. What advice would you give other Black people who may have to make the decision to participate on a clinical trial?
    a. Why would you say this?
3. Where would you say most of your ideas about clinical trials come from?
4. Where do you think most Black people get their ideas about clinical trials?
    a. Do you think these are accurate?
5. Do you think more black people would participate in clinical trials if they understood how important it is for others like them?
    a. How would that influence your decision to participate?
    b. What do you think is the most important thing for Black people to understand about this?

III. QUESTIONS ABOUT RACE AND CANCER TREATMENT

1. Think of any instances you know of where African Americans have been treated unfairly
    a. Can you describe what happened?
    b. Has this experience influenced how you view clinical trials?
2. Can you think of any instances where you have experienced racism?
    a. Can you describe what happened?
    b. Has this experience influenced how you view clinical trials?
3. How do you think racism influences African American cancer patients?
    a. What does your family think?
    b. How does your family/friends affect how you feel?
4. Do you know any friends/family who have been on a clinical trial?
    a. Do you know what their experience was like?
    b. How does this affect how you feel about clinical trials?
5. Who do you think clinical trials are supposed to benefit?
    a. Why do you think this is?
    b. Do you believe there is a benefit for African Americans? Why/Why not?
    c. What would be most important for you, personally in deciding whether to participate in a clinical trial?

IV. CONCLUDING QUESTIONS AND STATEMENTS?

1. Is there anything else you would like to add or share about this topic that you think is important for me to know?
    a. Besides what we talked about?

Concluding Statement

☐ Thank them for their participation

☐ Ask if they would like to see a copy of the results once the study is completed

☐ Record any observations, feelings, thoughts and/or reactions to the interview

Appendix H: Contact notification recruitment letter

July 29, 2011

«Street»
«City_», «State_»«Zip_Code_»

Dear Mr./Ms. «Last_Name_»:

I am sending this letter to let you know of a patient education study that the Washington Cancer Institute at Washington Hospital Center is doing as part of our commitment to serving the needs of our patients. The purpose of this patient education study is to learn more about the attitudes African Americans have toward clinical trials. We want to find better ways to provide information that patients need. I thought you might want to know more about this study and I want to give you a chance to take part if you like.

You will receive a telephone call from a study representative who will explain the study to you. They will call you so you can ask any questions you have and invite you personally to be part of the study.

The study will take about one hour of your time. Patients who complete the study will receive a $25 gift card as we truly appreciate your time. We will also be happy to cover your parking cost for this visit.

Being a part of this study is your choice. This is a patient education study, and is not related to your treatment, nor will it affect the care you receive from your doctor.

If for any reason you do not wish to be part of the study, please call 202.877.8448 and ask that we do not contact you.

Thank you for your consideration.

Best regards,

Sandra M. Swain, MD
Medical Director, Washington Cancer Institute

APPENDIX I: Exploratory Factor Analysis Results

Factor Loadings for Attitudes Scales Including Forced 4 Factor Solution.

1. Exploratory FA for 20 items comprising Attitudes Scale

Total Variance Explained

	Initial Eigen values			Rotation Sums of Squared Loadings		
Component	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %
1	4.832	24.159	24.159	2.900	14.501	14.501
2	1.782	8.911	33.069	2.380	11.899	26.401
3	1.681	8.404	41.473	2.136	10.679	37.079
4	1.333	6.664	48.137	1.721	8.607	45.686
5	1.306	6.528	54.664	1.628	8.138	53.825
6	1.111	5.555	60.219	1.279	6.394	60.219
7	.988	4.939	65.157			
8	.961	4.803	69.960			
9	.867	4.336	74.296			
10	.719	3.595	77.891			
11	.699	3.494	81.386			
12	.636	3.178	84.563			
13	.538	2.688	87.251			
14	.506	2.532	89.783			
15	.477	2.386	92.169			
16	.389	1.944	94.113			
17	.350	1.752	95.866			
18	.307	1.536	97.402			
19	.274	1.371	98.773			
20	.245	1.227	100.000			

Extraction Method: Principal Component Analysis.

