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Obstacles in Recruiting African Americans for Clinical Trials.

Betty Monroe Kennedy
Louisiana State University and Agricultural & Mechanical College

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OBSTACLES IN RECRUITING AFRICAN AMERICANS FOR CLINICAL TRIALS

A Dissertation

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Agricultural and Mechanical College
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by
Betty Monroe Kennedy
B.A., Miles College, 1973
M.P.A., Southern University, 1992
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TABLE OF CONTENTS

LIST OF TABLES

ABSTRACT

Previous abusive clinical trials have caused several obstacles in recruiting African Americans for clinical trials today. The memory of the Tuskegee Syphilis Study alone remains a hard pill to swallow and is a constant hindrance to recruiting potential African Americans specifically males, for clinical trials. The basic trust that African Americans have for physician researchers, U. S. government doctors, U. S. government-sponsored research, and biomedical research in general has been seriously, although not irrevocably, breached.

The purpose of this study was to gain an understanding of the knowledge, attitudes, and beliefs African Americans have that support decisions to either participate or not participate in a clinical trial. Specific areas that were examined by perceptual and demographic measures included: knowledge of clinical research processes, perceptions of clinical research purposes and procedures, advantages and disadvantages for the individual of participation in clinical research trials, characteristics of current and past participation in clinical research trials, exposure to selected experiences which are preliminary to participation in clinical research trials, perceptions regarding the need for selected changes in preparation for participation in clinical research trials; and selected personal demographic characteristics: gender, age, marital status, education level, employment status, household income, distance from research center, and overall health status.

The survey method was utilized in this study. The discriminant analysis model was used to determine if a model existed that significantly increased the researcher's ability to correctly classify volunteers on their participation status in clinical research trials. The

overall model was meaningful and successful in correctly classifying 74.6% of the original grouped cases.

The strongest findings suggest that African Americans are likely to participate in future clinical trials based on their knowledge and perceptions of clinical research trials. Principal Investigators and research teams which focus on African Americans in clinical research trials should therefore place an increased emphasis on strategic planning that involves participants representative of the study population. To yield results, the plan should be tailored to African Americans, presented as a credible study, designed to reflect trust in the medical care team, and implemented through a continuous educational process.

CHAPTER 1

INTRODUCTION

Previous abusive clinical trials have caused several obstacles in recruiting African Americans for clinical trials today. These past experiences, including those without written protocols and uninformed consent, have left nothing but doubt, fear, and mistrust among African Americans. The basic trust that African Americans have for physician researchers, United States government doctors, United States government-sponsored research, and biomedical research in general has been seriously, although not irrevocably, breached (Thomas, Pinto, Roach, & Vaughn, 1994a). Modern clinical trials are designed and monitored to safeguard against this type of abuse, however, the past effects of government-sponsored racism do not dissipate quickly (Thomas et al., 1994a). For this reason, many obstacles of the past hinder the successful recruitment of African Americans into clinical trials.

Some of the major obstacles experienced in the past by African Americans include the Tuskegee Study of Untreated Syphilis. This study involved over 400 African American farmers and was conducted by the United States Public Health Service from 1932 until 1972 (Jones, 1993). In this study African American men, with a diagnosis of syphilis, were given no specific antisyphilitic treatment for 40 years in order to observe the natural history of this infectious disease in a large cohort (Thomas et al.). Although this study concluded approximately 28 years ago, it is still very prevalent in the minds of African Americans today. The neglect and abuse of untreated syphilis for 40 years is a hard pill to swallow, then and now. If the United States government betrayed the trust of African Americans over 40 years ago, what about today?

Another obstacle from the past that deters African Americans from participation in clinical trials occurred between 1845 and 1849 when J. Marion Sims, known as the Father of American Gynecology, performed 42 operative procedures on African American slave women in Montgomery, Alabama in search of a surgical cure for vesico-vaginal fistulas (Sims, 1852). Each of the three slave women underwent up to thirty painful operations without the benefit of anesthetics. Postoperative medication consisted of opium at least twice in 24 hours (Allen, 1994). Consequently, these women were eventually made drug addicts as a result of high doses of opium.

Other obstacles using vulnerable populations, or those who have insufficient power, intelligence, resources, strength or other needed attributes to protect their own interests through negotiations for informed consent (Levine, 1986) include gynecologic and reproductive research that continued beyond the 19th century (Allen, 1994). Between 1957 and 1958 Armand J. Pereyra, M.D., developed his needle urethropexy procedure on inmates at the California Penal Institute for Women. The published report presented results of procedures performed on 31 inmates (Pereyra, 1959). The San Antonio Contraceptive Study involved poor Mexican-American women enrolled in a randomized, placebo-controlled, double-blind clinical trial designed to investigate the side effects of oral contraceptives (Levine, 1986). The women thought they were receiving an active contraceptive; none were informed they would be receiving a placebo (sugar pill). Because the trial involved a cross-over design, all participants received a placebo for some part of the trial. As a result, 11 of the 76 participants became pregnant during the course of the trial, 10 while on placebo (Levine, 1986).

It is because of studies such as these and especially the Tuskegee Study, that recruiting for clinical trials from the African American population is extremely difficult. Remarks like: "you are not going to use me as a guinea pig" or, "what are they putting in the food" and, "why are African Americans the only ones participating in this study", are just a few of the negative remarks a research recruiter encounters while trying to recruit this population. The challenge in recruiting African Americans is even more crucial because chronic disease disproportionately affects them and other minority populations in the United States (Singh, Kochanek, & MacDorman, 1996). For example, this is particularly true with hypertension, where the associated morbidity and mortality are greatest among African Americans (Vollmer, Svetkey, Appel, Obarzanek, Reams, Kennedy, Aicher, Charleston, Conlin, Evans, Harsha, & Hertert, 1998). The age-adjusted prevalence of hypertension in African American adults is 40 percent higher than in Caucasian adults (Burt, Whelton, Roccella, Brown, Cutler, & Higgins, 1995). In addition, mortality from blood pressure related cardiovascular diseases is 1.9 to 3.6 times greater in African American adults aged 25-64 than in similarly aged Caucasian adults (Singh et al., 1996).

The demand for proportionate representation of women, especially African American women, in clinical trials is relatively recent. In fact, the textbook description of a clinical trial calls for "homogeneous populations of patients" (Goodman & Gilman, 1990). Unfortunately, these homogeneous populations have been mostly white and male. As a result, the National Institutes of Health (NIH) established guidelines for the inclusion of women and minorities and their sub-populations in its funded research with human subjects (Federal Register, 1994).

Federal funding agencies now require that all proposals and applications with human subjects must include women and minority groups to improve gender and race representation in clinical trials. These requirements specifically target under-represented groups that are disproportionately affected by certain diseases (Kris-Etherton, Mustad, & Lichtenstein, 1999).

Although there have been notable improvements in health status in the United States over the past few decades, the picture of improved health status is not as impressive for African Americans and may have worsened in some cases (Braithwaithe and Taylor, 1992). In 1985, the Report of the Secretary's Task Force on Black and Minority Health reported the wide disparity in health status between whites and African Americans (Unites States Department of Health and Human Services [USDHHS], 1985). The report revealed that approximately 80,000 more African Americans than whites die each year, and recent estimates indicate that the numbers continue to increase (Green, Maisiak, Wang, Britt, & Ebeling, 1997). One of the wide disparities in health status between whites and African Americans has been linked to factors associated with utilization of health services.

Studies addressing the utilization rates of preventive health services by African Americans have been conducted in a number of settings (Berkanovic & Telesky, 1985; Caplan, 1992; Green et al., 1997; James, Wagner, Strogatz, Beresford, Kleinbaum, Williams, Cutchin, & Ibrahim, 1984; Thomas & Quinn, 1991; Williams, Lavizzo-Mourey, & Warren, 1994). The conclusions drawn in these studies indicate that there is a need for a better understanding of underutilization of health services, including those involving participation of African Americans in clinical research trials.

Purpose of the Study

The purpose of this study was to gain an understanding of the knowledge, attitudes, and beliefs African Americans have that support decisions to either participate or not participate in a clinical trial.

Objectives

The following specific objectives were formulated to guide the researcher:

1. To describe African Americans who were potential participants in clinical research trials on each of the following perceptual and demographic measures:
    a. Knowledge of clinical research processes;
    b. Perceptions of clinical research purposes and procedures;
    c. Advantages and disadvantages for the individual of participation in clinical research trials;
    d. Characteristics of current and past participation in clinical research trials;
    e. Exposure to selected experiences which are preliminary to participation in clinical research trials;
    f. Perceptions regarding the need for selected changes in preparation for participation in clinical research trials; and
    g. The following selected personal demographic characteristics:
        i. Gender,
        ii. Age,
        iii. Marital status
        iv. Education level,
        v. Employment status,

vi. Household income,

vii. Distance from research center, and

viii. Overall health status

2. To describe and compare African Americans who have participated in clinical research trials and those who have not participated in clinical research trials on each of the following perceptual and demographic measures:

a. Knowledge of clinical research processes;

b. Perceptions of clinical research purposes and procedures;

c. Advantages and disadvantages for the individual of participation in clinical research trials;

d. Characteristics of current and past participation in clinical research trials;

e. Exposure to selected experiences which are preliminary to participation in clinical research trials;

f. Perceptions regarding the need for selected changes in preparation for participation in clinical research trials; and

g. The following selected personal demographic characteristics:

i. Gender,

ii. Age,

iii. Marital status,

iv. Education level,

v. Employment status,

vi. Household income,

vii. Distance from research center, and

viii. Overall health status.

3. To determine if a model existed that significantly increased the researcher's ability to correctly classify volunteers on their participation status in clinical research trials from the following perceptual and demographic measures:

   a. Knowledge of clinical research processes;

   b. Perceptions of clinical research purposes and procedures;

   c. Advantages and disadvantages for the individual of participation in clinical research trials;

   d. Characteristics of current and past participation in clinical research trials;

   e. Exposure to selected experiences which are preliminary to participation in clinical research trials;

   f. Perceptions regarding the need for selected changes in preparation for participation in clinical research trials; and

   g. The following selected personal demographic characteristics:

      i. Gender,

      ii. Age,

      iii. Marital status,

      iv. Education level,

      v. Employment status,

      vi. Household income,

      vii. Distance from research center, and

      viii. Overall health status.

Significance of the Study

The success of a clinical trial is dependent upon the success of recruiting the required number of volunteers. To gain an understanding of the knowledge, attitudes, and beliefs African Americans have regarding clinical research trials is the first step in obtaining useful information that will assist and guide researchers for future recruitment of African Americans. The results of this study should further assist researchers in strengthening their recruitment efforts and strategies for increased participation of African Americans in clinical research trials.

Limitation of the Study

This study is limited to African Americans who participated and those who did not participate in a clinical trial at the Pennington Biomedical Research Center from 1992-2000. Since age, gender, and marital status are demographic characteristics collected on all potential volunteers, the Chi-square statistical test was used to determine if the respondents in this study were representative of the total population in the Pennington Biomedical Research Center's database. The Chi-square statistical test was significant revealing that the respondents in this study were significantly different on the examined characteristics from the total population as defined in the study.

However, it should be noted that even though the respondents in this study were different from the population of the study on the examined characteristics, they were in fact very similar to respondents in other studies of African American populations. Specifically, the respondents had a higher percentage of married individuals than were evident in the Pennington Biomedical Research Center's population, but the percentage of married individuals was very similar to the results of the study by (Appel, Vollmer,

Obarzanek, Aicher, Conlin, Kennedy, Charleston, & Reams, 1999). Likewise, the percentage of female respondents was higher than male respondents in this study and very similar to the results of the study by Corbie-Smith, Thomas, Williams, & Moody-Ayers, 1999). The highest percentage of respondents in this study were in the 46-55 age group and similar results were found in studies by (Appel et al., 1999; Corbie-Smith, et al., 1999; Green et al., 1997).

Definition of Terms

For the purpose and objectives of this study the following terms were operationally defined:

Clinical Trial: A clinical trial is a research study that can be used to answer questions about vaccines or new therapies or new ways of using known treatments. Clinical trials (also called medical research and research studies) are used to determine whether new drugs or treatments are both safe and effective. Carefully conducted clinical trials are the fastest and safest way to find treatments that work.

Informed Consent: Informed consent is the process of learning the key facts about a clinical trial before deciding whether or not to participate. These facts include:

- Why the research is being done.
- What the researchers want to accomplish.
- What will be done during the trial and for how long.
- What risks are involved in the trial.
- What benefits can be expected from the trial.
- What other treatments are available.
- And, the right to leave the trial at any time.

Nonparticipant: Eligible volunteers who either chose not to participate or were ineligible to participate in a clinical trial.

Participant: Eligible volunteers who chose to participate in a clinical trial.

Protocol: All clinical trials are based on a set of rules called a protocol. A protocol describes what types of people may participate in the trial; the schedule of tests, procedures, medications, and dosages; and the length of the study. While in a clinical trial, participants are seen regularly by the research staff to monitor their health and to determine the safety and effectiveness of their treatment.

CHAPTER 2

REVIEW OF RELATED LITERATURE

The review of related literature is divided into four sections. The first section will discuss obstacles to recruiting African Americans in clinical trials. The next section will discuss the importance of African American involvement in clinical trials. The third section will discuss relevant, related literature. The final section will discuss researcher biases that may have an impact on recruiting African Americans in clinical trials.

Obstacles to Recruiting African Americans in Clinical Trials

Historical Obstacles to Enrollment in Clinical Trials

There are many obstacles to the participation of African Americans in clinical trials. Historically, medical research is viewed with suspicion among many African Americans, and this creates a major hurdle. In perhaps the best known case of research abuse, the United States Public Health Service began enrolling 400 black men, without informed consent, into a natural history study of untreated, latent syphilis in 1932 (Allen, 1994). In 1946, it was reported that the death rate among those with syphilis was twice as high as among the controls, yet the U.S. Public Health Service continued the study, withholding treatment long after penicillin became available as standard therapy (Allen, 1994). It was not until the lay press exposed this in early 1970 that the study was interrupted (Jones, 1993). In another natural history study financed by the Army, mentally retarded infants and children at the Willowbrook State School were deliberately infected with hepatitis (Levine, 1986). In a recent study at the University of California, Los Angeles, schizophrenics were reportedly taken off their medication to determine what would happen. The "informed consent" offered little detail of possible consequences.

One of the subjects committed suicide after his family tried in vain to have his medication reinstated (Allen, 1994). In fact, 32 of 50 patients in the study suffered severe relapses. Some authors have expressed concern that racial minorities might be over-represented in general in clinical trials (El-Sadr & Capps, 1992). Levine (1986) stated, "The inner-city location of many university hospitals is problematic in that it increases the likelihood of disproportionate use of racial and ethnic minorities as well as impoverished people as research subjects." Stevenson, 1989 addressed this concern by reviewing the representation of African Americans in studies published in 1984, 1985, and 1986 in *Clinical Pharmacology and Therapeutics.* He found that in the majority of these studies, the proportion of African American participants was less than their proportion in the general population.

Traditionally, the recruitment of a patient for a clinical trial involves primarily the provision of information regarding the specifics of the trial prior to obtaining informed consent. However, for the patient who has no previous conception of a clinical trial, successful recruitment requires an extensive educational effort. This education must include an explanation of the meaning of a trial, random sampling, the nature of blinding, and the concept of a placebo, and a description of the responsibilities of the provider and the participant, among other information (El-Sadr & Capps, 1992). It is not until after the volunteer has a complete understanding of these issues that the specific protocol can be discussed. This is a time-consuming process that requires educational skills, patience, and the building of trust. It also requires the availability of creative and appropriate educational materials. Often the widely available educational materials are not suitable for the patient who has not had an extensive education (El-Sadr & Capps, 1992).

Poor, often minority, patients have traditionally sought care at their neighborhood institutions. They are reluctant to travel or to accept referral to unfamiliar institutions and providers. Thus, one of the most important barriers to their recruitment has been the fact that, until recently, few of the trials were conducted at institutions where many of these patients receive their primary care. The ability of the primary care provider to explain the clinical trial to his or her patient is more likely to overcome mistrust and reluctance, and the fact that the patient does not have to travel to another institution to participate in a trial may facilitate recruitment ((El-Sadr & Capps, 1992).

Socio-cultural Obstacles to Enrollment in Clinical Trials

The many social needs of minority volunteers often hinder their ability to participate in clinical trials. These issues are seldom addressed or funded by sponsors of clinical trials. Often the primary interests of sponsors are the rapid completion of the trial and maximum adherence at minimum cost. Many volunteers are homeless, active drug users, and many are women with young children. In addition, volunteers have limited income and lack resources for associated transportation, food, and nutritional supplements (El-Sadr & Capps, 1992). Thus, successful recruitment and, even more important, adherence to protocol visits are dependent on more than just providing the study drug. Successful recruitment and volunteer adherence depend on the availability of a social worker to provide advice on housing, substance abuse programs, and other services. They also depend on providing child care, convenient transportation, and a warm meal during visits (El-Sadr & Capps, 1992). The importance of a participant advocate who can track down volunteers and assist them in making protocol related visits is critical.

Other prevailing socio-cultural obstacles include racial and ethnic discrimination (Blendon, Scheck, Donelan, Hill, Smith, Beatrice, & Altman, 1995; El-Sadr & Capps, 1992; Freeman, 1989; Hutchinson, 1992; Swanson & Ward, 1995; Thomas et al., 1994a; Thomas, Quinn, Billingsley, & Caldwell, 1994b) and cultural beliefs about specific diseases or illness in general (Ballard, Nash, Raiford, & Harrell, 1993; Bennett, 1993; Freeman, 1993; Groce & Zola, 1993; Kaluzny, Brawley, Garson-Angert, Shaw, Godley, Warnecke et al., 1993; and Swanson & Ward, 1995). There is widespread fear and mistrust of the medical care system among various minority populations as a result of indifference and disrespect exhibited by some health care professionals toward those who are socio-economically disadvantaged (Freeman, 1993; Haynes & Bernard, 1992; Kaluzny et al., 1993; McCabe, Varricchio, & Padberg, 1994; Swanson & Ward, 1995; & Wray, 1992). Minorities have been devalued by the health care system, and their illnesses often have been labeled as deviance (Blendon et al. 1995; El-Sadr & Capps, 1992; Hutchinson, 1992; Swanson & Ward, 1995). In addition, general racial discrimination and segregation in our society produce fear and mistrust of federally sponsored projects, academic medicine, and clinical research (Nickens, 1990; Swanson & Ward, 1995 & Thomas et al., 1994a; Thomas et al., 1994b). Finally, differences in health beliefs and health behaviors also influence the potential for clinical trial participation. For example, some African American, Hispanic, and rural populations are more likely to delay seeking medical treatment and to under utilize preventive care, resulting in higher levels of presentation with later stage cancers (Durant, Ashworth, Newman, McGill, Raban, & Baranowski, 1992; Freeman, 1993; Swanson & Ward, 1995; Wray, 1992).

Economic Obstacles to Enrollment in Clinical Trials

The impact of socioeconomic status on health and use of medical services is receiving increased attention (Dutton & Levine, 1989; Epstein, Stern, Tognelti, Begg, Hartley, Cumella, & Ayanian, 1988; Feinstein, 1993; Rask, Williams, Parker, & McNagny; Adler, Boyce, Chesney, Folkman, & Syme, 1993). Recent studies have shown that insurance coverage alone does not guarantee use of timely and appropriate medical care (Dutton, 1978; Pappas, Queen, Hadden, & Fisher, 1993; Riportella-Muller, Richardson, Luchok, Donat, & Selby-Harrington, 1993; St. Peter, Newacheck, & Halfon, 1992; Savitz & Ricketts, 1993). Other economic obstacles faced by indigent volunteers include out-of-pocket medical expenses; lack of sick leave, child care costs, and lack of transportation (Kiefe & Harrison, 1993; Riportella-Muller et al., 1993; Savitz & Ricketts, 1993). Health care system and organizational barriers that are particularly likely to affect minority populations include availability of public health care facilities, lack of providers for Medicaid, and geographic accessibility of ambulatory care (Riportella-Muller et al., 1993; Savitz & Ricketts, 1993; Yudkowsky, Cartland, & Flint, 1990).

Additional specific or enabling factors can include language barriers, educational deficits, health beliefs, and dysfunctional social or home environments (Feinstein, 1993). Minority populations are also more likely to experience adverse environmental and social conditions, such as crime and violence, that hamper their ability to modify health-damaging behaviors and obtain adequate care (Adler et al., 1993; Dutton & Levine, 1989; Feinstein, 1993). If these economic, structural, and cultural factors are significant barriers to medical care, they may result in delays in seeking care and adverse health

outcomes independent of health insurance status (Shea, Miara, Ehrlich, Field, & Francis, 1992; Weissman, Stern, Fielding, & Epstein, 1991).