2. Factor loadings for 6 factor solution

Rotated Component Matrix[a]

	Component					
	1	2	3	4	5	6
4. I am suspicious of clinical trials	.811	.120	.104		.230	-.123
5. I am suspicious of information I receive from researchers	.798	.169			.112	
3. I can not trust health care workers	.605	.131				.291
7. Researchers do not care about me or my well being	.535	.286	.162		.254	
19. How often, if ever, do you think doctors prescribe medication as a way of experimenting on Black patients without their knowledge or permission?	.153	.690	.145	.148	-.213	.110
20. Black people are used more in research without their knowledge or permission than others races and ethnicities	.464	.641	.107			-.133
18. Compared with others, poor people are used more in research without their permission	.479	.594				-.124
9. I am confident the group of people who approve clinical trials make sure all participants are treated fairly		.577	.172		.448	
10. How likely do you think it is that you might be used as a guinea pig if you were in a clinical trial?		.562		-.137	.299	.103
12. If doctors took my blood they could do tests on it they have not told me about	.336	.381		-.242		-.351
11. I could still ask my doctors any questions that I want to	.128		.803			.158
13. I would only be agreeing to do what is explained to me in the consent form			.727	-.119	.143	-.349
14. I could still change my mind about participating at any time	.416	-.153	.599		-.288	
8. My doctor would not ask me to participate in a clinical trial if he or she thought it would hurt me		.277	.425		.131	.117
2. The reputation of the treatment center where the trial is done				.891		
1. Trust in the doctor who offers you the trial				.882		
17. If I were to enroll in a clinical trial my doctors would treat me with dignity and respect	.164				.775	
16. Black people in clinical trials receive the same care from doctors and health care workers as people of other races or ethnicities on clinical trials	.205	.207	.233		.484	.127
6. Most clinical research is ethical	.197		.114	-.106	.185	.749
15. The researchers would only do what is stated in the consent form	.227	.181	.475		.403	-.493

Forced 4 Factor Solution:

Total Variance Explained

Component	Initial Eigen values			Rotation Sums of Squared Loadings		
	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %
1	4.832	24.159	24.159	3.236	16.180	16.180
2	1.782	8.911	33.069	2.358	11.792	27.973
3	1.681	8.404	41.473	2.281	11.407	39.380
4	1.333	6.664	48.137	1.751	8.757	48.137
5	1.306	6.528	54.664			
6	1.111	5.555	60.219			
7	.988	4.939	65.157			
8	.961	4.803	69.960			
9	.867	4.336	74.296			
10	.719	3.595	77.891			
11	.699	3.494	81.386			
12	.636	3.178	84.563			
13	.538	2.688	87.251			
14	.506	2.532	89.783			
15	.477	2.386	92.169			
16	.389	1.944	94.113			
17	.350	1.752	95.866			
18	.307	1.536	97.402			
19	.274	1.371	98.773			
20	.245	1.227	100.000			

Factor loadings for forced 4 factor solution

Rotated Component Matrix[a]

	Component			
	1	2	3	4
20. Black people are used more in research without their knowledge or permission than others races and ethnicities	.708	.241	.150	
18. Compared with others, poor people are used more in research without their permission	.687	.269		
9. I am confident the group of people who approve clinical trials make sure all participants are treated fairly	.629			
10. How likely do you think it is that you might be used as a guinea pig if you were in a clinical trial?	.550	.171	-.145	-.174
12. If doctors took my blood they could do tests on it they have not told me about	.524		.202	-.158
19. How often, if ever, do you think doctors prescribe medication as a way of experimenting on Black patients without their knowledge or permission?	.522	.108		.248
5. I am suspicious of information I receive from researchers	.376	.650	.117	
6. Most clinical research is ethical		.644		-.131
3. I can not trust health care workers	.173	.639	.107	.121
4. I am suspicious of clinical trials	.428	.589	.240	
7. Researchers do not care about me or my well being	.435	.477	.190	
16. Black people in clinical trials receive the same care from doctors and health care workers as people of other races or ethnicities on clinical trials	.312	.323	.181	
17. If I were to enroll in a clinical trial my doctors would treat me with dignity and respect	.163	.311		-.225
13. I would only be agreeing to do what is explained to me in the consent form	.214	-.133	.770	-.134
11. I could still ask my doctors any questions that I want to		.205	.745	
14. I could still change my mind about participating at any time	-.133	.305	.657	.207
15. The researchers would only do what is stated in the consent form	.490		.563	
8. My doctor would not ask me to participate in a clinical trial if he or she thought it would hurt me	.196		.335	
1. Trust in the doctor who offers you the trial				.865
2. The reputation of the treatment center where the trial is done				.842

APPENDIX J: ANOVA Results

This was done to examine if any of the covariates related to the attitudinal barriers or to the proposed moderators. A one-way analysis of variance was used to test for differences in mean scores on each of the four attitudinal barriers scales by age category, gender, family history of cancer, US/foreign born, SES, marital status, experience with racism, and whether or not they had children. A one-way analysis of variance was also used to test for differences in mean scores on the proposed moderator variables by each of these covariates. These findings are summarized below

Association of Gender and Six Study Scales

Comparing mean scores between males and females in the sample on each of the four constructs representing attitudinal barriers revealed no significant difference. Similarly there was no significant difference found on scores of racial centrality. The only significant gender effect was seen in mean scores on the God as healer scale ($F(1,109) = 3.74$, $p < 0.05$), where on the average females had a significantly higher mean score than males in the sample.

Association of Age and Six Study Scales

There was no significant difference in mean scores on any of the attitudinal scales or the proposed moderators by age groups.

Association of Marriage and Six Study Scales Marital Status

There was no significant difference in mean scores on any of the independent variables or proposed moderators by marital status.

Association of Income and Six Study Scales

Income was significantly related to the total distrust scale (F (8,102) = 3.79, p = .001). Post hoc analyses using Tukey's test revealed significant mean differences in distrust scores for participants such that those making <$8,000 had lower distrust scores than those with incomes of $8,000- $11,9999. Similarly those in $8, 0000 - $11,999 had significantly higher distrust scores compared with those in the ($20,000- $29,999) income category and higher still than those in the ($50,000- $74,999) category. Finally those in the >$75,000 had the lowest mean distrust scores and these were significantly different from participants in the ($8,000- $11,999) and ($30,000-$39,999) respectively. An income effect was also found for participant's worry about being treated unfairly, F(8,102) = 2.08, p = *.04*; and for concern about losing one's rights F (8,102) = 2.85, p = *.01* Post hoc analyses with Tukey's test showed significant mean difference for groups with incomes in the ($8,000- $11,999) who had higher worry scores than those in the ($12000-$15,999) and compared with those with incomes > $75,000.

This evidence suggests that income or some proxy measure of socioeconomic status is likely a key covariate in a model predicting the relative importance of factors which predict intention to enroll in a clinical trial.

Association of Place of Birth and Six Study Scales

A comparison of mean scores revealed no significant difference for most of the study variables based on differences in country of birth. There was, however, a significant difference in mean scores on the racial centrality scale between participants who were US born and those who were born outside of the country (F (1, 109) = 5.06, p

= 0.027). Specifically, US born study participants had a statistically significant higher mean centrality score compared with their foreign born counterparts.

Association of SES and Six Study Scales

A SES variable was created using the income data within the sample to create groupings of low, middle and high SES. The resulting analysis of variance testing the differences in mean

scores for each of the independent and moderator variables revealed significant difference for two attitudinal scales. There was a significant difference in mean scores on the fear of losing one's rights after signing an informed consent ($F(2,108) = 3.48$, $p = .03$). Post hoc analyses using Tukey's test revealed a statistically significant mean difference between those classified as mid-SES compared with those of high-SES, such that the latter group had lower mean scores than the former (higher SES groups had less concern of loss of their rights). There was also a significant difference by SES on the trust score (F (2,108) = 3.68, $p = .03$) and post hoc analyses showing significant mean difference between high and mid SES. Again the relationship was such that there was a lower mean distrust score for the higher of the two income groups.

Association of Education and Six Study Scales

There was a significant education effect between groups on mean scores for total distrust scores (F (3,107) = 2.90, $p = .04$). Post hoc analysis using Tukey's criterion for significance indicated there was a significant difference between participants with less than a high school education and those with some college or technical school.

Association of Number of Children and Six Study Scales

There was no significant difference in mean scores on any of the independent variables or proposed moderators for participants who had no children compared with those having one or more child.

Association of Experiences of Racism Effect and Six Study Scales

There was no significant difference in mean scores on any of the independent variables or proposed moderators by experience of racism. Post hoc analyses revealed a significant mean difference between participants who reported experiencing *'very much'* racism in their lifetime compared with those reporting *'not much'*. There was also a significant difference for those reporting *'very much'* compared with those responding *'don't know'*

Association of Family History and Six Study Scales

There was no significant difference in mean scores on any of the independent variables or proposed moderators between participants with a family history of cancer and those who did not.