The overwhelming economic obstacles to the participation of many minority populations in clinical trials is lack of access to health care in general (Blendon et al., 1995; DuRant et al., 1992; Elks, 1993; Elks, Short, Cornelius, & Goldstone, 1990; Freeman, 1993; Kindig & Yan, 1993; Murdaugh, 1990; Reis, Sherman, & Macon, 1989; Swanson & Ward, 1995; Walker, Lucas, & Crespo, 1994; Wray, 1992). Lack of health insurance is a critical factor that limits access to health care among low-income, minority populations (Short et al., 1990; Swanson & Ward, 1995). The poor quality of general health services available in some African American and other low-income communities is another important factor that limits access to health care, thus to clinical trials (Blendon et al., 1989; Freeman, 1989; Kindig & Yan, 1993; Swanson & Ward, 1995, Wray, 1992). There is evidence that rural and elderly minority populations are subsets of minorities that have least often been included in clinical trials (Kindig & Yan, 1993; Swanson & Ward, 1995; Wray, 1992).

It is very difficult to unravel the effects of poverty on clinical trials participation from those issues related to race and ethnicity (Ballard et al., 1993; Blendon et al., 1989; Freeman, 1989; Freeman, 1993; Lacey, 1993; Nickens, 1990; Swanson & Ward, 1995; Thomas et al., 1994b). It is well recognized that poverty is a leading risk factor for cancer and other diseases (Freeman, 1989; Kindig & Yan, 1993; Swanson & Ward, 1995). The effects of poverty are extensive, ranging from dangerous living environments to poor nutrition and inadequate housing; to unemployment, financial instability, and

inability to obtain public assistance; to lack of telephones and transportation (Ballard et al.,1993; Blendon et al., 1989; Lacey, 1993; Swanson & Ward, 1995).

Obstacles Inherent in Study Design

Minority health care professionals are raising important issues about restrictive exclusion criteria. They indicate that entire segments of the population are effectively banned from obtaining the benefits of clinical trials, including improved medical care, better quality of life, longer survival, and access to compensation that accompanies some studies (Elks, 1993; El-Sadr & Capps, 1992; Jimenez & Jimenez, 1992; Milton-Underwood, Sanders, & Davis, 1993; Swanson & Ward, 1995). Differences in drug response and in other outcomes across diverse ethnic groups and by sex further prolong the problems resulting from limited access to clinical trials among these groups (Crews and Bindon, 1991; El-Sadr & Capps, 1992; Merkatz, Temple, Subel, Feiden, & Kessler, 1993; Milton-Underwood et al., 1993; Swanson & Ward, 1995).

Complexity of forms and procedures also inhibit participation of many populations (Elks, 1993; Haynes & Bernard, 1992; Kaluzny et al., 1993; McCabe et al., 1994; Swanson & Ward, 1995; Freeman, 1993; Wray, 1992;). Forms used to ensure informed consent are a good example of this problem, as most of them are well above the reading level of some populations, may not explain the benefits of the trial, may not explain that care given as routine is not very effective, or may actually induce fear if they are too complex (Elks, 1993; Haynes & Bernard, 1992; Swanson & Ward, 1995).

Importance of African Americans Involvement in Clinical Trials

Chronic disease disproportionately affects African Americans and other minority populations in the United States (Singh et al., 1996) and therefore, the need to enroll

African Americans into clinical trials is necessary to reduce this disparity. It is important for African Americans to participate in clinical trials because of the potential to identify effective prevention, and treatment strategies for many of the health conditions that afflict them. Yet, African Americans and other minorities do not participate in clinical trials in numbers proportional to their risk of disease (Thomas et al., 1994a). Since race can affect disease severity, progression, and response to drug therapy (Matthews, 1995), under-representation of African Americans and other ethnic minorities in clinical trials will decrease the ability to generalize study results to minority populations.

More specifically, applicability of findings would be questionable for the various racial/ethnic groups as documented by the National Cancer Institute (NCI). For example, the severity of the cancer problem among racial/ethnic populations compared with that among the general population is such that timely, definitive data are critical to improve cancer survival rates and reduce treatment side effects (Pickle, Mason, Neil, Hoover, & Fraumeni, 1990; Roberson, 1994). Results from clinical trials would be useful to determine the efficacy of treatments for sites where cancer rates are high for the various racial/ethnic groups compared with the general population.

For almost all health care problems, morbidity and mortality rates are substantially higher for the ethnic minority group than for the non-minority population (Raczynski, 1997). The mortality rates for African Americans in most all age levels for both males and females exceed those of whites with some of these rates double or more (Raczynski, 1997). While income and other benefits that go along with income are factors accounting for excess disease outcomes for African Americans, about one-third of the excess mortality in one analysis was accounted for by risk factors, suggesting a

greater importance for African Americans across the country lies in learning better methods of preventing disease outcomes (Otten, Teutsch, Williamson, & Marks, 1990).

Relevant Related Literature

Clinical trials play a dominant role in clinical oncology today (Devita, Hellman, & Rosenberg, 1989). Despite the state-of-the-art cancer treatment, however, there is mounting concern that the benefits of this medical and scientific progress is not being equitably shared by or distributed to all segments of the U.S. population (Byrd & Clayton, 1992).

The fact that racial/ethnic groups are under-represented in cancer clinical trials is supported by a review of literature that showed that very few volunteers, and in most cases no racial/ethnic volunteers, are enrolled in clinical trials (Byrd & Clayton, 1992; Roberson, 1994). Under-representation was further evident in the Clinical Trials Program of the NCI, in which recruitment efforts yielded low volunteer accrual since the initiation of the program in 1955 (Meinert & Tonascia, 1986; Roberson, 1994). It was not until 1990 that the NCI directed specific attention to the problem of low participation of racial/ethnic volunteers. Through its Minority Community Clinical Oncology Program, the NCI sought to improve volunteer accruals primarily through historically minority colleges and institutions (Byrd & Clayton, 1992).

Under-representation of racial/ethnic volunteers in cancer clinical trials also surfaced and became a critical issue during the Congressional Hearings 1992 on the NCI Breast Cancer Prevention Trial (BCPT). Among one of the key issues was the failure to address the recruitment of adequate numbers of racial/ethnic women for participation in the study. Within a 2-year period, fewer than 2% of minority women were enrolled

(Payne, 1992). No strategic plan was in place to include these women or improve accrual rates.

Researchers at the Pennington Biomedical Research Center (Baton Rouge, Louisiana) have also experienced several obstacles in recruiting African Americans for clinical trials. One of the specific research studies that had major obstacles was known as the Estrogen Patch Study for women who were postmenopausal and Type II diabetic. The goal was to recruit 70 African American women however, 18 enrolled, and only 15 (4 Caucasians and 11 African Americans) completed the one-year study. The purpose of the study was to determine if risk factors for heart disease could be improved, whether or not body composition and fat distribution could be altered, and if the ability of the body to deal with the sugar in the blood could be improved using a hormone patch. Half of the women received an active hormone patch while the other half received a placebo (non-active hormone patch).

Another study that had difficulties in recruiting African Americans was Dietary Approaches to Stop Hypertension (DASH). DASH was a national multi-center trial sponsored by the National Lung and Blood Institute (Bethesda, Maryland). The study was conducted at the Pennington Biomedical Research Center and 4 other Centers: Duke University (Durham, North Carolina), Brigham and Women's Hospital (Boston, Massachusetts), Johns Hopkins University (Baltimore, Maryland), and Kaiser Permanente Coordinating Center (Portland, Oregon). The task for the Pennington Center was to recruit 100 percent African Americans while the other centers had goals of either 50 percent other/50 percent minority or 60 percent other/40 percent minority. DASH was an eleven-week feeding study that required volunteers to eat the dinner meal

at the Center and all other meals (breakfast, lunch, and snacks) packed to go. In addition, volunteers earned $600 after completing the eleven-week study.

Although hypertension is a disease that disproportionately affects African Americans, the obstacles faced in recruiting them for the DASH trial was a challenge. Some of the challenges included rescheduling appointments, changed their minds, or they did not show up for original or rescheduled appointments. Other challenges included what they were saying about the trial such as: "why are you only recruiting African Americans", or "what are they putting in the food", or " I do not eat my food cooked like that", and finally, "what are they doing with my blood". To try and alleviate some of these obstacles, strategies must be established to gain trust among African Americans. One way to gain trust was to participate in the clinical trial so that potential participants would feel more at ease. However, gaining trust by participating in the trial may not be enough especially when the majority of other staff members (Principal Investigator, Co-Principal Investigators, Medical Director, Clinic Supervisor, Nurses, Dietitians, and Research Associates) having direct contact with this targeted group were non-African American. Although the goal was to enroll 100 percent African Americans in the DASH study, permission was granted to enroll 10 Caucasians and Other to complete the trial with the required number of participants.

Other studies with obstacles in recruiting African Americans at the Pennington Center included: DASH2 (Fourteen-week feeding study), Diabetes Prevention Program (Six-year on-going intervention/drug trial), and Healthy Transitions (Four-year longitudinal study of perimenopausal women). The goal of the Healthy Transitions study for example, was to recruit 50 percent African American and 50 percent Caucasian women

and observe them before, during, and after menopause. However, out of 183 women recruited, only 42 or 23 percent were African American.

Currently, there are two clinical trials at the Pennington Biomedical Research Center requiring 100 percent African American participants. The first study, Maternity Obesity Management Study (MOMS) is a study for females age 16 and over who gained and retained an excess of 25 pounds or more of weight after delivery of their baby, and had no complications during pregnancy such as gestational diabetes. The recruitment goal of the study was to have 56 volunteers enrolled by March 2001. As of February 2001 all 6 volunteers previously enrolled had dropped out of the study. Despite many recruitment efforts such as: TV appearances, radio (live talk show), flyers and luncheons taken to physician offices, flyers in pediatric clinics, day care centers, beauty shops, and several other medical and non-medical entities, African American women who had scheduled appointments did not show up and/or rescheduled appointments, did not show up. The principal investigator therefore, requested permission from NIH and it was granted, to extend recruitment to all females meeting the study criteria.

The second study currently being recruited is the Health Improvement Program-for Teens (HIP-Teens). This study is for overweight African American girls age 11-15 with at least one overweight parent. The goal is to recruit 60 families using the Internet to interact with both groups to prevent weight loss through either behavioral change or nutritional education. There are 12 families currently enrolled with another 48 required to meet the recruitment goal of the study.

Researcher Biases

Some of the obstacles that result from researcher bias are frequently viewed by the researchers as obstacles that are due to the individuals or populations to be recruited into clinical trials (DuRant et al., 1992; Freeman, 1993; Haynes & Bernard, 1992; Jimenez & Jimenez, 1992; Nelson, 1994; Swanson & Ward, 1995; Wermeling & Selwitz, 1993). The biases of researchers and clinical investigators include failure to accommodate cultural and economic diversity of potential study participants, failure to recognize that restrictive studies do not fully assess safety and efficacy of new treatments or preventive interventions for all populations, claims that statistical power will be reduced if women and minorities are included, inaccurate beliefs that certain populations are not at risk for specific conditions or illnesses, and failure to establish research clinics in minority institutions (DuRant et al., 1992; Freeman, 1993; Jimenez and Jimenez, 1992; Lacey, 1993; Swanson & Ward, 1995; Wermeling & Selwitz, 1993).

Finally, one of the most common excuses for not including minorities in prevention and treatment trials is that they are "hard to reach" (Lacey, 1993; Swanson & Ward, 1995). This is the typical example of researcher insensitivity and discrimination: the population is defined as difficult and problematic, conveniently ignoring the fact that it is the life conditions of these populations that are problematic; not the people (Swanson & Ward, 1995).

CHAPTER 3

METHODS AND PROCEDURES

The purpose of this chapter was to describe the procedures used in the study, including sampling, data collection, and data analysis. These procedures were used to address the purpose of the study: to gain an understanding of the knowledge, attitudes, and beliefs African Americans have that support decisions to either participate or not participate in a clinical trial.

Population and Sample

The target population was defined as all African Americans age 18 and older who were potential participants in a clinical trial. The accessible population were all African Americans in the Pennington Biomedical Research Center Database from 1992-2000. The frame of the accessible population was established as those who were currently enrolled at the time of the study, previously participated, and those who did not participate in a clinical trial. The sample consisted of 100% of the defined accessible population frame.

Instrument

A modified version of the questionnaire (Appendix B) "Perceptions of Participation in Clinical Research" (McLean & Jensen, 1998) was utilized in conducting this study. Permission to modify and utilize the original questionnaire was granted in writing by the authors (Appendix C). The original questionnaire was modified due to the relevance of questions applicable to African Americans, length of the instrument, and the approximate time it would take to complete.

The modified version of the questionnaire consisted of 8 pages, 58 questions, and 7 sections. The first section consisted of 7 items to measure knowledge of clinical research processes, section two consisted of 8 items to measure perceptions of clinical research purposes and procedures, section three contained two parts: advantages (8 items and other) and disadvantages (6 items and other) for the individual of participation in clinical research trials, section four consisted of 6 questions to examine the characteristics of current and past participation in clinical research trials, section five contained 4 items to determine the exposure to selected experiences which are preliminary to participation in clinical research trials, section six contained 6 choices and other to measure the perceptions regarding the need for selected changes in preparation for participation in clinical research trials, and section seven consisted of 8 selected personal demographic characteristics including gender, age, marital status, education level, employment status, household income, distance from research center, and overall health status. Participants were assured of confidentiality and that there were no right or wrong answers in completing the survey instrument. The questionnaire began with the definition of a clinical trial and instructions for completion.

The original instrument from which the study instrument was adapted had been validated by expert panels. Because modifications were made for the purpose of the current study, a validity assessment for the study instrument was needed. Face validity of the instrument was established through a review by three professors at Louisiana State University (three from the School of Human Resource Education and Workforce Development, two active and one emeritus), and one professor from the Biostatistics Department, Pennington Biomedical Research Center.

Reliability of the instrument was assessed in September 2000 by conducting a field test with African Americans who were not a part of the study, but similar to those in the target population. The purpose of the field test was to determine what kind of feedback to expect from African Americans who would respond to the questionnaire in this study. Based on a favorable response from African Americans in the field test, the researcher concluded the questionnaire favorable for potential respondents in this study. Reliability of the scaled response sections of the instrument was estimated using Cronbach's Alpha internal consistency coefficient. This included sections I, II, III, and VI of the modified questionnaire.

The Cronbach's Alpha internal consistency coefficients were as follows:

Scale	Number of items	Cronbach's Alpha
Section I - Knowledge	7	.78
Section II - Perceptions	8	.81
Section III - Part I Advantages	8	.83
Section III - Part II Disadvantages	6	.85
Section VI - Ideas/Suggestions	6	.83

Data Collection

The questionnaire was mailed to 3302 African American adults (770 participants and 2532 nonparticipants) who were potential participants in a clinical trial at the Pennington Biomedical Research Center during the years of 1992-2000. A total of 117 questionnaires (49 participants and 68 nonparticipants) were returned undeliverable. Since the addresses in the database for participants and nonparticipants were up to 8

years past, the researcher believed that many participants and nonparticipants did not respond because they had moved and the forwarding order had expired.

Labels were printed and addressed to each participant and nonparticipant in the Pennington Biomedical Research Center database from 1992-2000. Questionnaires were mailed along with a self-addressed stamped envelope. A letter of introduction (Appendix A) accompanied the questionnaire. Along with instructions and guidelines, the letter stressed the importance of completing the survey. The questionnaires were coded by seven digits of non-repeated random numbers to allow follow-up for unreturned questionnaires. Participants were asked to return questionnaires within two weeks after receiving.

After the third week, questionnaires began to decrease in numbers and immediately follow-up began and continued for one month and nine days. Follow-up included calling and reminding potential participants that it was not too late to return questionnaires. Some questionnaires came back with a new address and they were resent locally as well as to those who had moved out-of-state. Some respondents completed and dropped-off questionnaires to the researcher at the Pennington Biomedical Research Center. A total of 386 (158 participants or 21 percent, and 228 nonparticipants or 9 percent) responded to the questionnaire.

Data Analysis

Data collected in this study was analyzed using the following procedures for each respective study objective:

- Objective one was to describe African Americans who were potential participants in clinical research trials on (a) knowledge of clinical research

processes, (b) perceptions of clinical research purposes and procedures, (c) advantages and disadvantages for the individual of participation in clinical research trials, (d) characteristics of current and past participation in clinical research trials, (e) exposure to selected experiences which are preliminary to participation in clinical research trials, (f) perceptions regarding the need for selected changes in preparation for participation in clinical research trials, and (g) selected personal demographic characteristics to include: gender, age, marital status, education level, employment status, household income, distance from research center, and overall health status.

The researcher used descriptive statistics (frequency, percentage, mean, standard deviation, range) and factor analysis for objective one. Sections one, two, three, and six of the instrument was collected as continuous (interval data). Sections four, five, and seven was collected as categorical (nominal and ordinal data).

- Objective two was to describe and compare African Americans who have participated in clinical research trials and those who have not participated in clinical research trials on each of the items in objective one listed above. An alpha level of .05 was used to determine significance throughout the study.

To describe the groups, the researcher used descriptive statistics (mean, standard deviation) and factor analysis for objective two. To compare the groups, the researcher used the independent samples t-test procedure and Chi-square statistical techniques as applicable.

- Objective three was to determine if a model existed that significantly increased the researcher's ability to correctly classify volunteers on their participation status in clinical research trials on each of the items in objective one listed above.

The researcher used discriminant analysis to accomplish objective three.

CHAPTER 4

FINDINGS

Knowledge of Clinical Research Processes

Findings presented in this chapter are organized by objectives of the study. The first objective was to describe African Americans who were potential participants in clinical research trials on their level of knowledge of clinical research processes. To measure the level of knowledge of clinical research processes, a seven item scale was used. The response scale utilized was a five-point Likert-type scale with values ranging from 1 = "Strongly Disagree" to 5 = "Strongly Agree". The middle point (3) on the scale did allow the respondents the option of an "Unsure" answer. To aid in the interpretation of this data, the researcher established an interpretive scale based on the responses available to the study participants. This scale had descriptions and corresponding values as follows: 1.00 to 1.50 = "Strongly Disagree;" 1.51 to 2.50 = "Disagree;" 2.51 to 3.49 = "Unsure;" 3.50 to 4.49 = "Agree;" and 4.50 to 5.00 = "Strongly Agree."

When the data from the responses to the seven statements on the scale were examined, the statement with which the respondents most strongly agreed was, "Volunteers can refuse to participate in a clinical trial" (mean = 4.61, SD = .67). This statement was classified using the interpretive scale as "Strongly Agree". The statement with which participants least agreed was, "Volunteers usually receive a cash stipend for participation in a clinical trial" (mean = 4.00, SD = .89). The mean response to this statement was classified in the "Agree" category. Overall, one statement in this scale

was classified as "Strongly Agree," and six statements were classified as "Agree" (see Table 1).

Table 1

Level of Knowledge of Clinical Research Trials of Potential African American Participants

Item	n	Mean[a]	SD	Classification[b]
Volunteers can refuse to participate in a clinical trial.	385[c]	4.61	.67	Strongly Agree
Clinical trials are needed to study the effects of treatments.	385[c]	4.46	.68	Agree
Volunteers can change their mind at any time and withdraw from a clinical trial.	384[d]	4.20	.98	Agree
Volunteers receive information needed to decide whether they want to take part in a clinical trial.	385[c]	4.10	1.03	Agree
Volunteers are told about the possible risks and benefits of taking part in a clinical trial.	386	4.08	.98	Agree
Volunteers are made aware of any possible complications or side effects of taking part in a clinical trial.	385[c]	4.02	1.01	Agree

(Table continues)

Volunteers usually receive a cash stipend for participation in a clinical trial.	385[c]	4.00	.89	Agree

[a]Response scale: 1 = strongly disagree; 2 = disagree; 3 = unsure, 4 = agree; 5 = strongly agree.
[b]Mean responses were classified using the following descriptors for specified value ranges: 1.00-1.50 = strongly disagree; 1.51-2.50 = disagree; 2.51-3.49 = unsure; 3.50-4.49 = agree; 4.50-5.00 = strongly agree.
[c]One respondent did not answer this item.
[d]Two respondents did not answer this item.

To further summarize the information regarding level of knowledge of clinical research processes, the researcher used factor analysis to determine if underlying constructs could be identified in the scale. The analysis procedure used was principal components analysis with a varimax rotation method.

The first step in conducting the factor analysis was to determine the optimum number of factors to be extracted from the scale. Using a combination of the latent root criterion, and the scree test criterion, the number of factors to be extracted was determined to be two. The results of the factor analysis including the factor, it's label based on the content of the items included in the factor, the percentage of variance explained by each factor, and factor loadings for each of the statements in each of the factors is presented in Table 2. The two sub-scales were labeled by the researcher as "Information Provided," and "Awareness." The first factor identified in the scale was information provided that related to knowledge of clinical research processes. Items in this factor included, "Volunteers are told about the possible risks and benefits of taking part in a clinical trial", "Volunteers are made aware of any possible complications or side effects of taking part in a clinical trial", "Volunteers receive information needed to decide

whether they want to take part in a clinical trial," and "Volunteers usually receive a cash stipend for participation in a clinical trial." The factor loadings ranged from a high of .90 to a low of .57 and explained 35.8 percent of the overall variance in the scale.

The second factor explained an additional 24.7 percent of the overall scale variance and included items related to awareness of clinical research processes. Items in this factor included, "Volunteers can change their mind at any time and withdraw from a clinical trial", "Volunteers can refuse to participate in a clinical trial," and "Clinical trials are needed to study the effects of treatments." The factor loadings ranged from a high of .83 to .48.

Table 2

Factor Analysis of Level of Knowledge of Clinical Research Trials of Potential African American Participants

Factor-Information Provided **(35.8% of variance explained)**	**Factor 1**	Factor 2
Volunteers are told about the possible risks and bene- fits of taking part in a clinical trial.	.90	.08
Volunteers are made aware of any possible complications or side effects of taking part in a clinical trial.	.86	.07
Volunteers receive information needed to decide whether they want to take part in a clinical trial.	.64	.32

(Table continues)

Volunteers usually receive a cash stipend for participation in a clinical trial.	.57	.31
Factor-Awareness **(24.7% of variance explained)**	Factor 1	**Factor 2**
Volunteers can change their mind at any time and withdraw from a clinical trial.	.02	.83
Volunteers can refuse to participate in a clinical trial.	.25	.77
Clinical trials are needed to study the effects of treatments.	.40	.48

After the two sub-scales and items to be included in each were identified, the researcher computed scale scores for each of the two identified sub-scales. These sub-scale scores were identified as the mean of the items included in each of the respective factors. For the first scale labeled "Information Provided," the individual subject mean scores ranged from a low of 4.00 to a high of 4.10 with an overall mean of 4.05 (SD = .76). Using the interpretive scale, this scale received an overall rating classified as "Agree." The second scale was "Awareness," and had individual subject means that ranged from 4.20 to 4.61. The overall mean score was 4.42 (SD = .58) which was classified in the "Agree" category. When the sub-scale scores were examined, the factor which received the highest mean score was the "Awareness" sub-scale (mean = 4.42, SD = .58) (see Table 3).

Table 3

Knowledge of Clinical Research Trials Sub-Scale Scores of Potential African American Participants

Sub-Scale	Items	Mean[a]	SD	Classification[b]	Range
Awareness	3	4.42	.58	Agree	4.20-4.61
Information Provided	4	4.05	.76	Agree	4.00-4.10

[a]Response scale: 1 = strongly disagree; 2 = disagree; 3 = unsure; 4 = agree; and 5 = strongly agree.
[b]Mean responses were classified using the following descriptors for specified value ranges: 1.00-1.50 = strongly disagree; 1.51-2.50 = disagree; 2.51-3.49 = unsure; 3.50-4.49 = agree; 4.50-5.00 = strongly agree.

Perceptions of Clinical Research Purposes and Procedures

Objective (1b) was to describe African Americans who were potential participants in clinical research trials on their perception of clinical research purposes and procedures. To measure the perception of clinical research purposes and procedures, an eight item scale was used. The response scale utilized was a five-point Likert-type scale with values ranging from 1 = "Strongly Disagree" to 5 = "Strongly Agree." The middle point (3) on the scale did allow the respondents the option of an "Unsure" answer. To aid in the interpretation of this data, the researcher established an interpretive scale based on the responses available to the study participants. This scale had descriptions and corresponding values as follows: 1.00 to 1.50 = "Strongly Disagree," 1.51 to 2.50 = "Disagree," 2.51 to 3.49 = "Unsure," 3.50 to 4.49 = "Agree," and 4.50 to 5.00 = "Strongly Agree."

When the data from the responses to the eight items on the scale were examined, the statement with which the participants most strongly agreed was, "Participation in a

clinical trial can help future generations" (mean = 4.46, SD = .65). This statement was classified using the interpretive scale as "Agree." The statement with which participants least agreed was, "Participation in a clinical trial can delay a disease" (mean = 3.19, SD = 1.15). The mean response to this statement was classified in the "Unsure" category. Overall, six items were classified as "Agree," and two items were classified as "Unsure."

Table 4

Perception of Clinical Research Trial Purposes and Procedures of Potential African American Participants

Item	n	Mean[a]	SD	Classification[b]
Participation in a clinical trial can help future generations.	386	4.46	.65	Agree
Clinical trials are a necessary way to learn about treatments.	385[c]	4.39	.77	Agree
The information in the consent form is important to help volunteers decide about participation in a clinical trial.	386	4.26	.81	Agree
It is important for people to take part in clinical trials.	386	4.24	.84	Agree
Participation in a clinical trial can help me and my family.	386	4.21	.80	Agree
Blood work is necessary in a clinical trial.	386	4.10	.93	Agree

(Table continues)

Participation in a clinical trial can prevent a disease.	386	3.24	1.17	Unsure
Participation in a clinical trial can delay a disease.	385[c]	3.19	1.15	Unsure

[a]Response scale: 1 = strongly disagree; 2 = disagree; 3 = unsure, 4 = agree; 5 = strongly agree.
[b]Mean responses were classified using the following descriptors for specified value ranges: 1.00-1.50 = strongly disagree; 1.51-2.50 = disagree; 2.51-3.49 = unsure; 3.50-4.49 = agree; 4.50-5.00 = strongly agree.
[c]One respondent did not answer this item.

To further summarize the information regarding level of perception of clinical research purposes and procedures, the researcher used factor analysis to determine if underlying constructs could be identified in the scale. The analysis procedure used was principal component analysis with a varimax rotation method.

The first step in conducting the factor analysis was to determine the optimum number of factors to be extracted from the scale. Using a combination of the latent root criterion, and the scree test criterion, the number of factors to be extracted was determined to be two. The results of the factor analysis including the factor, it's label based on the content of the items included in the factor, the percentage of variance explained by each factor, and factor loadings for each of the statements in each of the factors is presented in Table 5. The two sub-scales were labeled by the researcher as "Participation Benefits," and "Prevention." The first factor identified in the scale related to perceived benefits as a result of participation in clinical research trials. Items in this factor included, "Participation in a clinical trial can help future generations," "Participation in a clinical trial can help me and my family", "It is important for people to take part in clini-

cal trials", "Clinical trials are a necessary way to learn about treatments," "The information in the consent form is important to help volunteers decide about participation in a clinical trial", and "Blood work is necessary in a clinical trial." The factor loadings ranged from a high of .83 to a low of .54 and explained 41.4 percent of the overall variance in the scale.

The second factor explained an additional 23.6 percent of the overall scale variance and included items related to prevention as a result of participation in clinical research trials. Items in this factor included, "Participation in a clinical trial can delay a disease", and "Participation in a clinical trial can prevent a disease." The factor loadings ranged from a high of .93 to .91.

Table 5

Factor Analysis of Perception of Clinical Research Trial Purposes and Procedures of Potential African American Participants

Factor-Participation Benefits **(41.4% of variance explained)**	**Factor 1**	Factor 2
Participation in a clinical trial can help future genera-tions.	.83	.10
Participation in a clinical trial can help me and my family.	.79	.26
It is important for people to take part in clinical trials.	.79	.07

(Table continues)

Clinical trials are a necessary way to learn about treatments.	.77	.06
The information in the consent form is important to help volunteers decide about participation in a clinical trial.	.67	.08
Blood work is necessary in a clinical trial.	.54	.31
Factor- Prevention **(23.6% of variance explained)**	Factor 1	**Factor 2**
Participation in a clinical trial can delay a disease.	.11	.93
Participation in a clinical trial can prevent a disease.	.15	.91

After the two sub-scales and items to be included in each were identified, the researcher computed scale scores for each of the two identified sub-scales. These sub-scale scores were identified as the mean of the items included in each of the respective factors. For the first scale labeled "Participation Benefits," the individual subject mean scores ranged from a low of 4.09 to a high of 4.46 with an overall mean of 4.28, (SD = .60). Using the interpretive scale, this scale received an overall rating classified as "Agree." The second scale was "Prevention," and had individual subject means that ranged from 3.19 to 3.24. The overall mean score was 3.22 (SD = 1.09) which was classified in the "Unsure" category. When the sub-scale scores were examined, the factor which received the highest mean score was the "Participation Benefits" sub-scale (mean = 4.28, SD = .60) (see Table 6).

Table 6

Perception of Clinical Research Trial Purposes and Procedures Sub-Scale Scores of Potential African American Participants

Sub-Scale	Items	Mean[a]	SD	Classification[b]	Range
Participation Benefits	6	4.28	.60	Agree	4.09-4.46
Prevention	2	3.22	1.09	Unsure	3.19-3.24

[a]Response scale: 1 = strongly disagree; 2 = disagree; 3 = unsure; 4 = agree; and 5 = strongly agree.
[b]Mean responses were classified using the following descriptors for specified value ranges: 1.00-1.50 = strongly disagree; 1.51-2.50 = disagree; 2.51-3.49 = unsure; 3.50-4.49 = agree; 4.50-5.00 = strongly agree.

Advantages for the Individual of Participation in Clinical Research Trials

Objective (1c)was to describe African Americans who were potential participants in clinical research trials on perceived advantages for the individual of participation in clinical research trials. To measure the perceived advantages for the individual of participation in clinical research trials, an eight item scale was used. The response scale utilized was a five-point Likert-type scale with values ranging from 1 = "Strongly Disagree" to 5 = "Strongly Agree." The middle point (3) on the scale did allow the respondents the option of an "Unsure" answer. To aid in the interpretation of this data, the researcher established an interpretive scale based on the responses available to the study participants. This scale had descriptions and corresponding values as follows: 1.00 to 1.50 = "Strongly Disagree;" 1.51 to 2.50 = "Disagree;" 2.51 to 3.49 = "Unsure;" 3.50 to 4.49 = "Agree;" and 4.50 to 5.00 = "Strongly Agree."

When the data from the responses to the eight items on the scale were examined, the statement with which the participants most strongly agreed was, "Doing something

that will help others" (mean = 4.42, SD = .61). This statement was classified using the interpretive scale as "Agree." The statement with which participants least agreed was, "Getting free medications" (mean = 3.53, SD = 1.04). The mean response to this statement was classified in the "Agree" category. Overall, all eight items were classified in the "Agree" category as shown in Table 7.

Table 7

Perceived Advantages of Participation in Clinical Research Trials of Potential African American Participants

Item	n	Mean[a]	SD	Classification[b]
Doing something that will help others.	386	4.42	.61	Agree
Doing something positive for self.	383[c]	4.21	.82	Agree
Getting better care and follow-up (for example, with laboratory tests).	383[c]	4.20	.83	Agree
Receiving the newest treatment.	382[d]	3.93	.86	Agree
Helping to prevent a disease.	385[e]	3.73	1.00	Agree
Getting a cash stipend.	384[f]	3.73	1.01	Agree
Helping to delay a disease.	386	3.55	1.03	Agree
Getting free medication.	384[f]	3.53	1.04	Agree

[a]Response scale: 1 = strongly disagree; 2 = disagree; 3 = unsure, 4 = agree; 5 = strongly agree.
[b]Mean responses were classified using the following descriptors for specified value ranges: 1.00-1.50 = strongly disagree; 1.51-2.50 = disagree; 2.51-3.49 = unsure; 3.50-4.49 = agree; 4.50-5.00 = strongly agree.
[c]Three respondents did not answer this item.
[d]Four respondents did not answer this item.
[e]One respondent did not answer this item.
[f]Two respondents did not answer this item.

To further summarize the information regarding perceived advantages for the individual of participation in clinical research trials, the researcher used factor analysis to determine if underlying constructs could be identified in the scale. The analysis procedure used was principal components analysis with a varimax rotation method.

The first step in conducting the factor analysis was to determine the optimum number of factors to be extracted from the scale. Using a combination of the latent root criterion, the a´ priori criterion, and the scree test criterion, the number of factors to be extracted was determined to be one. The results of the factor analysis including the factor, it's label based on the content of the items included in the factor, the percentage of variance explained by each factor, and factor loadings for each of the items in the factor is presented in Table 8. Since only one factor was extracted, the varimax rotation method was not applicable. The sub-scale was labeled by the researcher as "Primary Benefits." The only factor identified in the scale related to the primary benefits of participation in clinical research trials. Items in this factor included, "Getting better care and follow-up (for example, with laboratory tests)", "Doing something positive for self," "Receiving the newest treatment", "Doing something that will help others", "Helping to delay a disease", "Helping to prevent a disease", "Getting free medications", and "Getting a cash stipend." The factor loadings ranged from a high of .79 to a low of .58 and explained 47.4 percent of the overall variance in the scale (see Table 8).

Table 8

Factor Analysis of Perceived Advantages of Participation in Clinical Research Trials of Potential African American Participants

Factor- Primary Benefits **(explained 47.4% of variance)**	Factor
Getting better care and follow-up (for example, with laboratory tests).	.79
Doing something positive for self.	.77
Receiving the newest treatment.	.70
Doing something that will help others.	.70
Helping to delay a disease.	.68
Helping to prevent a disease.	.65
Getting free medications.	.60
Getting a cash stipend.	.58

Since all the items loaded on one factor, the researcher computed an advantage scale score labeled as "Primary Benefits." This scale score was identified as the mean of the items included in the factor. The "Primary Benefits" scale had individual subject mean scores that ranged from a low of 3.53 to a high of 4.43 with an overall mean of 3.91 (SD = .61). Using the interpretive scale, this scale received an overall rating classified as "Agree.

In addition to the eight specified advantages, respondents were provided the opportunity to indicate an "Other" perceived advantage. If they did so, they were also asked to specify what this "Other" advantage was. The respondents' overall list of "Other" advantages to participation in clinical research trials were combined into the categories: participants (see Appendix D, question 24) and nonparticipants (see Appen-

dix E, question 24). There were nine respondents in the participant category that specified "Learn about medicine and body," and three specified "Meeting others" as other advantages to participation in clinical trials. In addition, there were eleven respondents in the nonparticipant category that specified "Knowledge obtained is beneficial", and five specified "If a clinical trial helps find a cure for a particular disease" as other advantages to participation in clinical trials.

Disadvantages for the Individual of Participation in Clinical Research Trials

Objective (1c, Part II) was to describe African Americans who were potential participants in clinical research trials on perceived disadvantages for the individual of participation in clinical research trials. To measure the perceived disadvantages for the individual of participation in clinical research trials, a six item scale was used. The response scale utilized was a five-point Likert-type scale with values ranging from 1 = "Strongly Disagree" to 5 = "Strongly Agree." The middle point (3) on the scale did allow the respondents the option of an "Unsure" answer. To aid in the interpretation of this data, the researcher established an interpretive scale based on the responses available to the study participants. This scale had descriptions and corresponding values as follows: 1.00 to 1.50 = "Strongly Disagree;" 1.51 to 2.50 = "Disagree;" 2.51 to 3.49 = "Unsure;" 3.50 to 4.49 = "Agree;" and 4.50 to 5.00 = "Strongly Agree."

When the data from the responses to the six items on the scale were examined, the statement with which the participants most strongly agreed was, "Experiencing side effects of the treatment" (mean = 3.26, SD = 1.10). This statement was classified using the interpretive scale as "Unsure." The statement with which participants least agreed was, "Being treated like a "guinea pig" (mean = 2.71, SD = 1.25). The mean response

to this statement was classified in the "Unsure" category. Overall, all six items were classified in the "Unsure" category (see Table 9).

Table 9

Perceived Disadvantages of Participation in Clinical Research Trials of Potential African American Participants

Item	n	Mean[a]	SD	Classification[b]
Experiencing side effects of the treatment.	384[c]	3.26	1.10	Unsure
Disrupting one's normal daily routine.	379[d]	3.15	1.19	Unsure
Having to miss work.	382[e]	2.99	1.27	Unsure
Having to arrange childcare.	373[f]	2.89	1.26	Unsure
Losing one's privacy.	384[c]	2.72	1.16	Unsure
Being treated like a "guinea pig."	384[c]	2.71	1.25	Unsure

[a]Response scale: 1 = strongly disagree; 2 = disagree; 3 = unsure, 4 = agree; 5 = strongly agree.
[b]Mean responses were classified using the following descriptors for specified value ranges: 1.00-1.50 = strongly disagree; 1.51-2.50 = disagree; 2.51-3.49 = unsure; 3.50-4.49 = agree; 4.50-5.00 = strongly agree.
[c]Two respondents did not answer this item.
[d]Seven respondents did not answer this item.
[e]Four respondents did not answer this item.
[f]Thirteen respondents did not answer this item.

To further summarize the information regarding perceived disadvantages for the individual of participation in clinical research trials, the researcher used factor analysis to determine if underlying constructs could be identified in the scale. The analysis procedure used was principal components analysis with a varimax rotation method.

The first step in conducting the factor analysis was to determine the optimum number of factors to be extracted from the scale. Using a combination of the latent root

criterion, the a´ priori criterion, and the scree test criterion, the number of factors to be extracted was determined to be one. The results of the factor analysis including the factor, it's label based on the content of the items included in the factor, the percentage of variance explained by the factor, and factor loadings for each of the items in the factor is presented in Table 10. Since only one factor was extracted, the varimax rotation method was not applicable. The sub-scale was labeled by the researcher as "Drawbacks." The only factor identified in the scale related to circumstances that would hinder participation in clinical research trials. Items in this factor included, "Having to miss work", "Disrupting one's normal daily routine", "Having to arrange childcare," "Experiencing side effects of the treatment", "Losing one's privacy", and "Being treated like a "guinea pig." The factor loadings ranged from a high of .80 to a low of .69 and explained 58.2 percent of the overall variance in the scale (see Table 10).

Table 10

Factor Analysis of Perceived Disadvantages of Participation in Clinical Research Trials of Potential African American Participants

Factor- Drawbacks **(explained 58.2% of variance)**	Factor
Having to miss work.	.80
Disrupting one's normal daily routine.	.80
Having to arrange childcare.	.77
Experiencing side effects of the treatment.	.76
Losing one's privacy.	.75
Being treated like a "guinea pig."	.69

Since all the items loaded on one factor, the researcher computed a disadvantage scale score. This scale score was identified as the mean of the items included in the factor. The disadvantage scale was labeled by the researcher as "Drawbacks." This scale had individual subject mean scores that ranged from a low of 2.69 to a high of 3.25 with an overall mean of 2.95 (SD = .92). Using the interpretive scale, this scale received an overall rating classified as "Unsure."

In addition to the six specified disadvantages, respondents were provided the opportunity to indicate an "Other" perceived disadvantage. If they did so, they were also asked to specify what this "Other" disadvantage was. The respondents overall list of "Other" disadvantages to participation in clinical research trials were combined into the categories: participants (see Appendix D, question 31) and nonparticipants (see Appendix E, question 31). There were ten respondents in the participant category that specified "Dates and times can't be changed or rescheduled, inconvenient," five specified "Forcing someone to overeat to maintain a specific weight; many studies are too long" and, four individuals specified "Trip to clinic" as other disadvantages for the individual of participation in clinical research trials. In addition, eleven nonparticipants specified "Risk to your health," seven specified "Getting to clinic," four specified "Time consuming; inconvenient," three specified "Overcoming past atrocities where African Americans were deliberately infected (i.e. syphilis virus)," and, three specified "Not knowing if you are receiving treatment or sugar pill" as other disadvantages for the individual of participation in clinical research trials.

Characteristics of Current and Past Participation in Clinical Research Trials

Objective one (d) was to describe African Americans who were potential participants in clinical research trials on characteristics of current and past participation in clinical research trials. Respondents were asked a series of six questions that were designed to accomplish this part of the descriptive objective. First, they were asked if they had ever been asked to participate in a clinical trial. More than half (n = 213, 55.3%) indicated that they had been asked to participate in a clinical trial (see Table 11). In addition, study participants were asked if they had previously participated in a clinical trial. Slightly more than a third of the participants (n = 145, 37.7%) indicated a response of "Yes" to this question. However, when asked if they were currently participating in a clinical trial, a total of 64 (16.7%) indicated that they were currently enrolled in a clinical research trial (see Table 11).

Those individuals who responded "No" to all three of the initial items asked above were asked if they would participate in clinical research trials in the future if they were invited to do so. Of the eligible respondents to this item, 111 (90.2%) indicated that they would participate in the future if they were asked (see Table 11).