One-way ANOVA Results for Comparison of Means, by Demographic Characteristics

		ANOVA Statistics			
Demographic variable and predictor variable		***df***	**MSE**	***F***	*p-value*
Gender	Distrust	1	10.79	0.34	0.560
	Ethics	1	12.97	1.33	0.25
	Worry	1	16.03	0.5	0.483
	Rights	1	9.9	0.29	0.865
	Racial Centrality	1	61.07	0.17	0.690
	Belief in God as Healer	1	51.54	3.73	0.056
	Intention to Enroll (Likert)	1	1.874	1.52	0.221
Age	Distrust	4	11.07	0.15	0.961
	Ethics	4	13.26	0.48	0.747
	Worry	4	15.87	1.16	0.332
	Rights	4	10.14	0.11	0.977
	Racial Centrality	4	59.96	1.3	0.275
	Belief in God as Healer	4	54.42	0.2	0.94
	Intention to Enroll (Likert)	4	1.883	0.995	0.413
Marital Status	Distrust	4	10.48	1.66	0.165
	Ethics	4	13.38	0.23	0.920
	Worry	4	15.55	1.73	0.148
	Rights	4	9.45	2.06	0.091
	Racial Centrality	4	62.33	0.24	0.915
	Belief in God as Healer	4	52.82	1	0.410
	Intention to Enroll (Likert)	4	1.808	2.141	0.081

Demographic variable and predictor variable		*df*	MSE	*F*	*p-value*
Income	**Distrust**	**8**	**8.92**	**3.79***	**0.001**
	Ethics	8	12.54	1.52	0.169
	Worry	**8**	**14.8**	**2.08***	**0.045**
	Rights	**8**	**8.65**	**2.85***	**0.007**
	Racial Centrality	8	62.16	0.66	0.727
	Belief in God as Healer	8	51.36	1.39	0.209
	Intention to Enroll (Likert)	8	1.965	0.42	0.905
US Born vs Immigrant	Distrust	1	10.66	1.67	0.199
	Ethics	1	13.07	0.51	0.477
	Worry	1	16.1	0.04	0.844
	Rights	1	9.9	0.02	0.888
	Racial Centrality	**1**	**58.45**	**5.06***	**0.027**
	Belief in God as Healer	1	53.23	0.16	0.694
	Intention to Enroll (Likert)	1	1.893	0.385	0.536
SES	**Distrust**	**2**	**10.23**	**3.675***	**0.029**
	Ethics	2	13.13	0.48	0.618
	Worry	2	15.68	1.97	0.144
	Rights	**2**	**9.39**	**3.480***	**0.034**
	Racial Centrality	2	61.02	0.63	0.535
	Belief in God as Healer	2	53.27	0.55	0.582
	Intention to Enroll (Likert)	2	1.908	0.27	0.766
Education Level	**Distrust**	**3**	**10.2**	**2.9***	**0.038**
	Ethics	3	12.54	2.38	0.074
	Worry	3	15.8	1.37	0.257
	Rights	3	9.83	0.93	0.429
	Racial Centrality	3	61.68	0.36	0.781
	Belief in God as Healer	3	51.18	2.18	0.095
	Intention to Enroll (Likert)	3	1.921	0.27	0.847
Number of Children	Distrust	1	10.82	0.006	0.939
	Ethics	1	13.12	0.07	0.798
	Worry	1	16.08	0.18	0.677
	Rights	1	9.9	0.001	0.971
	Racial Centrality	1	59.37	3.3	0.072
	Belief in God as Healer	1	53.28	0.07	0.793
	Intention to Enroll (Likert)	1	1.867	1.97	0.164

Demographic variable and predictor variable		*df*	MSE	*F*	*p-value*
Experience of Racism	Distrust	4	10.92	0.5	0.733
	Ethics	4	12.77	1.51	0.205
	Worry	4	15.91	1.08	0.368
	Rights	4	9.64	1.49	0.210
	Racial Centrality	4	57.96	2.68*	0.048
	Belief in God as Healer	4	53.72	0.54	0.505
	Intention to Enroll (Likert)	4	1.832	1.75	0.143
Family History of Cancer	Distrust	1	10.81	0.14	0.711
	Ethics	1	13.12	0.04	0.852
	Worry	1	16.01	0.66	0.420
	Rights	1	0.01	0.001	0.971
	Racial Centrality	1	60.99	0.31	0.580
	Belief in God as Healer	1	53.17	0.59	0.591
	Intention to Enroll (Likert)	1	1.89	0.54	0.465

$_B$ = between groups *p <.05 **p <.01

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