Participants were also asked to report whether or not they had ever decided to decline participation in a clinical trial after they had been classified as eligible to be a research participant. The majority of the participants (n = 288, 78.3%) indicated a "No" response to this question. Respondents were provided a list of possible reasons for choosing not to participate in the research activity and were asked to identify the primary reason for their negative decision. The reason that was identified most often was,

Table 11

Clinical Research Trial Current and Past Participation Status of African Americans

Item	Yes		No		Total	
	n	%	n	%	n	%
Have you ever been asked to participate in a clinical trial?	213	55.3	172	44.7	385[a]	100
Have you previously participated in a clinical trial?	145	37.7	240	62.3	385[a]	100
Are you currently enrolled in a clinical trial?	64	16.7	320	83.3	384[b]	100
If you were asked to participate in a clinical trial in the future, would you participate?	111	90.2	12	9.8	123[c]	100
Have you ever decided not to participate in a clinical trial after being eligible?	80	21.7	288	78.3	368[d]	100

[a]One respondent did not answer this item.
[b]Two respondents did not answer this item.
[c]This item was not applicable for 263 respondents.
[d]Eighteen respondents did not answer this item.

"Changed jobs, schedule would not permit" (n = 20, 26.3%). Each of two other reasons were identified by 12 (15.8%) of the study participants. These reasons were, "Changed mind, due to fear" and "Live too far from the research center" (see Table 12). Seventeen of the respondents indicated that some "Other" reason was their primary reason for choosing not to participate. These individuals were also asked to specify what that

"Other" reason was. Some of the "Other" primary reasons for choosing not to participate was, "Busy schedule," and "Hours of participation were during work hours" (see Appendices D and E for a complete list).

Table 12

Primary Reason Cited for Not Participating by African Americans Who Were Eligible But Chose Not to Participate in Clinical Research Trials

Item	n	%
Changed jobs, schedule would not permit.	20	26.3
Changed mind, due to fear.	12	15.8
Live too far from research center.	12	15.8
Too much effort involved.	8	10.5
Too many lab tests required.	6	7.9
Work too far from research center.	1	1.3
Other[a] (please specify)	17	22.4
Total	76[b]	100

[a]A complete listing of other reasons reported by respondents is presented in Appendices D and E.
[b]Four respondents did not answer this item.

Exposure to Selected Experiences Which are Preliminary to Participation in Clinical Research Trials

Objective one (e) was to describe African Americans who were potential participants in clinical research trials based on exposure to selected experiences which are preliminary to participation in clinical research trials. Respondents were asked a series of four questions that were designed to accomplish this part of the descriptive objective.

First, they were asked if they received any verbal or written materials that described what the clinical trial was about and what they would need to do. More than half (n = 242, 66.5%) indicated that they did receive verbal or written materials that described what the clinical trial was about and what they would need to do (see Table 13). Second, study participants were asked if they talked to family or friends before making their decision to participate or not participate in a clinical research trial. More than half (n = 217, 59.6%) indicated that they did not talk to family or friends before making their decision to participate or not participate in a clinical research trial (see Table 13). Third, study participants were asked if they talked to their doctor before making their decision to participate or not participate in a clinical research trial. Two hundred ninety eight (81.6%) of study participants did not talk with their doctor before making their decision to participate or not participate in a clinical research trial (see Table 13). Finally, study participants were asked if they had a family history of the disease being researched that prompted their decision to participate or not participate in a clinical research trial. Slightly more than half (n = 184, 51.1%) indicated that they did not have a family history of the disease being researched that prompted their decision to participate or not participate in a clinical research trial as shown in Table 13.

In addition to the four specified exposures to selected experiences which are preliminary to participation in clinical research trials, respondents were provided the opportunity to indicate an "Other" exposure to selected experiences which are preliminary to participation in clinical research trials. The respondents overall list of other selected experiences were combined into the categories: participants (see Appendix D, question 42) and nonparticipants (see Appendix E, question 42). The responses varied for exam-

Table 13

Exposure to Selected Experiences by Potential African Americans Which are Preliminary to Participation in Clinical Research Trials

Item	Yes		No		Unsure		Total	
	n	%	n	%	n	%	n	%
Did you receive any verbal or written materials that described what the clinical trial was about?	242	66.5	98	26.9	24	6.6	364[a]	100
Did you talk to family or friends before making your decision?	133	36.5	217	59.6	14	3.8	364[a]	100
Did you talk to your doctor before making your decision?	55	15.1	298	81.6	12	3.3	365[b]	100
Did you have a family history of the disease being researched?	149	41.4	184	51.1	27	7.5	360[c]	100

[a]Twenty two respondents did not answer this item.
[b]Twenty one respondents did not answer this item.
[c]Twenty six respondents did not answer this item.

ple, the participant category had 17 respondents that specified "Having family history of disease," while 12 in the nonparticipant category specified "Never asked to participate" and another 12 nonparticipants specified "Did not fit profile," as other exposures to selected experiences which are preliminary to participation in clinical research trials.

Perceptions Regarding the Need for Selected Changes in Preparation for Participation in Clinical Research Trials

Objective one (f) was to describe African Americans who were potential participants in clinical research trials on their perception regarding the need for selected changes in preparation for participation in clinical research trials. To measure

perceptions regarding the need for selected changes in preparation for participation by African Americans in clinical research trials, a six item scale was used. The response scale utilized was a five-point Likert-type scale with values ranging from 1 = "Strongly Disagree" to 5 = "Strongly Agree." The middle point (3) on the scale did allow the respondents the option of an "Unsure" answer. To aid in the interpretation of this data, the researcher established an interpretive scale based on the responses available to the study participants. This scale had descriptions and corresponding values as follows: 1.00 to 1.50 = "Strongly Disagree;" 1.51 to 2.50 = "Disagree;" 2.51 to 3.49 = "Unsure;" 3.50 to 4.49 = "Agree;" and 4.50 to 5.00 = "Strongly Agree."

When the data from the responses to the six items on the scale were examined, the statement with which the participants most strongly agreed was, "Hearing about the good things that have been discovered from clinical trials" (mean = 4.37, SD = .76). This statement was classified using the interpretive scale as "Agree." The statement with which participants least agreed was, "Informational meeting about the clinical trial, presented by the nurse" (mean = 3.91, SD = .97). The mean response to this statement was classified in the "Agree" category (see Table 14).

To further summarize the perceptions regarding the need for selected changes in preparation for participation in clinical research trials, the researcher used factor analysis to determine if underlying constructs could be identified in the scale. The analysis procedure used was principal components analysis with a varimax rotation method.

The first step in conducting the factor analysis was to determine the optimum number of factors to be extracted from the scale. Using a combination of the latent root

Table 14

Perceptions Regarding the Need for Selected Changes in Preparation for Participation of Potential African Americans in Clinical Research Trials

Item	n	Mean[a]	SD	Classification[b]
Hearing about the good things that have been discovered from clinical trials.	381[c]	4.37	.76	Agree
Informational meeting about the clinical trial presented by the physician.	382[d]	4.27	.83	Agree
Talking to other African Americans who have taken part in clinical trials.	381[c]	4.18	.93	Agree
TV shows or videotapes with African Americans in clinical trials.	380[e]	4.00	1.01	Agree
Informational meeting about the clinical trial presented by African Americans.	381[c]	3.98	.99	Agree
Informational meeting about the clinical trial presented by the nurse.	381[c]	3.91	.97	Agree

[a]Response scale: 1 = strongly disagree; 2 = disagree; 3 = unsure, 4 = agree; 5 = strongly agree.
[b]Mean responses were classified using the following descriptors for specified value ranges: 1.00-1.50 = strongly disagree; 1.51-2.50 = disagree; 2.51-3.49 = unsure; 3.50-4.49 = agree; 4.50-5.00 = strongly agree.
[c]Five respondents did not answer this item.
[d]Four respondents did not answer this item.
[e]Six respondents did not answer this item.

criterion, the a´ priori criterion, and the scree test criterion, the number of factors to be extracted was determined to be one. The results of the factor analysis including the fac-

tor, it's label based on the content of the items included in the factor, the percentage of variance explained by the factor, and factor loadings for each of the items in the factor is presented in Table 15. Since only one factor was extracted, the varimax rotation method was not applicable. The sub-scale was labeled by the researcher as "Ideas/ Suggestions." The only factor identified in the scale related to ideas/suggestions for ways to help people learn more about clinical research trials. Items in this factor included, "Informational meeting about the clinical trial presented by African Americans," "TV shows or videotapes with African Americans in clinical trials", "Talking to other African Americans who have taken part in clinical trials", "Hearing about the good things that have been discovered from clinical trials", "Informational meeting about the clinical trial presented by the physician", and "Informational meeting about the clinical trial presented by the nurse." The factor loadings ranged from a high of .79 to a low of .64 and explained 55.1 percent of the overall variance in the scale (see Table 15).

Table 15

Factor Analysis of Perceptions Regarding the Need for Selected Changes in Preparation for Participation of Potential African Americans in Clinical Research Trials

Factor- Ideas/Suggestions **(explained 55.1% of variance)**	Factor
Informational meeting about the clinical trial, presented by African Americans.	.79
TV shows or videotapes with African Americans in clinical trials.	.78
Talking to other African Americans who have taken part in clinical trials.	.78

(Table continues)

Hearing about the good things that have been discovered from clinical trials.	.73
Informational meeting about the clinical trial, presented by the physician.	.72
Informational meeting about the clinical trial, presented by the nurse.	.64

Since all the items loaded on one factor, the researcher computed an ideas/ suggestion scale score. This scale score was identified as the mean of the items included in the factor. The "Ideas/Suggestions" scale had individual subject mean scores that ranged from a low of 3.92 to a high of 4.37 with an overall mean of 4.12 (SD = .68). Using the interpretive scale, this scale received an overall rating classified as "Agree."

In addition to the six specified perceptions regarding the need for selected changes in preparation for participation in clinical research trials, respondents were provided the opportunity to indicate an "Other" perceptions regarding the need for selected changes in preparation for participation in clinical research trials. The respondents overall list of other perceptions regarding the need for selected changes in preparation for participation in clinical research trials were combined into the categories: participants (see Appendix D, question 49) and nonparticipants (see Appendix E, question 49). The responses varied for example, nine respondents in the participant group specified "More advertising in African American periodicals, TV commercials with African Americans, post newsletters in African American communities." There were six respondents in the nonparticipant category that specified "Research about the test not just from African Americans but whomever has participated."

Demographic Characteristics

Objective one (g) was to describe African Americans who were potential participants in clinical research trials on selected personal demographic characteristics. Respondents were asked to provide personal background information in the following areas: (1) gender, (2) age, (3) marital status, (4) education level, (5) employment status, (6) household income, (7) distance from research center, and (8) overall health status.

- Gender. The largest group (n = 308, 79.8%) of respondents were female and 20.2% (n = 78) were male.
- Age. Respondents were given several age groups and asked to select the category that represented their age. The largest age group (n = 133, 34.5%) of respondents selected the 46-55 year group. The second largest age group (n = 107, 27.8%) of respondents was the 36-45 years group. The remaining age groups are shown in Table 16.

Table 16

Age Group of Potential African American Participants in a Clinical Research Trial

Item	n	%
< 18 years	1	.3
18-25 yrs.	23	6.0
26-35 yrs.	55	14.3
36-45 yrs.	107	27.8
46-55 yrs.	133	34.5
56-65 yrs.	51	13.2
66 yrs. and over	15	3.9

(Table continues)

Total	385[a]	100.0

[a]One respondent did not answer this item.

- Marital Status. Respondents were asked to choose whether they were married, divorced/separated, never married or widowed. The largest group (n = 192, 49.9%) of respondents indicated they were married. The second largest group (n = 98, 25.5%) of respondents were divorced/separated. Responses for all categories of marital status are shown in Table 17.

Table 17

Marital Status of Potential African American Participants in a Clinical Trial

Item	n	%
Married	192	49.9
Divorced/Separated	98	25.4
Never married	70	18.2
Widowed	25	6.5
Total	385[a]	100.0

[a]One respondent did not answer this item.

- Education. Respondents were given a list of education levels and asked to select the highest education level they had completed. The largest group (n = 151, 39.3%) of respondents indicated that they had completed 1-3 years of college/business or technical school. The second largest group (n = 82, 21.4%) of respondents had a college degree. The third largest group (n = 67, 17.5%) of respondents had post graduate degrees. The respondents' education levels are shown in Table 18.

Table 18

Education Level of Potential African American Participants in a Clinical Research Trial

Item	n	%
Grades 0-8	4	1.0
Some High School (HS)	27	7.0
HS diploma/GED	53	13.8
1-3 yrs. college/business/technical	151	39.3
College degree	82	21.4
Post graduate degree	67	17.5
Total	384[a]	100.0

[a]Two respondents did not answer this item.

- Employment status. Respondents were asked to indicate their present employment status. The largest group (n = 271, 70.4%) of respondents indicated they were employed full time. The employment status for all respondents is shown in Table 19.

Table 19

Employment Status of Potential African American Participants in Clinical Research Trials

Item	n	%
Full time	271	70.4
Unemployed	33	8.6
Retired	32	8.3
Part time	31	8.0
Medical disability	18	4.7

(Table continues)

Total	385[a]	100.0

[a]One respondent did not answer this item.

- Household income. Respondents were asked to indicate their approximate household income. The largest group (n = 76, 20.5%) of respondents indicated a house- hold income in the $20,000 - $29,999 range. The second largest group (n = 67, 18.1%) of respondents indicated a household income of $70,000 and up. The third largest group (n = 62, 16.7%) of respondents indicated a household income of $10,000 - $19,999 per year. Household income of respondents is presented in Table 20.

Table 20

Household Income of Potential African American Participants in a Clinical Research Trial

Item	n	%
< $10,000 per year	52	14.0
$10,000 - $19,999	62	16.7
$20,000 - $29,999	76	20.5
$30,000 - $39,999	42	11.3
$40,000 - $49,999	30	8.1
$50,000 - $59,999	42	11.3
$70,000 and above	67	18.1
Total	371[a]	100.0

[a]Fifteen respondents did not answer this item.

- Distance from Respondents Domicile to Research Center. Respondents were asked to indicate the approximate distance from their domicile to

the research center from a list of specified distances. The largest group (n = 115, 30.4%) of respondents indicated that they lived within 15 miles of the research center. One hundred two (27.0%) of respondents indicated that they lived within 7 miles of the research center (see Table 21).

Table 21

Distance to the Research Center from Domicile Reported by Potential African American Participants in a Clinical Research Trial

Item	n	%
Within 3 miles	57	15.0
Within 7 miles	102	27.0
Within 15 miles	115	30.4
Within 20 miles	52	13.8
More than 20 miles	52	13.8
Total	378[a]	100.0

[a]Eight respondents did not answer this item.

- Distance from Respondents Worksite to the Research Center. Respondents were also asked to report the approximate distance from their worksite to the research center. The largest group (n = 99, 30.2%) of respondents indicated that their worksite was within 7 miles of the research center. The second largest group (n = 78, 23.8%) of respondents indicated that they worked within 15 miles of the research center. The third largest group (n = 61, 18.6%) of respondents indicated that they worked with 3 miles of the research center (see Table 22).

Table 22

Distance to the Research Center from Worksite Reported by Potential African American Participants in a Clinical Research Trial

Item	n	%
At Research Center	13	4.0
Within 3 miles	61	18.6
Within 7 miles	99	30.2
Within 15 miles	78	23.8
Within 20 miles	35	10.6
More than 20 miles	42	12.8
Total	328[a]	100.0

[a]Fifty eight respondents did not answer this item.

- Overall Health Status. Respondents were asked to indicate the item that best described their current health status. The largest group (n = 152, 39.5%) of respondents indicated that they were in "Good" health. The second largest group (n = 126, 32.7%) of respondents indicated they were in "Very Good" health. The health status of respondents is shown in Table 23.

Table 23
Overall Health Status of Potential African American Participants in a Clinical Research Trial

Item	n	%
Good	152	39.5
Very Good	126	32.7
Excellent	65	16.9

(Table continues)

Fair	36	9.4
Poor	6	1.6
Total	385[a]	100.0

[a]One respondent did not answer this item.

Objective Two

Objective two (a) of the study was to describe and compare African Americans who have participated in clinical research trials and those who have not participated in clinical research trials on selected perceptual and demographic measures. The first of these measures was knowledge of clinical research processes. The first step in this process was to describe the research respondents on their knowledge of clinical research trials. As identified previously, knowledge was measured using seven items to which respondents were asked to respond using a five point Likert-type scale. The item with which the participant group most strongly agreed was "Volunteers can refuse to participate in a clinical trial" (Mean = 4.73) (see Table 24). The item with which participants were found to exhibit the lowest level of agreement was "Volunteers are made aware of any possible complications or side effects of taking part in a clinical trial" (Mean = 4.17). The nonparticipants in the study reported the highest level of agreement with the same item as the participant group. This item was "Volunteers can refuse to participate in a clinical trial" (Mean = 4.52). However, the item with which nonparticipants expressed the lowest level of agreement was "Volunteers usually receive a cash stipend for participation in a clinical trial" with a mean rating of 3.81 (see Table 24).

Table 24

Level of Knowledge of Clinical Research Trials Among African Americans by Participation Status

Item	Participants		Nonparticipants	
	Mean[a]	SD	Mean[a]	SD
Volunteers can refuse to participate in a clinical trial.	4.73	.48	4.52	.76
Clinical trials are needed to study the effects of treatments.	4.50	.64	4.44	.70
Volunteers can change their mind at any time and withdraw from a clinical trial.	4.46	.83	4.02	1.03
Volunteers receive information needed to decide whether they want to take part in a clinical trial.	4.45	.73	3.86	1.14
Volunteers usually receive a cash stipend for participation in a clinical trial.	4.28	.78	3.81	.90
Volunteers are told about the possible risks and benefits of taking part in a clinical trial.	4.20	.91	4.00	1.01
Volunteers are made aware of any possible complications or side effects of taking part in a clinical trial.	4.17	.95	3.91	1.03

[a]Response scale: 1 = strongly disagree; 2 = disagree; 3 = unsure, 4 = agree; 5 = strongly agree. Mean responses were classified using the following descriptors for specified value ranges: 1.00-1.50 = strongly disagree; 1.51-2.50 = disagree; 2.51-3.49 = unsure; 3.50-4.49 = agree; 4.50-5.00 = strongly agree.

To accomplish the second aspect of this objective, the researcher needed to compare the participants and nonparticipants on their level of knowledge of clinical research trials. However, to conduct individual statistical comparisons on each of the items used in the knowledge scale would have created an unacceptably inflated alpha level due to the inflation of experiment-wise error which occurs when related items are used in multiple statistical comparisons. Therefore, to accomplish this task, the researcher utilized the underlying constructs and the corresponding sub-scale scores derived from the factor analysis in objective one of the study.

When these two sub-scale scores were compared by participation status of the study respondents using the independent samples t-test procedure, the results showed that the two groups were significantly different on both of the sub-scale scores. On the first knowledge factor which was labeled by the researcher as "Information Provided," the participant group had a mean score of 4.28 (SD = .63) and the nonparticipant group had a mean score of 3.90 (SD = .81) ($t_{384} = 4.943$, $p < .001$). This indicated that the participant group reported significantly higher levels of agreement with items in the "Information Provided" knowledge factor than did the nonparticipants.

For the second knowledge factor, labeled as "Awareness" by the researcher, similar results were found ($t_{384} = 4.093$, $p < .001$). With the mean values for the groups identified as 4.57 (SD = .48) for the participant group and 4.32 (SD = .63) for the nonparticipant group, these results also indicated that the participants had a significantly higher level of agreement with the items in the "Awareness" knowledge factor than did the nonparticipants.

Objective two (b) of the study was to describe and compare African Americans who have participated in clinical research trials and those who have not participated in clinical research trials on their perceptions of clinical research purposes and procedures. The first step in objective two (b) was to describe the research respondents on their perceptions of clinical research purposes and procedures. As identified previously, perceptions were measured using eight items to which respondents were asked to respond using a five point Likert-type scale. The item with which the participant group most strongly agreed was "Participation in a clinical trial can help future generations" (Mean = 4.59) (see Table 25). The item with which participants were found to exhibit the lowest level of agreement with was "Participation in a clinical trial can prevent a disease" (Mean = 3.35). The item with which the nonparticipants most strongly agreed was "Clinical trials are a necessary way to learn about treatments" (Mean = 4.39) (see Table 25). The item with which the nonparticipants expressed the lowest level of agreement was "Participation in a clinical trial can delay a disease" (Mean = 3.07).

Table 25

Perceptions of Clinical Research Trials Among African Americans by Participation Status

Item	Participants		Nonparticipants	
	Mean[a]	SD	Mean[a]	SD
Participation in a clinical trial can help future generations.	4.59	.55	4.37	.70
Participation in a clinical trial can help me and my family.	4.39	.70	4.09	.85

(Table continues)

Clinical trials are a necessary way to learn about treatments.	4.39	.76	4.39	.77
The information in the consent form is important to help volunteers decide about participation in a clinical trial.	4.37	.75	4.18	.84
It is important for people to take part in clinical trials.	4.32	.79	4.18	.86
Blood work is necessary in a clinical trial.	4.30	.84	3.96	.97
Participation in a clinical trial can delay a disease.	3.37	1.11	3.07	1.16
Participation in a clinical trial can prevent a disease.	3.35	1.13	3.16	1.20

[a]Response scale: 1 = strongly disagree; 2 = disagree; 3 = unsure, 4 = agree; 5 = strongly agree. Mean responses were classified using the following descriptors for specified value ranges: 1.00-1.50 = strongly disagree; 1.51-2.50 = disagree; 2.51-3.49 = unsure; 3.50-4.49 = agree; 4.50-5.00 = strongly agree.

To accomplish the second aspect of objective two (b), the researcher needed to compare the participants and nonparticipants on their perceptions of clinical research purposes and procedures. However, to conduct individual statistical comparisons on each of the items used in the perception scale would have created an unacceptably inflated alpha level due to the inflation of experiment-wise error. Therefore, to accomlish this task, the researcher utilized the underlying constructs and the corresponding sub-scale scores derived from the factor analysis in objective one.

When these two sub-scale scores were compared by participation status of the study respondents using the independent samples t-test procedure, the results showed that the two groups were significantly different on both of the sub-scale scores. On the

first perception factor which was labeled by the researcher as "Participation Benefits," mean scores included for the participant group 4.39 (SD = .54) and for the nonparticipant group 4.19 (SD = .62)($t_{384} = 3.249$, $p = .001$). This indicated that the participant group reported significantly higher levels of agreement with items in the "Participation Benefits" perception factor than did the nonparticipants.

For the second perception factor, labeled as "Prevention" by the researcher, similar results were found ($t_{384} = 2.241$, $p = .026$). With the mean values for the groups identified for the participant group as 3.37 (SD = 1.07) and for the nonparticipant group 3.12 (SD = 1.09) these results also indicated that the participants had a significantly higher level of agreement with the items in the "Prevention" perception factor than did the nonparticipants.

Objective two (c) Part I was to describe and compare African Americans who have participated in clinical research trials and those who have not participated in clinical research trials on perceived advantages for the individual of participation in clinical research trials. The first step in this process was to describe the research respondents on their perceived advantages for the individual of participation in clinical research trials. As identified previously, the perceived advantages were measured using eight items to which respondents were asked to respond using a five point Likert-type scale. The item with which the participant group most strongly agreed was "Doing something that will help others" (Mean = 4.51) (see Table 26). The item with which participants were found to exhibit the lowest level of agreement with was "Getting free medications" (Mean = 3.61). The nonparticipants in the study reported the highest level of agreement with the same item as the participant group. This item was "Doing something that will help

others" (Mean = 4.36). However, the item with which nonparticipants expressed the lowest level of agreement was "Helping to delay a disease" with a mean rating of 3.46 (see Table 26).

Table 26

Perceived Advantages of Clinical Research Trials Among African Americans by Participation Status

Item	Participants		Nonparticipants	
	Mean[a]	SD	Mean[a]	SD
Doing something that will help others.	4.51	.58	4.36	.62
Getting better care and follow-up (for example, with laboratory tests).	4.40	.79	4.06	.83
Doing something positive for self.	4.38	.74	4.09	.86
Getting a cash stipend.	3.99	.97	3.54	.99
Receiving the newest treatment.	3.88	.90	3.96	.83
Helping to prevent a disease.	3.78	1.02	3.70	.98
Helping to delay a disease.	3.70	1.05	3.46	1.01
Getting free medications.	3.61	1.14	3.48	.97

[a]Response scale: 1 = strongly disagree; 2 = disagree; 3 = unsure, 4 = agree; 5 = strongly agree. Mean responses were classified using the following descriptors for specified value ranges: 1.00-1.50 = strongly disagree; 1.51-2.50 = disagree; 2.51-3.49 = unsure; 3.50-4.49 = agree; 4.50-5.00 = strongly agree.

To accomplish the second aspect of Part I of this objective, the researcher needed to compare the participants and nonparticipants on their perceived advantages for the individual of participation in clinical research trials. However, to conduct individual statis-

tical comparisons on each of the items used in the advantage scale would have created an unacceptably inflated alpha level due to the inflation of experiment-wise error. Therefore, to accomplish this task, the researcher utilized the underlying construct and the corresponding sub-scale score derived from the factor analysis conducted in objective one.

When this sub-scale score was compared by participation status of the study respondents using the independent samples t-test procedure, the results showed that the two groups were significantly different. There was one advantage factor labeled by the researcher as "Primary Benefits" with a mean score of 4.03 (SD = .60) for the participant group and 3.83 (SD = .61) for the nonparticipant group ($t_{384} = 3.179$, $p = .002$). This indicates that the participant group reported significantly higher levels of agreement with items in the "Primary Benefits" advantage factor than did the nonparticipants.

Objective two (c) Part II was to describe and compare African Americans who have participated in clinical research trials and those who have not participated in clinical research trials on perceived disadvantages for the individual of participation in clinical research trials. The first step in this process was to describe the research respondents on their perceived disadvantages for the individual of participation in clinical research trials. The perceived disadvantages were measured using six items to which respondents were asked to respond using a five point Likert-type scale. The item with which the participant group most strongly agreed was "Experiencing side effects of the treatment" (Mean = 2.99) (see Table 27). The item with which participants were found to exhibit the lowest level of agreement with was "Being treated like a "guinea pig" (Mean = 2.31). The nonparticipants in the study reported the highest level of agreement with the same item as the participant group. This item was "Experiencing side effects of the treatment"

(Mean = 3.46). However, the item with which nonparticipants expressed the lowest level of agreement was "Losing one's privacy" with a mean rating of 2.94 (see Table 27).

Table 27

Perceived Disadvantages of Clinical Research Trials Among African Americans by Participation Status

Item	Participants		Nonparticipants	
	Mean[a]	SD	Mean[a]	SD
Experiencing side effects of the treatment.	2.99	1.08	3.46	1.07
Disrupting one's normal daily routine.	2.90	1.24	3.32	1.13
Having to miss work.	2.74	1.33	3.17	1.20
Having to arrange child-care.	2.58	1.28	3.11	1.20
Losing one's privacy.	2.39	1.11	2.94	1.14
Being treated like a "guinea pig."	2.31	1.16	2.98	1.23

[a]Response scale: 1 = strongly disagree; 2 = disagree; 3 = unsure, 4 = agree; 5 = strongly agree. Mean responses were classified using the following descriptors for specified value ranges: 1.00-1.50 = strongly disagree; 1.51-2.50 = disagree; 2.51-3.49 = unsure; 3.50-4.49 = agree; 4.50-5.00 = strongly agree.

To accomplish the second aspect of Part II of this objective, the researcher needed to compare the participants and nonparticipants on their perceived disadvantages for the individual of participation in clinical research trials. However, to conduct individual statistical comparisons on each of the items used in the disadvantage scale would have created an unacceptably inflated alpha level due to the inflation of experiment-wise error. Therefore, to accomplish this task, the researcher utilized the underlying construct

and the corresponding sub-scale score derived from the factor analysis conducted in objective one.

When this sub-scale score was compared by participation status of the study respondents using the independent samples t-test procedure, the results showed that the two groups were significantly different on their perceptions regarding disadvantages for the individual of participation in clinical research trials. There was one disadvantage factor labeled by the researcher as "Drawbacks" with a mean score of 2.65 (SD = .87) for the participant group and 3.16 (SD = .90) for the nonparticipant group ($t_{384} = -5.595$, $p < .001$). This indicates that the nonparticipant group reported significantly higher levels of agreement with the items in the "Drawbacks" disadvantage factor than did the participants.

Objective two (d) was to describe and compare African Americans who have participated in clinical research trials and those who have not participated in clinical research trials on characteristics of their current and past participation in clinical research trials. A total of six aspects of clinical research participation status were examined as part of this objective. The first aspect was whether or not the respondents had ever been asked to participate in a clinical trial. For the participant group, the majority ($n = 126$, 79.7%) of respondents indicated that they had been asked to participate in a clinical trial. In contrast, the majority of nonparticipants ($n = 140$, 61.7%) indicated that they had not been asked to participate in a clinical trial (see Table 28).

The next part of this objective was to compare the participant and nonparticipant groups on whether or not they had ever been asked to participate in a clinical trial. This was accomplished using the Chi-square test of independence to determine if the two

Table 28

Crosstabulation of Clinical Research Trial Participation Status and Whether or Not African Americans Indicated That They Had Ever Been Asked to Participate

Have you ever been asked to participate in a clinical trial?	Participation Status	
	Participant	Nonparticipant
Yes	126 79.7%	87 38.3%
No	32 20.3%	140 61.7%
Total	158 100%	227 100%

Note. $\chi^2_{(1)} = 64.67$, $p < .001$

variables (whether or not they had participated and whether or not they had ever been asked to participate) were independent. The resulting calculated Chi-square value ($\chi^2_{(1)} = 64.67$, $p < .001$) indicated that the variables were not independent. The nature of the association between the variables was such that a greater proportion of the participants indicated that they had been asked to participate while a greater proportion of the nonparticipants indicated they had not been asked to participate.

The second aspect of characteristics of current and past participation in clinical research trials was, whether or not the respondents had previously participated in a clinical trial. For the participant group, the majority ($n = 114$, 72.2%) of respondents indicated that they had previously participated in a clinical trial. In contrast, the majority of nonparticipants ($n = 196$, 86.3%) indicated that they had not previously participated in a clinical trial (see Table 29).

Table 29

Crosstabulation of Clinical Research Trial Participation Status and Whether or Not African Americans Indicated That They Had Previously Participated

Have you previously participated in a clinical trial?	Participation Status	
	Participant	Nonparticipant
Yes	114 72.2%	31 13.7%
No	44 27.8%	196 86.3%
Total	158 100%	228 100%

Note. $\chi^2_{(1)} = 135.77, p < .001$

The next part of this objective was to compare the participant and nonparticipant groups on whether or not they previously participated in a clinical trial. This was accomplished using the Chi-square test of independence to determine if the two variables (whether or not they participated and whether or not they had previously participated) were independent. The resulting calculated Chi-square value ($\chi^2_{(1)} = 135.77, p < .001$) indicates that the variables were not independent. The nature of the association between the variables was such that a greater proportion of the participants (72.2%) indicated that they previously participated while a greater proportion of the nonparticipants (86.3%) indicated they had not previously participated.

The third aspect of characteristics of current and past participation in clinical research trials was, whether or not the respondents were currently enrolled in a clinical trial. For the participant group, approximately one third ($n = 53$, 33.5%) of respondents indicated they were currently enrolled in a clinical trial. In contrast, fewer of the

nonparticipants (n = 11, 4.9%) indicated that they were not currently enrolled in a clinical trial (see Table 30).

Table 30

Crosstabulation of Clinical Research Trial Participation Status and Whether or Not African Americans Indicated That They Were Currently Enrolled

Are you currently enrolled in a clinical trial?	Participation Status	
	Participant	Nonparticipant
Yes	53 33.5%	11 4.9%
No	105 66.5%	215 95.1%
Total	158 100%	226 100%

Note. $\chi^2_{(1)} = 55.06$, $p < .001$

The next part of this objective was to compare the participant and nonparticipant groups on whether or not they were currently enrolled in a clinical trial. This was accomplished using the Chi-square test of independence to determine if the two variables (whether or not they had participated and whether or not they were currently enrolled) were independent. The resulting calculated Chi-square value ($\chi^2_{(1)} = 55.06$, $p < .001$) indicated that the variables were not independent. The nature of the association between the variables was such that a greater proportion of the participants (33.5%) indicated that they were currently enrolled in a clinical trial while a greater proportion of the nonparticipants (95.1%) indicated they were not currently enrolled in a clinical trial.

The fourth aspect of characteristics of current and past participation in clinical research trials was, "If you said "No" to ever been, previously, or currently enrolled in a clinical trial, and you were asked to participate in a clinical trial in the future, would you

participate?" This was accomplished using the Chi-square test of independence to determine if the two variables (whether or not they had participated and whether or not they would participate in a future clinical trial, if asked to do so) were independent. The resulting calculated Chi-square value ($\chi^2_{(1)} = .07$, $p = .79$) was not significant, indicating that the two variables were independent.

The fifth aspect of characteristics of current and past participation in clinical research trials was whether or not the respondents had ever decided not to participate in a clinical trial after being eligible. For the participant group, less than one fourth ($n = 24$, 15.6%) of respondents indicated that they had decided not to participate in a clinical trial after being eligible. In contrast, more than one fourth of nonparticipants ($n = 56$, 26.2%) indicated that they had decided not to participate in a clinical trial after being eligible (see Table 31).

Table 31

Crosstabulation of Clinical Research Trial Participation Status and Whether or Not African Americans Decided Not to Participate After Being Eligible

Have you ever decided not to participate in a clinical trial after being eligible?	Participation Status	
	Participant	Nonparticipant
Yes	24 15.6%	56 26.2%
No	130 84.4%	158 73.8%
Total	154 100%	214 100%

Note. $\chi^2_{(1)} = 5.90$, $p = .015$

The next part of this objective was to compare the participant and nonparticipant groups on whether or not they ever decided not to participate in a clinical trial after

being eligible. This was accomplished using the Chi-square test of independence to determine if the two variables (whether or not they had participated and whether or not they ever decided not to participate in a clinical trial after being eligible) were independent. The resulting calculated Chi-square value ($\chi^2_{(1)} = 5.90$, $p = .015$) was significant, indicating that the variables were not independent. The nature of the association between the variables was such that a smaller proportion of the participants (15.6%) indicated they decided not to participate in a clinical trial after being eligible while a greater proportion of the nonparticipants (26.2%) indicated they had decided not to participate in a clinical trial after being eligible.

The sixth aspect of characteristics of current and past participation in clinical research trials was to select the primary reason respondents decided not to participate in a clinical trial after being eligible. For the participant group, the largest group ($n = 5$, 25.0%) of respondents indicated "Other" as the primary reason they decided not to participate in a clinical trial after being eligible. For the nonparticipants, the largest group ($n = 17$, 30.4%) of respondents indicated "Changed jobs, schedule would not permit" (see Table 32) as their primary reason for deciding not to participate after being eligible. There was a total of 76 individuals responding to this aspect of clinical research participation status of which 17 indicated "Other" as their reason for not participating. Refer to Appendices D and E (question number 37) for a complete listing of participant and nonparticipant responses.

The next part of this objective was to compare the participant and nonparticipant groups on responses to the question, "If yes, what is the primary reason that you decided not to participate in a clinical trial." Table 32 clearly indicates that the numbers required

Table 32

Crosstabulation of Clinical Research Trial Participation Status and If Yes, Primary Reason African Americans Decided Not to Participate

If yes, what is the primary reason that you decided not to participate in the clinical trial?	Participation Status	
	Participant	Nonparticipant
Other[a]	5 25.0%	12 21.4%
Changed jobs, schedule would not permit	3 15.0%	17 30.4%
Live too far	3 15.0%	9 16.0%
Too much effort involved	3 15.0%	5 8.9%
Too many lab tests required	3 15.0%	3 5.4%
Changed mind, due to fear	2 10.0%	10 17.9%
Work too far	1 5.0%	-0-
Total	20 100%	56 100%

[a]See Appendices D and E for a complete list of other reasons reported by respondents.

to conduct the Chi-square test of independence were not adequate and therefore, no reason to run the test to determine if the two variables (whether or not they had participated and primary reason decided not to participate) were independent.

Objective two (e) was to describe and compare African Americans who have participated in clinical research trials and those who have not participated in clinical research trials based on their exposure to selected experiences which are preliminary to participa-

tion in clinical research trials. A total of four selected experiences preliminary to participation in clinical research trials were examined as part of this objective. The first experience was whether or not the respondents received any verbal or written materials that described what the clinical trial was about and what needed to be done. For the participant group, the majority (n = 137, 88.4%) of respondents indicated that they received verbal or written materials that described what the clinical trial was about and what needed to be done. In contrast, only slightly more than half of the nonparticipants (n = 105, 50.2%) indicated that they had received verbal or written materials that described what the clinical trial was about and what was needed to be done (see Table 33).

Table 33

Crosstabulation of Clinical Research Trial Exposures and Whether or Not African Americans Indicated They Received Any Verbal or Written Materials

Did you receive any verbal or written materials that described what the clinical trial was about and what you needed to do?	Participation Status	
	Participant	Nonparticipant
Yes	137 88.4%	105 50.2%
No	10 6.5%	88 42.1%
Unsure	8 5.1%	16 7.7%
Total	155 100%	209 100%

Note. $\chi^2_{(2)} = 62.34$, $p < .001$

The next part of this objective was to compare the participant and nonparticipant groups on whether or not they received any verbal or written materials that described what the clinical trial was about and what needed to be done. This was accomplished using the Chi-square test of independence to determine if the two variables (whether or not they participated and whether or not they received any verbal or written materials that described what the clinical trial was about and what needed to be done) were independent. The resulting Chi-square value ($\chi^2_{(2)} = 62.34$, $p < .001$) indicated that the variables were not independent. The nature of the association between the variables was such that a greater proportion of the participants indicated that they had received verbal or written materials that described what the clinical trial was about and what needed to be done while a greater proportion of the nonparticipants indicated that they had not received any verbal or written materials describing what the clinical trial about and what was needed to be done.

The second exposure to selected experiences which are preliminary to participation in clinical research trials was whether or not respondents talked to family or friends before making their decision to participate or not participate in a clinical trial. For the par- ticipant group, almost half ($n = 75$, 48.1%) of respondents indicated that they talked to family or friends before making their decision to participate or not participate in a clinical trial. In contrast, only slightly more than one fourth of the nonparticipants ($n = 98$, 27.9%) indicated that they talked to family or friends before making their decision to participate or not participate in a clinical trial (see Table 34).

Table 34

Crosstabulation of Clinical Research Trial Exposures and Whether or Not African Americans Indicated They Talked to Family or Friends Before Making Their Decision to Participate or Not Participate

Did you talk to family or friends before making your decision to participate or not participate?	Participation Status	
	Participant	Nonparticipant
Yes	75 48.1%	58 27.9%
No	77 49.4%	140 67.3%
Unsure	4 2.5%	10 4.8%
Total	156 100%	208 100%

Note. $\chi^2_{(2)} = 15.93, p < .001$

The next part of this objective was to compare the participant and nonparticipant groups on whether or not they talked to family or friends before making their decision to participate or not participate in a clinical trial. This was accomplished using the Chi-square test of independence to determine if the two variables (whether or not they had participated and whether or not they talked to family or friends before making their decision to participate or not participate) were independent. The resulting calculated Chi-square value ($\chi^2_{(2)} = 15.93, p < .001$) indicated that the variables were not independent. The nature of the association between the variables was such that more of the participants indicated that they talked to family or friends before making their decision to participate or not participate while the majority of the nonparticipants indicated they did not talk to family or friends before making their decision to participate or not participate in a clinical trial.

The third exposure to selected experiences which are preliminary to participation in clinical research trials was whether or not the respondents talked to their doctor before making their decision to participate or not participate in a clinical trial. For the participant group, less than one fifth (n = 29, 18.6%) of respondents indicated that they talked to their doctor before making their decision to participate or not participate in a clinical trial. Slightly more than one tenth of the nonparticipants (n = 26, 12.4%) indicated that they talked to their doctor before making their decision to participate or not participate in a clinical trial (see Table 35).

Table 35

Crosstabulation of Clinical Research Trial Exposures and Whether or Not African Americans Indicated They Talked to Their Doctor Before Making Their Decision to Participate or Not Participate

Did you talk to your doctor before making your decision to participate or not participate?	Participation Status	
	Participant	Nonparticipant
Yes	29 18.6%	26 12.4%
No	122 78.2%	176 84.2%
Unsure	5 3.2%	7 3.3%
Total	156 100%	209 100%

Note. $\chi^2_{(2)} = 2.64$, $p = .27$

The next part of this objective was to compare the participant and nonparticipant groups on whether or not they talked to their doctor before making their decision to participate or not participate in a clinical trial. This was accomplished using the Chi-

square test of independence to determine if the two variables (whether or not they had participated and whether or not they talked to their doctor before making the decision to partici- pate or not participate in a clinical trial) were independent. The resulting calculated Chi-square value ($\chi^2_{(2)} = 2.64$, $p = .27$) was not significant, indicating that the two variables were independent.

The fourth exposure to selected experiences which are preliminary to participation in clinical research trials was whether or not the respondents had a family history of the disease being researched that prompted their decision to participate or not participate in a clinical trial. For the participant group, almost half ($n = 71$, 47.0%) of the respondents indicated that they had a family history of the disease being researched that prompted their decision to participate or not participate in a clinical trial. In addition, a little more than a third of the nonparticipants ($n = 78$, 37.3%) indicated that they had a family history of the disease being researched that prompted their decision to participate or not participate in a clinical trial (see Table 36).

The next part of this objective was to compare the participant and nonparticipant groups on whether or not they had a family history of the disease being researched that prompted their decision to participate or not participate. This was accomplished using the Chi-square test of independence to determine if the two variables (whether or not they had participated and whether or not they had a family history of the disease being researched that prompted their decision to participate or not participate in a clinical trial) were independent. The resulting calculated Chi-square value ($\chi^2_{(2)} = 3.67$, $p = .16$) was not significant, indicating that the two variables were independent.

Table 36

Crosstabulation of Clinical Research Trial Exposures and Whether or Not African Americans Indicated They Had a Family History of the Disease That Prompted Their Decision to Participate or Not Participate

Did you have a family history of the disease being researched that prompted your decision to participate or not participate?	Participation Status	
	Participant	Nonparticipant
Yes	71 47.0%	78 37.3%
No	71 47%	113 54.1%
Unsure	9 6.0%	18 8.6%
Total	151 100%	209 100%

Note. $\chi^2_{(2)} = 3.67$, $p = .16$

Objective two (f) was to describe and compare African Americans who have participated in clinical research trials and those who have not participated in clinical research trials on their perceptions regarding the need for selected changes in preparation for participation in clinical research trials. The first step in this process was to describe the research respondents on their perceptions regarding the need for selected changes in preparation for participation in clinical research trials. The perceptions regarding the need for selected changes in preparation for participation in clinical research trials were measured using six items to which respondents were asked to respond using a five point Likert-type scale. The item with which the participant group most strongly agreed was, "Hearing about the good things that have been discovered from clinical trials" (Mean = 4.39) (see Table 37). The item which participants were found to exhibit the lowest level

of agreement with was, "Informational meeting about the clinical trial presented by African Americans" (Mean = 4.00). The nonparticipants in the study reported the highest level of agreement with the same item as the participant group. This item was "Hearing about the good things that have been discovered from clinical trials" (Mean = 4.35) (see Table 37). However, the item with which nonparticipants expressed the lowest level of agreement was, "Informational meeting about the clinical trial presented by the nurse" (Mean = 3.82).

To accomplish the second aspect of this objective, the researcher needed to compare the participants and nonparticipants on their perceptions regarding the need for selected changes in preparation for participation in clinical research trials. However, to conduct individual statistical comparisons on each of the items individually would have created an unacceptably inflated alpha level due to the inflation of experiment-wise error. Therefore, to accomplish this task, the researcher utilized the underlying construct and the corresponding sub-scale score derived from the factor analysis reported in objective one.

When the sub-scale score for perceptions regarding the need for selected changes in preparation for participation in clinical research trials was compared by participation status of respondents using the independent samples t-test procedure, the results showed that the two groups were not significantly different ($t_{381} = 1.176$, $p = .24$). There was one scale score regarding the perceived need for selected changes in preparation for participation in a clinical research trial factor labeled by the researcher as "Ideas/Sugges-

Table 37

Perceptions Regarding the Need for Selected Changes in Preparation for Clinical Research Trials Among African Americans by Participation Status

Item	Participants		Nonparticipants	
	Mean[a]	SD	Mean[a]	SD
Hearing about the good things that have been discovered from clinical trials.	4.39	.79	4.35	.75
Informational meeting about the clinical trial presented by the physician.	4.39	.69	4.18	.90
Talking to other African Americans who have taken part in clinical trials.	4.17	.92	4.19	.94
Informational meeting about the clinical trial presented by the nurse.	4.05	.94	3.82	.99
TV shows or videotapes with African Americans in clinical trials.	4.01	1.00	4.00	1.01
Informational meeting about the clinical trial presented by African Americans.	4.00	.97	3.96	1.00

[a]Response scale: 1 = strongly disagree; 2 = disagree; 3 = unsure, 4 = agree; 5 = strongly agree. Mean responses were classified using the following descriptors for specified value ranges: 1.00-1.50 = strongly disagree; 1.51-2.50 = disagree; 2.51-3.49 = unsure; 3.50-4.49 = agree; 4.50-5.00 = strongly agree.

tions" with a mean score of 4.17 (SD = .63) for the participant group and 4.08 (SD = .70) for the nonparticipant group.

Objective two g (i) was to describe and compare African Americans who have participated in clinical research trials and those who have not participated in clinical research trials based on their gender. The majority (n = 121, 76.6%) of the respondents

in the participant group were female and the majority (n = 187, 82.0%) of the respondents in the nonparticipant group were female (see Table 38).

Table 38

Description of Participants and Nonparticipants in Clinical Research Trials by Gender Among African Americans

Gender	Participants		Nonparticipants	
	n	%	n	%
Female	121	76.6	187	82.0
Male	37	23.4	41	18.0
Total	158	100.0	228	100.0

Note. $\chi^2_{(1)} = 1.71$, $p = .20$

The second aspect of this objective was to compare the participant and nonparticipant groups based on gender. This was accomplished using the Chi-square test of independence to determine if the two variables (whether or not they participated and whether they were male or female) were independent. The resulting calculated Chi-square value ($\chi^2_{(1)} = 1.71$, $p = .20$) was not significant, indicating that the two variables were independent.

Objective two g (ii) was to describe and compare African Americans who have participated in clinical research trials and those who have not participated in clinical research trials based on their age. The first aspect was to describe the participant and nonparticipant groups based on age. The largest number (n = 67, 42.4%) of the respondents in the participant group were in the 46-55 year age group. The largest number (n = 70, 30.8%) of the respondents in the nonparticipant group were in the 36-45 year age group. The second largest number (n = 37, 23.4%) of respondents in the

participant group were in the 36-45 year age group. The second largest number (n = 66, 29.1%) of the respondents in the nonparticipant group were in the 46-55 year age group (see Table 39).

Table 39

Description of Participants and Nonparticipants in Clinical Research Trials by Age Among African Americans

Age Group	Participants		Nonparticipants	
	n	%	n	%
< 18 years	1	0.6	0	0.0
18-25 years	12	7.6	11	4.8
26-35 years	11	7.0	44	19.4
36-45 years	37	23.4	70	30.8
46-55 years	67	42.4	66	29.1
56-65 years	25	15.8	26	11.5
66 years and over	5	3.2	10	4.4
Total	158	100.0	227[a]	100.0

Note. $\chi^2_{(6)} = 21.02$, $p = .002$

[a]One respondent did not answer this item.

The next part of this objective was to compare the participant and nonparticipant groups on whether or not they participated in clinical research trials based on age. This was accomplished using the Chi-square test of independence to determine if the two variables (whether they participated and age group) were independent. The resulting calculated Chi-square value ($\chi^2_{(6)} = 21.02$, $p = .002$) indicated that the variables were not independent. The nature of the association between the variables was such that a greater proportion of the participants were in the 46-55 year and the 56-65 year age categories

while a greater proportion of the nonparticipants were in the 26-35 year and the 36-45 year age range categories.

Objective two g (iii) was to describe and compare African Americans who have participated in clinical research trials and those who have not participated in clinical research trials based on their marital status. The first aspect was to describe the participant and nonparticipant groups based on marital status. Half (n = 79, 50.0%) of the respondents in the participant group indicated they were married. Approximately half (n = 113, 49.8%) of the respondents in the nonparticipant group indicated they were married. The next largest group (n = 36, 22.8%) of the respondents in the participant group indicated they were divorced/separated. More than one fourth (n = 62, 27.3%) of the respondents in the nonparticipant group indicated they were divorced/separated (see Table 40).

The second aspect of this objective was to compare the participant and nonparticipant groups on whether or not they participated in clinical research trials based on marital status. This was accomplished using the Chi-square test of independence to determine if the two variables (whether they participated and whether they were married, divorced/ separated, never married, or widowed) were independent. The resulting calculated Chi-square value ($\chi^2_{(3)} = 1.56$, $p = .67$) was not significant, indicating that the two variables were independent.

Objective two g (iv) was to describe and compare African Americans who have participated in clinical research trials and those who have not participated in clinical research trials based on their education level. The first aspect was to describe the participant and nonparticipant groups based on education level. Less than one third (n = 47,

Table 40

Description of Participants and Nonparticipants in Clinical Research Trials by Marital Status Among African Americans

Marital Status	Participants		Nonparticipants	
	n	%	n	%
Married	79	50.0	113	49.8
Divorced/Separated	36	22.8	62	27.3
Never Married	31	19.6	39	17.2
Widowed	12	7.6	13	5.7
Total	158	100.0	227[a]	100.0

Note. $\chi^2_{(3)} = 1.56$, $p = .67$

[a]One respondent did not answer to item.

29.9%) of the respondents in the participant group indicated 1-3 years college, business or technical school education level. Almost half (n = 104, 45.8%) of the respondents in the nonparticipant group indicated 1-3 years college, business or technical school education level. Almost one fourth (n = 38, 24.2%) of the respondents in the participant group indicated they had college degrees. Less than one fifth (n = 44, 19.4%) of the respondents in the nonparticipant group indicated they had college degrees (see Table 41).

The next part of this objective was to compare the participant and nonparticipant groups on their level of education. This was accomplished using the Chi-square test of independence to determine if the two variables (whether they participated and education level) were independent. The resulting calculated Chi-square value ($\chi^2_{(5)} = 13.47$, $p = .02$) indicated that the variables were not independent. The nature of the association

Table 41

Description of Participants and Nonparticipants in Clinical Research Trials by Education Level Among African Americans

Education Level	Participants		Nonparticipants	
	n	%	n	%
Grades 0-8	3	2.0	1	0.4
Some High School	11	7.0	16	7.0
High School Diploma/GED	22	14.0	31	13.7
1-3 years college, business or technical school	47	29.9	104	45.8
College degree	38	24.2	44	19.4
Post graduate degree	36	22.9	31	13.7
Total	157[a]	100.0	227[b]	100.0

Note. $\chi^2_{(5)} = 13.47$, $p = .02$
[a]One respondent did not answer to item.
[b]One respondent did not answer to item.

between the variables was such that a greater proportion of the participants reported college degree and post graduate degree as their highest level of education completed. Among the nonparticipants, a greater proportion indicated 1-3 years college, business or technical school as their highest level of education completed.

Objective two g (v) was to describe and compare African Americans who have participated in clinical research trials and those who have not participated in clinical research trials based on their employment status. The first aspect was to describe the participant and nonparticipant groups based on employment status. The majority (n = 111, 70.3%) of the respondents in the participant group were employed full time. Like-

wise, the majority (n = 160, 70.5%) of the respondents in the nonparticipant group were employed full time (see Table 42).

Table 42

Description of Participants and Nonparticipants in Clinical Research Trials by Employment Status Among African Americans

Employment Status	Participants		Nonparticipants	
	n	%	n	%
Employed full time	111	70.3	160	70.5
Employed part-time	12	7.6	19	8.4
Retired	13	8.2	19	8.4
Unemployed	17	10.8	16	7.0
Medical disability	5	3.1	13	5.7
Total	158	100.0	227[a]	100.0

Note. $\chi^2_{(4)} = 2.88$, $p = .58$

[a]One respondent did not answer this item.

The second aspect of this objective was to compare the participant and nonparticipant groups based on employment status. This was accomplished using the Chi-square test of independence to determine if the two variables (whether they participated and whether they were employed full time, part-time, retired, unemployed, or medically disabled) were independent. The resulting calculated Chi-square value ($\chi^2_{(4)} = 2.88$, $p = .58$) was not significant, indicating that the two variables were independent.

Objective two g (vi) was to describe and compare African Americans who have participated in clinical research trials and those who have not participated in clinical research trials based on their approximate household income. The first aspect was to describe the participant and nonparticipant groups based on approximate household in-

come. The largest number (n = 37, 24.2%) of the respondents in the participant group reported an approximate household income range of $70,000 and over per year. The largest number (n = 48, 22.0%) of the respondents in the nonparticipant group reported an approximate household income in the range of $20,000 - $29,999 per year (see Table 43).

Table 43

Description of Participants and Nonparticipants in Clinical Research Trials by Household Income Among African Americans

Household Income	Participants		Nonparticipants	
	n	%	n	%
< $10,000 per year	17	11.0	35	16.1
$10,000 - $19,999	24	15.7	38	17.4
$20,000 - $29,999	28	18.3	48	22.0
$30,000 - $39,999	16	10.5	26	11.9
$40,000 - $49,999	13	8.5	17	7.8
$50,000 - $59,999	18	11.8	24	11.0
$70,000 and above	37	24.2	30	13.8
Total	153[a]	100.0	218[b]	100.0

Note. $\chi^2_{(6)} = 8.02$, $p = .24$

[a]Five respondents did not answer this item.

[b]Twenty respondents did not answer this item.

The second aspect of this objective was to compare the participant and nonparticipant groups on approximate household income. This was accomplished using the Chi-square test of independence to determine if the two variables (whether they participated and level of household income) were independent. The resulting calculated Chi-square

value ($\chi^2_{(6)} = 8.02$, $p = .24$) was not significant, indicating that the two variables were independent.

Objective two g (vii) part I was to describe and compare African Americans who have participated in clinical research trials and those who have not participated in clinical research trials based on distance they lived from the research center. The first aspect was to describe the participant and nonparticipant groups based on distance lived from the research center. The largest number ($n = 49$, 31.6%) of respondents in the participant group indicated that they lived within 15 miles of the research center. Likewise, the largest number ($n = 66$, 29.6%) of respondents in the nonparticipant group lived within 15 miles of the research center (see Table 44).

Table 44

Description of Participants and Nonparticipants in Clinical Research Trials by Distance Live From Research Center Among African Americans

Distance Live from Research Center	Participants		Nonparticipants	
	n	%	n	%
Within 3 miles	27	17.4	30	13.4
Within 7 miles	41	26.4	61	27.4
Within 15 miles	49	31.6	66	29.6
Within 20 miles	19	12.3	33	14.8
> 20 miles	19	12.3	33	14.8
Total	155[a]	100.0	223[b]	100.0

Note. $\chi^2_{(4)} = 1.96$, $p = .74$
[a]Three respondents did not answer this item.
[b]Five respondents did not answer this item.

The next part of this objective was to compare the participant and nonparticipant groups based on distance they lived from the research center. This was accomplished

using the Chi-square test of independence to determine if the two variables (whether they participated and distance lived from the research center) were independent. The resulting calculated Chi-square value ($\chi^2_{(4)} = 1.96$, $p = .74$) was not significant, indicating that the two variables were independent.

Objective two g (vii) part II was to describe and compare African Americans who have participated in clinical research trials and those who have not participated in clinical research trials based on distance they worked from the research center. The first aspect was to describe the participant and nonparticipant groups based on distance worked from the research center. The largest number ($n = 49$, 35.5%) of the respondents in the participant group worked within 7 miles of the research center and the two response categories with the largest numbers ($n = 50$, 26.3% each) of the respondents in the nonparticipant group worked within 7-15 miles of the research center (see Table 45).

The next part of this objective was to compare the participant and nonparticipant groups based on distance worked from the research center. This was accomplished using the Chi-square test of independence to determine if the two variables (whether they participated and distance worked from the research center) were independent. The resulting calculated Chi-square value ($\chi^2_{(5)} = 12.29$, $p = .03$) indicated that the variables were not independent. The nature of the association between the variables was such that greater proportions of the participants indicated that they worked at the research center and within 7 miles of the center. In contrast, among the nonparticipants, greater propor-

Table 45

Description of Participants and Nonparticipants in Clinical Research Trials by Distance Work From Research Center Among African Americans

Distance Work from Research Center	Participants		Nonparticipants	
	n	%	n	%
At research center	10	7.2	3	1.6
Within 3 miles	25	18.1	36	19.0
Within 7 miles	49	35.5	50	26.3
Within 15 miles	28	20.3	50	26.3
Within 20 miles	11	8.0	24	12.6
> 20 miles	15	10.9	27	14.2
Total	138[a]	100.0	190[b]	100.0

Note. $\chi^2_{(5)} = 12.29$, $p = .03$
[a]Ten respondents did not answer to this item.
[b]Thirty eight respondents did not answer to this item.

tions indicated that they worked within 15 miles, within 20 miles, and more than 20 miles from the research center.

Objective two g (viii) was to describe and compare African Americans who have participated in clinical research trials and those who have not participated in clinical research trials based on overall health status. The first aspect was to describe the participant and nonparticipant groups based on overall health status. The largest number (n = 55, 34.8%) of respondents in the participant group indicated their overall health was good. The largest number (n = 97, 42.7%) of respondents in the nonparticipant group indicated their overall health was good (see Table 46).

Table 46

Description of Participants and Nonparticipants in Clinical Research Trials by Overall Health Status Among African Americans

Overall Health Status	Participants		Nonparticipants	
	n	%	n	%
Good	55	34.8	97	42.7
Very Good	54	34.2	72	31.7
Excellent	32	20.2	33	14.5
Fair	17	10.8	19	8.4
Poor	0	0.0	6	2.7
Total	158	100.0	227[a]	100.0

Note. $\chi^2_{(4)} = 8.20$, $p = .09$

[a]One respondent did not answer to this item.

The next part of this objective was to compare the participant and nonparticipant groups based on their overall health status. This was accomplished using the Chi-square test of independence to determine if the two variables (whether they participated and overall health status) were independent. The resulting calculated Chi-square value ($\chi^2_{(4)} = 8.20$, $p = .09$) was not significant, indicating that the two variables were independent.

Objective Three

Objective three of the study was to determine if a model existed that significantly increased the researcher's ability to correctly classify subjects on their participation status in clinical research trials based on (1) knowledge of clinical research processes, (2) perceptions of clinical research purposes and procedures, (3) advantages and disadvantages for the individual of participation in clinical research trials, (4) characteristics of current and past participation in clinical research trials, (5) exposure to selected experi-

ences which are preliminary to participation in clinical research trials, (6) perceptions regarding the need for selected changes in preparation for participation in clinical research trials, and (7) the following selected personal demographic characteristics: (i) gender, (ii) age, (iii) marital status, (iv) education level, (v) employment status, (vi) household income, (vii) distance from research center, and (viii) overall health status.

To accomplish objective three of the study, the researcher examined the data for the existence of a statistically significant discriminant model. This model included all available information and was for the purpose of maximizing the researcher's ability to correctly classify subjects on the outcome measure of whether or not African Americans participated in a clinical research trial. In addition, this model included all summary perceptual items measured in the study as well as selected demographic information.

The alpha level was established a´priori at .05 and substantive significance of the discriminant model in this study was defined as a 25% improvement over chance, the acceptable margin for a two category variable (Barrick and Warmbrod, 1988).

The Discriminant Model

The first step in examining the discriminant model was to compare the groups on each of the independent variables. This information is presented in Table 47. Comparisons were made using the one-way analysis of variance procedure. Of the 43 factors on which comparisons were made, the groups (participants and nonparticipants) were found to be significantly different on 16 variables. The variables on which the groups were most different were: knowledge factor one ("Information Provided"),

Table 47

Comparison of Mean Values for Discriminating Variables in the Model by Participation Status Among African Americans

Discriminating Variable	Group		F ratio	p
	Participants	Nonparticipants		
VERBALY (Did you receive any verbal materials, Yes)	m 1.90 sd .30	m 1.54 sd .50	51.90	<.01
VERBALN (Did you receive any verbal materials, No)	1.06 .23	1.37 .48	44.25	<.01
AGEGRP4 (46-55 years)	.48 .50	.25 .43	18.22	<.01
AGEGRP2 (26-35 years)	.06 .25	.25 .43	17.96	<.01
KFACTOR1 (Information Provided)	4.22 .66	3.85 .79	17.31	<.01
DISADVAN (Drawbacks)	2.74 .84	3.17 .92	16.20	<.01
KFACTOR2 (Awareness)	4.58 .47	4.33 .58	16.17	<.01
FAMILYY (Did you talk to family, Yes)	1.46 .50	1.24 .43	15.70	<.01
PFACTOR1 (Participation Benefits)	4.40 .54	4.18 .55	10.53	.001
FAMILYN (Did you talk to family, No)	1.52 .50	1.70 .46	9.22	.003

(Table continues)

WORK7 (Within 7 miles)	m .40 sd .49	m .24 sd .43	8.62	.004
ADVAN (Primary Benefits)	3.98 .61	3.79 .55	7.72	.00
WIDOWED (Marital Status)	1.07 .26	1.02 .13	5.33	.02
PFACTOR2 (Prevention)	3.34 1.07	3.05 1.05	5.24	.023
SOMECOLL (1-3 yrs. College)	.32 .47	.45 .50	5.20	.02
HEALTH STATUS	2.31 .86	2.52 .89	4.27	.04
POSTGRAD (Post graduate)	.23 .43	.15 .35	3.72	.06
HISTORYY (Did you have a family history, Yes)	1.47 .50	1.36 .48	3.59	.06
WORK20 (Within 20 miles)	.06 .25	.13 .33	3.10	.08
WORK15 (Within 15 miles)	.20 .40	.28 .45	2.63	.11
LIVE3 (Within 3 miles)	.17 .38	.11 .31	2.20	.14
LESS10 (Household income < $10,000/year)	.08 .27	.13 .34	2.00	.16
WORKMORE (> 20 miles)	.09 .29	.14 .35	1.75	.19
AGEGRP3 (36-45 years)	.27 .45	.35 .48	1.67	.20
LIVE20 (Within 20 miles)	.13 .34	.18 .39	1.47	.23

(Table continues)

UNEMPLOY (Unemployed)	m 1.04 sd .20	m 1.02 sd .13	1.29	.26
RETIRED (Employment status)	1.05 .22	1.02 .15	1.23	.27
DOCTORY (Did you talk to your doctor, Yes)	1.15 .36	1.11 .31	1.23	.27
HISTORYN (Did you have a family history, No)	1.48 .50	1.54 .50	.87	.35
COLLEGE (College degree)	.26 .44	.22 .41	.62	.43
RECRUIT (Ideas/Suggestions)	4.14 .65	4.08 .64	.61	.44
LIVEMORE (More than 20 miles)	.10 .31	.13 .34	.54	.46
PARTTIME (Employment status)	1.07 .26	1.10 .30	.53	.47
GENDER	1.77 .43	1.80 .40	.48	.49
TEN20 (Household income, $10-$19,999/year)	.15 .35	.18 .38	.48	.49
DIVORCED (Marital status)	1.23 .43	1.27 .44	.40	.53
THIRTY40 (Household income, $30-$39,999/year)	.12 .33	.15 .35	.36	.55
LIVE15 (Within 15 miles)	.32 .47	.30 .46	.22	.64

(Table continues)

DOCTORN (Did you talk to your doctor, No)	m 1.83 sd .38	m 1.85 sd .36	.17	.68
AGEGRP5 (56-65 years)	.10 .30	.08 .28	.12	.73
DISABIL (Medical disability)	1.02 .13	1.01 .11	.08	.77
TWENTY30 (Household income, $20-$29,999/year)	.19 .40	.21 .41	.07	.79
SINGLE (Marital status)	1.19 .39	1.19 .40	.03	.86

knowledge factor two ("Awareness"), disadvantage factor ("Drawbacks"), whether or not they responded "Yes" to the question "Did you receive any verbal or written materials that described what the clinical trial was about and what you would need to do,"whether or not they responded "No" to the question "Did you receive any verbal or written materials that described what the clinical trial was about and what you would need to do,"whether or not they responded "Yes" to the question "Did you have a family history of the disease being researched that prompted your decision to participate or not participate," whether or not they responded "No" to the question "Did you have a family history of the disease being researched that prompted your decision to participate or not participate, whether or not they were in the 26-35 year age group, and whether or not they were in the 46-55 year age group.

After comparing the discriminating variable means, the next step in conducting a discriminant analysis was to examine the independent variables to be included in the analysis for the presence of multicollinearity. Several techniques are available for con-

ducting this assessment, however, Lewis-Beck (1980) indicates that the preferred method for assessing multicollinearity is to, "Regress each independent variable on all the other independent variables" (p. 60). This procedure takes into account the relationship of each of the independent variables with all of the other independent variables. If any of the cumulative R^2 values are near 1.0, there is high multicollinearity. It is also important to note that values which are considered to be high in multicollinearity are more stringent for studies which have small sample sizes, while larger sample sizes reduce the seriousness of the consequences of multicollinearity. When the cumulative R^2 was checked for each of the independent variables regressed on all the other included independent variables, no instances of excessive multicollinearity were found.

In the third step, the computed standardized canonical discriminant function coefficients were examined. The centroids for the groups were determined to be .75 for the participant group and -.56 for the nonparticipant group. A total of 7 factors entered the discriminant model and produced an overall canonical correlation of $\underline{R} = .544$. This indicated that the combination of the 7 factors in the model explained a total of 29.6% (R^2) of the variability in whether or not African Americans participated in clinical research trials.

The factors which were found to have the highest standardized coefficients were (1) knowledge factor 2 labeled by the researcher as "Awareness", (2) disadvantage factor labeled by the researcher as "Drawbacks", (3) "Did you receive any verbal or written materials that described what the clinical trial was about and what you would need to do" (whether or not they responded "Yes"), (4) whether or not their marital status was Widowed, (5) whether or not they were in the 26-35 year age group, (6)

whether or not they were in the 46-55 year age group, and (7) whether or not their place of employment was within 15 miles of the Pennington Center. Each of the factors that entered this model was statistically significant. When the structure coefficients were examined for substantive significance, five of the factors were found to meet the criteria of substantive significance. This criteria includes all factors which are one-half or larger of the magnitude of the largest structure coefficient. However, since the purpose of this model was to increase the researcher's ability to correctly classify subjects on their participation status in clinical research trials, all variables were retained that met the statistical criteria for inclusion (see Table 48).

Table 48

Summary Data for Stepwise Discriminant Analysis (n = 311)

Variables	b	s	Discriminant Group	Centroids
VERBALY (Did you receive any verbal materials, Yes)	.61	.66	Participants	.75
			Nonparticipants	-.56
KFACTOR2 (Awareness)	.41	.37		
AGEGRP2 (26-35 years)	.36	-.39		
DISADVAN (Drawbacks)	-.32	-.37		

(Table continues)

WIDOWED (Marital Status)	.28	.21	
WORK15 (Within 15 miles)	-.27	-.15	
AGEGRP4 (46-55 years)	.25	.39	

Eigen value	Rc	Wilk's Lambda
.420	.544	.704

b = standardized discriminant function coefficient
s = within group structure coefficient
Rc = canonical correlation coefficient

Finally, the correctly classified cases were examined. Seventy five (19.4%) of the subjects were eliminated from the calculation of the discriminant model due to at least one missing discriminating variable. A total of 311 respondents were used in the calculated discriminant model. The researcher directed the classification portion of the program to classify all cases by using the mean-substitution function for missing values. This procedure functions as an additional check for the effectiveness of the model. The model correctly classified 74.6% of the cases analyzed (see Table 49).

Table 49

Classification of Cases by the Discriminant Model for Participation Status of Potential African Americans in Clinical Research Trials

Actual Group	No. of Cases	Predicted Group	
		Participants	Nonparticipants
Participants	135	108 80.0%	27 20.0%
Nonparticipants	176	52 29.5%	124 70.5%

Note. Percent of cases correctly classified: 74.6%.

To determine the substantive value of the derived discriminant model, the researcher used the Tau statistic. This statistic measures the proportional reduction in error and provides a standardized measurement of improvement from the model for any number of dependent variable groups (Barrick and Warmbrod, 1988). It is calculated using the following formula:

$$\text{tau} = \frac{n_c - \sum p_i n_i}{n - \sum p_i n_i}$$

where: n_c = number of cases correctly classified
n = total number of cases
p_i = prior probability of group membership
n_i = number of cases in group i

A measurement of 25 or higher is generally considered to be indicative of a meaningful model (Barrick and Warmbrod, 1988). The Tau value for this discriminant model was computed as follows:

$$\text{tau} = \frac{n_c - \sum p_i n_i}{n - \sum p_i n_i}$$

$$\text{tau} = \frac{232 - (67.5 + 88)}{311 - (67.5 + 88)}$$

$$\text{tau} = \frac{232 - 155.5}{311 - 155.5}$$

$$\text{tau} = \frac{76.5}{155.5}$$

$$\text{tau} = 49.2$$

The 49.2 derived Tau was greater than the minimum value which indicates that the model is meaningful.

CHAPTER 5

SUMMARY

The purpose of this study was to gain an understanding of the knowledge, attitudes, and beliefs African Americans have that support decisions to either participate or not participate in a clinical trial.

Objectives

The following specific objectives were formulated to guide the researcher:

1. To describe African Americans who were potential participants in clinical research trials on each of the following perceptual and demographic measures:
   a. Knowledge of clinical research processes;
   b. Perceptions of clinical research purposes and procedures;
   c. Advantages and disadvantages for the individual of participation in clinical research trials;
   d. Characteristics of current and past participation in clinical research trials;
   e. Exposure to selected experiences which are preliminary to participation in clinical research trials;
   f. Perceptions regarding the need for selected changes in preparation for participation in clinical research trials; and
   g. Perceptions regarding the need for selected changes in preparation for participation in clinical research trials; and
   h. The following selected personal demographic characteristics:
      i. Gender,
      ii. Age,

iii. Marital status,

iv. Education level,

v. Employment status,

vi. Household income,

vii. Distance from research center, and

viii. Overall health status.

2. To describe and compare African Americans who have participated in clinical research trials and those who have not participated in clinical research trials on each of the following perceptual and demographic measures:

   a. Knowledge of clinical research processes;

   b. Perceptions of clinical research purposes and procedures;

   c. Advantages and disadvantages for the individual of participation in clinical research trials;

   d. Characteristics of current and past participation in clinical research trials;

   e. Exposure to selected experiences which are preliminary to participation in clinical research trials;

   f. Perceptions regarding the need for selected changes in preparation for participation in clinical research trials; and

   g. The following selected personal demographic characteristics:

      i. Gender,

      ii. Age,

      iii. Marital status,

      iv. Education level,

v. Employment status,

vi. Household income,

vii. Distance from research center, and

viii. Overall health status.

3. To determine if a model existed that significantly increased the researcher's ability to correctly classify volunteers on their participation status in clinical research trials from the following perceptual and demographic measures:

   a. Knowledge of clinical research processes;

   b. Perceptions of clinical research purposes and procedures;

   c. Advantages and disadvantages for the individual of participation in clinical research trials;

   d. Characteristics of current and past participation in clinical research trials;

   e. Exposure to selected experiences which are preliminary to participation in clinical research trials;

   f. Perceptions regarding the need for selected changes in preparation for participation in clinical research trials; and

   g. The following selected personal demographic characteristics:

      i. Gender,

      ii. Age,

      iii. Marital status,

      iv. Education level,

      v. Employment status,

      vi. Household income,

vii. Distance from research center, and

viii Overall health status.

The survey method was utilized in this study. The target population was defined as all African Americans age 18 and older who were potential participants in a clinical trial. The accessible population were all African Americans in the Pennington Biomedical Research Center's Database from 1992-2000. The frame of the accessible population was established as those who were currently enrolled at the time of the study, previously participated, and those who did not participate in a clinical trial. The sample consisted of 100% of the defined accessible population frame.

A modified version of the questionnaire (Appendix B) "Perceptions of Participation in Clinical Research" (McLean and Jensen, 1998) was utilized in conducting this study. The original questionnaire was modified due to the relevance of questions applicable to African Americans, length of the instrument, and the approximate time it would take to complete. The modified version of the questionnaire consisted of 8 pages, 58 questions, and 7 sections.

The questionnaire was mailed to 3302 African American adults (770 participants and 2532 nonparticipants) who were potential participants in a clinical trial at the Pennington Biomedical Research Center during the years of 1992-2000. A letter of introduction (Appendix A) accompanied the questionnaire. Along with instructions and guidelines, the letter stressed the importance of completing the survey. Participants were asked to return questionnaires within two weeks after receiving. A total of 386 (158 participants or 21 percent, and 228 nonparticipants or 9 percent) responded to the questionnaire.

The following is a summary of the major findings in the study:

1. Knowledge of clinical research processes- Overall respondents most strongly agreed with the item, "Volunteers can refuse to participate in a clinical trial". When comparing the participant group to the nonparticipant group, the item with which both groups strongly agreed was, "Volunteers can refuse to participate in a clinical trial". However, the item with which the participant group exhibited the lowest level of agreement was, "Volunteers are made aware of any possible complications or side effects of taking part in a clinical trial." The nonparticipant group expressed the lowest level of agreement with the item, "Volunteers usually receive a cash stipend for participation in a clinical trial." To further summarize these findings, the researcher utilized the underlying constructs and the corresponding sub-scale scores derived from the factor analysis conducted in objective one of the study. Two sub-scale scores for the knowledge factor were derived. The first was labeled by the researcher as "Information Provided". The participant group reported significantly higher levels of agreement in the "Information Provided" knowledge factor than did the nonparticipants. The second knowledge factor, labeled as "Awareness" by the researcher, produced similar results in that the participant group had a significantly higher level of agreement with the items in the "Awareness" knowledge factor than did the nonparticipants.
2. Perceptions of clinical research purposes and procedure- Overall respondents most strongly agreed with the item, "Participation in a clinical trial can help

future generations," and the statement with which respondents least agreed was, "Participation in a clinical trial can delay a disease." To further summarize these findings, the researcher utilized the underlying constructs and the corresponding sub-scale scores derived from the factor analysis conducted in objective one of the study. Two sub-scale scores for the perception factor were derived. The first perception factor was labeled by the researcher as "Participation Benefits." The participant group reported significantly higher levels of agreement with items in the "Participation Benefits" perception factor than did the nonparticipants. For the second perception factor labeled by the researcher as "Prevention," the participant group had a significantly higher level of agreement with the items in the "Prevention" perception factor than did the nonparticipants.

3. Advantages for the Individual of Participation in Clinical Research Trials- Overall respondents most strongly agreed with the item, "Doing something that will help others," and least agreed with the item, "Getting free medications." To further summarize these findings, the researcher utilized the underlying constructs and the corresponding sub-scale scores derived from the factor analysis conducted in objective one of the study. Only one sub-scale score was derived and labeled by the researcher as, "Primary Benefits." The participant group reported significantly higher levels of agreement with items in the "Primary Benefits" advantage factor than did the nonparticipants. In addition, respondents were asked to specify other advantages they perceived for the individual of participation in clinical research trials. The participant group

specified, "Learn about medicine and body," and "Meeting others" as other advantages to participation in clinical trials. The nonparticipant group specified, "Knowledge obtained is beneficial," and "If a clinical trial helps find a cure for a particular disease," as other advantages to participation in clinical trials.

4. Disadvantages for the Individual of Participation in Clinical Research Trials- Overall respondents most strongly agreed with the item, "Experiencing side effects of the treatment," and least agreed with the item, "Being treated like a "guinea pig" as disadvantages for the individual of participation in clinical research trials. To further summarize these findings, the researcher utilized the underlying constructs and the corresponding sub-scale scores derived from the factor analysis conducted in objective one of the study. Only one sub-scale score was derived and labeled by the researcher as, "Drawbacks." The nonparticipant group reported significantly higher levels of agreement with items in the "Drawbacks" disadvantage factor than did the participants. In addition, respondents were asked to specify other disadvantages they perceived for the individual of participation in clinical research trials. The participant group specified, "Dates and times can't be changed or rescheduled, inconvenient," "Forcing someone to overeat to maintain a specific weight; many studies too long," and "Trip to clinic" as other disadvantages for the individual of participation in clinical research trials. The nonparticipant group specified, "Risk to your health," "Getting to clinic," "Time consuming; inconvenient," "Overcoming past atrocities where African Americans were deliberately infected (i.e. syphilis virus)," and "Not knowing if you are receiving treatment or sugar pill"

as other disadvantages for the individual of participation in clinical research trials.

5. Characteristics of Current and Past Participation in Clinical Research Trials- Six aspects of clinical research participation status were examined. The first aspect was whether or not the respondents had ever been asked to participate in a clinical trial. The majority of the participant group indicated that they had been asked to participate in a clinical trial. In contrast, the majority of the non-participant group indicated that they had not been asked to participate in a clinical trial. The second aspect was whether or not the respondents had previously participated in a clinical trial. The majority of the participant group indicated that they had previously participated in a clinical trial. In contrast, the majority of the nonparticipant group indicated that they had not previously participated in a clinical trial. The third aspect was whether or not the respondents were currently enrolled in a clinical trial. The nature of the association between the variable was such that a greater proportion of the participant group indicated that they were currently enrolled in a clinical trial while a greater proportion of the nonparticipants indicated that they were not currently enrolled in a clinical trial. The fourth aspect was whether or not respondents would participate in future clinical trials if they had said "No", to ever been, previously, or currently enrolled in a clinical trial. There was no significant difference in these two variables indicating that the two variables were independent. The fifth aspect was whether or not the respondents had ever decided not to participate in a clinical trial after being eligible. The nature of the

association between the variables was such that a smaller proportion of the participant group indicated they decided not to participate in a clinical trial after being eligible while a greater proportion of the nonparticipants indicated they had decided not to participate in a clinical trial after being eligible. The sixth aspect of characteristics of current and past participation in clinical research trials was to select the primary reason respondents decided not to participate in a clinical trial after being eligible. Overall the reason respondents most often identified was, "Changed jobs, schedule would not permit" as the primary reason not to participate in a clinical trial. Respondents were also asked to specify other primary reasons for choosing not to participate in a clinical trial. The participant group indicated, "Busy schedule," "Illness in family," "Was not selected,", and "Didn't lose weight." The nonparticipant group indicated, "Disqualification; eligibility criteria for the study," "Hours of participation were during work hours," "No transportation,", and "Friend talked me out of it" as primary reasons not to participate in a clinical trial. The results of the respondents' other specified responses were not significant, indicating that the two variables (whether or not they had participated and if yes, other primary reason decided not to participate after being eligible) were independent.

6. Exposure to Selected Experiences Which are Preliminary to Participation in Clinical Research Trials- A total of four selected experiences preliminary to participation in clinical research trials were examined. The first exposure was whether or not the respondents received any verbal or written materials that

described what the clinical trial was about and what was needed to be done. The nature of the association between the variables was such that a greater proportion of the participant group indicated that they had received verbal or written materials that described what the clinical trial was about and what was needed to be done while a greater proportion of the nonparticipants indicated that they had not received any verbal or written materials describing what the clinical trial was about and what was needed to be done. The second exposure to selected experiences, which are preliminary to participation in clinical research trials, was whether or not respondents talked to family or friends before making their decision to participate or not participate in a clinical trial. The nature of the association between the variables was such that more of the participant group indicated that they talked to family or friends before making their decision to participate or not participate while the majority of the nonparticipants indicated they did not talk to family or friends before making their decision to participate or not participate in a clinical trial. The third exposure was whether or not the respondents talked to their doctor before making their decision to participate or not participate in a clinical trial. The two variables (whether or not they participated and whether or not they talked to their doctor before making the decision to participate or not participate in a clinical trial) were not significant, indicating that the two variables were independent. The fourth exposure was whether or not the respondents had a family history of the disease being researched that prompted their decision to participate or not participate in a clinical trial. The two variables (whether or not they

participated and whether or not they had a family history of the disease being researched that prompted their decision to participate or not participate in a clinical trial) were not significant, indicating that the two variables were independent. In addition, respondents were asked to specify other exposures to selected experiences, which are preliminary to participation in clinical research trials. The largest response from the participant group was, "Having family history of disease," and the two largest responses from the nonparticipant group were, "Never asked to participate," and "Did not fit profile" as other specified exposures to selected experiences, which are preliminary to participation in clinical research trials.

7. Perceptions Regarding the Need for Selected Changes in Preparation for Participation in Clinical Research Trials- Overall the statement with which the respondents most strongly agreed was, "Hearing about the good things that have been discovered from clinical trials," and least agreed was, "Informational meeting about the clinical trial, presented by the nurse." When comparing the participant group to the nonparticipant group, the item with which both the participant and nonparticipant group most strongly agreed was, "Hearing about the good things that have been discovered from clinical trials." The item with which the participant group least agreed was, "Informational meeting about the clinical trial presented by African Americans." The item with which the nonparticipant group least agreed was, "Informational meeting about the clinical trial presented by the nurse." To further summarize these findings, the researcher utilized the underlying constructs and the corresponding sub-scale

scores derived from the factor analysis conducted in objective one of the study. Only one sub-scale score was derived and labeled by the researcher as, "Ideas/ Suggestions." When comparing the participant group to the nonparticipant group based on the sub-scale score, there was no significant difference in the two groups. In addition, respondents were asked to specify other perceptions regarding the need for selected changes in preparation for participation in clinical research trials. The largest response specified from the participant group was, "More advertising in African American periodicals," "TV commercials with African Americans," and "Post newsletters in African American communities." The nonparticipant group specified, "Research about the test not just from African Americans but whomever has participated."

8. Demographic Characteristics

a) Gender- The majority of the respondents overall were female. Likewise, the majority of the respondents in both the participant and nonparticipant groups were female. The two variables (whether or not they participated and gender) were not significant, indicating that the two variables were independent.

b) Age- The largest number of respondents was in the 46-55 year age group. Likewise, the largest number of respondents in the participant group was in the 46-55 year age group, while the largest group of respondents in the nonparticipant group was in the 36-45 year age group. The nature of the association between the two variables (whether they participated and age) were significant, indicating that the variables were not independent.

c) Marital Status- Approximately half of the respondents were married. Likewise, approximately half of the respondents in both the participant and nonparticipant groups were married. In comparing the participant group to the nonparticipant group, the two variables (whether they participated and marital status) were not significant, indicating that the two variables were independent.

d) Education Level- The largest group of respondents overall and in both the participant and nonparticipant groups completed 1-3 years college/ business/technical school. In comparing the participant group to the nonparticipant group, the two variables (whether they participated and education levels) were significant, indicating that the variables were not independent.

e) Employment Status- The majority of respondents in both the participant and nonparticipant groups were employed full time. In comparing the participant group to the nonparticipant group, the two variables (whether they participated and employment status) were not significant, indicating that the two variables were independent.

f) Household Income- Overall, the largest group of respondents had a house-hold income in the range of $20,000 - $29,999 per year. The largest number of respondents in the participant group reported an approximate household income range of $70,000 and over per year, while the largest number of respondents in the nonparticipant group reported an approximate household income in the range of $20,000 - $29,9999 per year. In comparing the participant group to the nonparticipant group, the two variables (whether they

participated and household income) were not significant, indicating that the two variables were independent.

g) Distance from Respondents Domicile to Research Center- The largest group of respondents overall and in both the participant and nonparticipant groups live within 15 miles of the research center. In comparing the participant and nonparticipant groups, the two variables (whether they participated and distance lived from the research center) were not significant, indicating that the two variables were independent.

h) Distance from Respondents Worksite to the Research Center- The largest group of respondents overall and in both the participant and nonparticipant groups work within 7 miles of the research center. In comparing the participant and nonparticipant groups, the two variables (whether they participated and distance worked from the research center) were significant, indicating that the two variables were not independent.

i) Overall Health Status- The largest group of respondents overall and in both the participant and nonparticipant groups were in good health. In comparing the participant and nonparticipant groups, the two variables (whether they participated and overall health status) were not significant, indicating that the two variables were independent.

9. The Discriminant Analysis Model- The factors attributable to the success of this model were 1) knowledge factor "Awareness," 2) disadvantage factor "Drawbacks," 3) "Did you receive any verbal or written materials that described what the clinical trial was about and what you would need to do" (whether or not

they responded "Yes"), 4) whether or not their marital status was Widowed, 5) whether or not they were in the 26-35 year age group, 6) whether or not they were in the 46-55 year age group, and 7) whether or not their place of employment was within 15 miles of the Pennington Center. As a result, this model correctly classified seventy five percent of the cases analyzed, which exceeded the minimum requirement. The Post Hoc Tau test statistic further supported the model as meaningful in yielding almost double the minimum value required.

Conclusions, Implications, and Recommendations

1. African Americans who are potential participants in clinical research trials have high levels of knowledge in the dimension of awareness of issues surrounding clinical research trials.

This conclusion is based on the finding that the mean score for African Americans on the knowledge dimension labeled by the researcher as "Awareness" was 4.42 on a five-point scale. This finding suggests that African Americans were aware of their right to change their mind at any time and withdraw from a clinical trial and they can refuse to participate. This finding further indicates that the research center is clearly conveying the message that participation in a clinical research trial is voluntary to potential African American participants.

Based on this conclusion and these findings the researcher recommends that the Principal Investigator and research team of clinical research trials which focus on African Americans place an increased emphasis on issues that would potentially increase voluntary participation of African Americans in clinical research trials. Some of the ways this might be accomplished include: increasing the involvement of members of the research

team in recruitment activities. The literature suggest that Investigators would do well to solicit and incorporate the suggestions of African American community members and potential participants in designing research protocols and recruitment strategies (Corbie-Smith et al., 1999).

2. African Americans who have been participants in a clinical research trial have higher levels of knowledge regarding clinical research trials than those who have not participated.

This conclusion is based on the findings that the participant group have higher levels of knowledge on both the "Awareness" ($t_{384} = 4.093$, $p < .001$) and the "Information Provided" ($t_{384} = 4.943$, $p < .001$) sub-scales of the knowledge scale than did the non-participant group. Providing the information necessary for a decision to participate or not participate in a clinical research trial is supported by another study which showed that African Americans were interested primarily in being educated about the study and that lack of information was a primary reason they did not participate in clinical trials (Roberson, 1994). In addition, African Americans in another study requested broader education about the importance of and opportunities for participation in medical research (Corbie-Smith et al., 1999).

Based on this conclusion and these findings the researcher recommends that the Principal Investigators and research team of clinical research trials which focus on African Americans place an increased emphasis on education about clinical research trials in the African American community. Some of the ways this might be accomplished include: informational meetings through workshops and seminars to build trust through first acknowledging the abuses surrounding previous clinical research trials. This may

prove to create an opportunity for dialogue to heal the breached trust represented by the Tuskegee Syphilis Study. The informational meetings should be held in African American neighborhoods to include churches, community centers, state and local public meetings, and colleges or universities.

3. African Americans who have participated in a clinical research trial have more positive perceptions of the "Participation Benefits" of clinical research trials than those who have not participated.

This conclusion is based on the finding that the participant group more strongly agreed with the items in the factor "Participation Benefits" than did the nonparticipant group. The mean score for the participant group was 4.39 (SD = .54) and for the nonparticipant group 4.19 (SD = .62) ($t_{384} = 3.249$, $p < .001$). Studies have shown that the belief in the benefit of participation is an indication that racial/ethnic groups are likely to be influenced to enroll in clinical research trials with some assurance that treatment could improve survival (Roberson, 1994). Other investigators have shown that participants expect to obtain personal benefit while contributing knowledge to medical science for the good of society (Blumenthal, Sung, Coates, Williams, & Liff, 1995; Mattson, Curb, & McArdle, 1985; Robinson, Ashley, & Haynes, 1996).

Based on this conclusion and these findings the researcher recommends that the Principal Investigators and the research team of clinical research trials which focus on African Americans place an increased emphasis on publishing the results of all clinical trials whether successful or unsuccessful. This will serve the purpose of building additional trust, increasing awareness and providing information that will inevitably enhance recruitment of African Americans in clinical research trials. Some of the ways to publi-

cize the results of a clinical trial include: production of research final report summaries written in lay terminology, culturally sensitive, and published regularly in outlets that reach the African American community.

4. African Americans who have participated in a clinical research trial have more positive perceptions regarding the advantages of clinical research trials than those who have not participated.

This conclusion is based on the finding that the participant group more strongly agreed with the items in the factor "Primary Benefits" than did the nonparticipant group. The mean score for the participant group was 4.03 (SD = .60) and for the nonparticipant group 3.83 (SD = .61) ($t_{384} = 3.179$, $p = .002$). Studies have shown that the perceived benefits of clinical research trial participation, medical monitoring and treatment (Aby, Pheley, & Steinberg, 1996; Cunny & Miller, 1994; Tangrea, Adrianza, & Helsel, 1992; Wilcox & Schroer, 1994) altruism (Aby et al., 1996; Cunny et al., 1994) and financial compensation (Bigorra & Banos, 1990; Cunny et al., 1994) were described by participants as important.

Based on this conclusion and these findings the researcher recommends that the Principal Investigators and research team of clinical research trials which focus on African Americans, place an increased emphasis on the benefits of participation in clinical research trials. The participant group in this study supported this increased emphasis by indicating "Other" perceived advantages for the individual of participation in clinical research trials. Some of the "Other" perceived advantages included: "Learn about medicine and body," "Lose weight, medical exam," and "aid research by being available." These "Other" perceived advantages are seen as benefits to the individual of participation

in clinical research trials. The perceived benefits of clinical research trials are further indicated by the nonparticipant group in this study. Some of the "Other" perceived advantages from the nonparticipant group included: "Knowledge obtained is beneficial," "If clinical research trial helps find a cure for a particular disease," and "Providing the proper information; discussing the Phase I, II, III, IV trial results and expected outcomes. Clients need to know all expectations and consequences."

These "Other" perceived advantages by both the participant and nonparticipant groups indicated that the message from Principal Investigators and the research team of clinical research trials should be clear and focused such as, the results of the clinical research trial indicated a decrease in cholesterol levels, blood pressure, blood sugar, and weight loss.

5. African Americans who have not participated in a clinical research trial more strongly agreed with potential disadvantages to the individual of participation in clinical research trials than those who have participated.

This conclusion is based on the finding that the nonparticipant group more strongly agreed with the items in the factor "Drawbacks" than did the participant group. The mean score for the nonparticipant group was 3.16 (SD = .90) and for the participant group 2.65 (SD = .87) ($t_{384} = -5.595$, $p < .001$). "Experiencing side effects of the treatment" was the item with which nonparticipants most strongly agreed.

Based on this conclusion and these findings the researcher recommends that Principal Investigators and research team of clinical research trials which focus on African Americans participate in all procedures required by the trial. If the research team members have taken part in the clinical research trial processes and procedures they will have

increased credibility and trust among African American participants. Studies have shown that a trusting relationship was important for African Americans to feel comfortable as participants in clinical studies (Corbie-Smith et al., 1991). Other authors have suggested that trust developed between a primary care provider and a patient is the only way fear of exploitation in research can be overcome (El-Sadr & Capps, 1992) and that lack of trust in the researcher is the primary barrier to African American participation in clinical trials (Mouton, Harris, Rovi, Solorzano, & Johnson, 1997). The nonparticipant group in this study supported this increased emphasis by indicating "Other" perceived disadvantages for the individual of participation in clinical research trials. Some of the "Other" perceived disadvantages included: "Risk to your health,""Overcoming past atrocities where African Americans were deliberately infected (i.e. syphilis virus)," and "Uncertainty of integrity of researchers/study."

These "Other" perceived disadvantages by both the participant and nonparticipant groups indicated that "Trip to clinic," "Dates and times can't be changed or rescheduled, inconvenient," and "No benefits if in control group" sends a clear message to Principal Investigators and the research team of clinical research trials indicating that flexibility of clinic hours as well as location of additional research sites other than at the research center may prove to enhance recruitment and retention of potential African Americans for participation in clinical research trials.

6. African Americans who have participated in clinical research trials and received verbal or written materials that described what the clinical trial was about and what was needed are more likely to participate in future clinical research trials.

This conclusion is based on the results obtained through comparison of mean values for discriminating variables by participation status among African Americans. The results of the one way analysis of variance (F_{311}, $p < .01$) was highly significant in the model suggesting that increased participation in clinical research trials was based on African Americans receiving verbal or written materials describing what the clinical trial was about and what was needed. The literature coincides with this conclusion in that novel methods of transmitting information such as instructional videos alone, or in combination with the written form, have been shown to be preferred by patients (Agre, McKee, Gargon, & Kurtz, 1997).

Based on this conclusion and these findings the researcher recommends that Principal Investigators and research team of clinical research trials which focus on African Americans produce effective and innovative presentations culturally sensitive to include: graphics that illustrate the purpose, procedures, time commitments, benefits, and incentives for participation. Studies have shown that people might be retained for clinical trials if they are informed, educated, and counseled (Roberson, 1994). This may also increase trust among African Americans especially if they feel as a result of participation in clinical research trials, that their contribution to the study was valuable.

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APPENDIX A

LETTER OF INTRODUCTION

Dear Mr./Ms.

My name is Betty Kennedy. I am a Research Recruiter and graduate student in the School of Vocational Education at Louisiana State University, Baton Rouge, Louisiana. As a Research Recruiter at the Pennington Biomedical Research Center for seven years, the task of recruiting African Americans into clinical trials remains a challenge. Since African Americans are disproportionately affected and have a higher prevalence of high blood pressure, diabetes, and obesity, the goal to enroll African Americans into clinical trials is crucial, especially finding ways to delay or prevent these diseases from occurring. Therefore, I need your help so that I can become more precise and efficient at recruiting African Americans into clinical trials. I am conducting a study to determine the reasons African Americans do and do not participate in clinical research. The purpose of this study is to gain an understanding of the knowledge, attitudes, and beliefs African Americans have that either support their decision to participate or not participate in a clinical trial. The findings from this study may improve the recruitment of volunteers in future clinical research.

Your participation in this study will involve completing the enclosed questionnaire. It will take no more than **20 minutes** for you to complete. Please do not put your name on the questionnaire or the return envelope. All replies will be kept confidential. No names will appear on the questionnaire, only a code number.

Participation in this study is strictly voluntary and returning the completed questionnaire will imply your consent. The responses will be stored in a locked filing cabinet under my control. The information that you provide will not be used for any purpose except for this study.

If you agree to participate, please complete and seal the questionnaire in the self-addressed stamped envelope provided. If you have any questions about this questionnaire, please contact me or my dissertation chair at the telephone numbers listed below. A copy of the completed study will be available at the School of Vocational Education (Old Forestry Building).

PLEASE RETURN THE COMPLETED QUESTIONNAIRE by: October 16, 2009

Thank you in advance, for your assistance in completing this questionnaire.

Betty Kennedy, MPA, Ph.D. Candidate
Research Recruiter
Pennington Biomedical Research Center
6400 Perkins Road
Baton Rouge, Louisiana 70898-0025
(225) 763-3090

Dr. Geraldine Holmes
Associate Professor, Dissertation Chair
Louisiana State University
127 Old Forestry Bldg.
Baton Rouge, Louisiana 70803
(225) 388-2464

APPENDIX B

PERCEPTIONS OF PARTICIPATION IN CLINICAL RESEARCH
(MODIFIED McLean & Jensen, 1998)

The questions in this survey are about "clinical trials research".

A **"clinical trial"** is a research study that can be used to answer questions about new ways of both delaying and preventing diseases such as cancer, diabetes, heart disease, high blood pressure, and obesity. Researchers obtain funding through federal, state, and local means and generally utilize a research recruiter in obtaining volunteers to enroll in the study.

Instructions for Completing the Questionnaire

Please read each question carefully. **There are no right or wrong answers.** Please answer each question to the best of your knowledge. On a few questions, you will have space provided so that you can write out a specific answer. For most of the statements you will be asked to select (1) strongly disagree, (2) disagree, (3) are unsure, (4) agree, or (5) strongly agree. By selecting "strongly disagree" you are saying that you do not believe or agree with the statement. By selecting "disagree" you are saying that although you may not strongly disagree with the statement, you are still not 100% sure of it. By selecting "are unsure" you are saying that you do not know. By selecting "agree" you are saying that you don't disagree with it. By selecting "strongly agree" you are saying that you believe or agree with the statement. Please circle or check where applicable, only **one choice** in response to each question or statement.

CONFIDENTIAL

THIS QUESTIONNAIRE CONTAINS 8 PAGES

SECTION 1

The statements below are about your **knowledge of** clinical research. On a scale of 1-5, do you (1) strongly disagree, (2) disagree, (3) are unsure, (4), agree or (5) strongly agree as it relates to your knowledge of clinical research. **Please circle only one choice** per statement.

	Strongly Disagree	Disagree	Unsure	Agree	Strongly Agree
1. Volunteers receive information needed to decide whether they want to take part in a clinical trial.	1	2	3	4	5
2. Volunteers can refuse to participate in a clinical trial.	1	2	3	4	5
3. Volunteers can change their mind at any time and withdraw from a clinical trial.	1	2	3	4	5
4. Volunteers are made aware of any possible complications or side effects of taking part in a clinical trial.	1	2	3	4	5
5. Volunteers are told about the possible risks and benefits of taking part in a clinical trial.	1	2	3	4	5
6. Clinical trials are needed to study the effects of treatments.	1	2	3	4	5
7. Volunteers usually receive a cash stipend for participation in a clinical trial.	1	2	3	4	5

SECTION II

The following statements are about your **perceptions** of clinical research. On a scale of 1-5, do you (1) strongly disagree, (2) disagree, (3) are unsure, (4) agree, or (5) strongly agree as it relates to your perceptions of clinical research. Please **circle only one choice** per statement.

	Strongly Disagree	Disagree	Unsure	Agree	Strongly Agree
8. Clinical trials are a necessary way to learn about treatments.	1	2	3	4	5
9. It is important for people to take part in clinical trials.	1	2	3	4	5
10. The information in the consent form is important to help volunteers decide about participation in a clinical trial.	1	2	3	4	5
11. Participation in a clinical trial can help me and my family.	1	2	3	4	5
12. Participation in a clinical trial can help future generations.	1	2	3	4	5
13. Blood work is necessary in a clinical trial.	1	2	3	4	5
14. Participation in a clinical trial can delay a disease.	1	2	3	4	5
15. Participation in a clinical trial can prevent a disease.	1	2	3	4	5

SECTION III

Below is a list of possible **advantages and disadvantages** of participating in a clinical trial. Your answers are very important whether you participated or decided not to participate in a clinical trial. On a scale of 1-5, do you (1) strongly disagree, (2) disagree, (3) are unsure, (4) agree, or (5) strongly agree with the advantages and disadvantages of participating in a clinical trial. Please **select only one choice** per statement.

	Strongly Disagree	Disagree	Unsure	Agree	Strongly Agree
Advantages of Participation					
16. Receiving the newest treatment.	1	2	3	4	5
17. Doing something that will help others.	1	2	3	4	5
18. Getting free medications.	1	2	3	4	5
19. Helping to delay a disease.	1	2	3	4	5
20. Helping to prevent a disease.	1	2	3	4	5
21. Doing something positive for self.	1	2	3	4	5
22. Getting a cash stipend.	1	2	3	4	5
23. Getting better care and follow-up (for example, with laboratory tests)	1	2	3	4	5
24. Other **advantages:** (please specify)_____					
Disadvantages of Participation					
25. Being treated like a "guinea pig".	1	2	3	4	5
26. Having to miss work.	1	2	3	4	5
27. Having to arrange childcare.	1	2	3	4	5
28. Losing one's privacy.	1	2	3	4	5
29. Experiencing side effects of the treatment.	1	2	3	4	5
30. Disrupting one's normal daily routine.	1	2	3	4	5

31. Other **disadvantages:** (please specify)

_____

SECTION IV

The questions in this section are about participants' and non-participants' **current and past participation** in clinical trials. Please **check one appropriate choice.**

32. Have you **ever been** asked to participate in a clinical trial?

1. YES ☐
2. NO ☐

33. Have you **previously** participated in a clinical trial?

1. YES ☐
2. NO ☐

34. Are you **currently** enrolled in a clinical trial?

1. YES ☐
2. NO ☐

35. If you said **"No"** to questions 32 through 34 above, and you were asked to participate in a clinical trial in the future, would you participate?

1. YES ☐
2. NO ☐

36. Have you ever decided **not to participate** in a clinical trial after being eligible? If **no**, go to **Section V.**

1. YES ☐
2. NO ☐

37. If **yes**, what is the **primary reason** that you **decided not to participate** in the clinical trial? (Please **check only one choice**).

1. Changed jobs, schedule would not permit ☐
2. Changed mind, due to fear ☐
3. Live too far from research center ☐
4. Work too far from research center ☐
5. Too much effort involved ☐
6. Too many lab tests required ☐
7. Other (please specify) _____

SECTION V

The next questions ask about **who and what influenced** your decision to participate or not participate in a clinical trial. Your answers are important whether or not you decided to participate in the trial. If you have been asked to participate in a clinical trial more than once, please refer to the most recent time. **Please check one appropriate choice.**

38. Did you receive any verbal or written materials that described what the clinical trial was about and what you would need to do?

1. YES ☐
2. NO ☐
3. UNSURE ☐

39. Did you talk to family or friends before making your decision to participate or not participate?

1. YES ☐
2. NO ☐
3. UNSURE ☐

40. Did you talk to your doctor before making your decision to participate or not participate?

1. YES ☐
2. NO ☐
3. UNSURE ☐

41. Did you have a family history of the disease being researched that prompted your decision to participate or not participate?

1. YES ☐
2. NO ☐
3. UNSURE ☐

42. Other (please specify)

_____

SECTION VI

Below is a list of **ideas/suggestions** for ways to help people learn more about clinical trials. Please indicate if you (1) strongly disagree, (2) disagree, (3) are unsure, (4) agree, or (5) strongly agree that the statement is an appropriate means of helping people learn more about clinical trials. **Circle only one choice** for each statement.

	Strongly Disagree	Disagree	Unsure	Agree	Strongly Agree
43. Informational meeting about the clinical trial, presented by the physician.	1	2	3	4	5
44. Informational meeting about the clinical trial, presented by the nurse.	1	2	3	4	5
45. Informational meeting about the clinical trial, presented by African Americans.	1	2	3	4	5
46. Hearing about the good things that have been discovered from clinical trials.	1	2	3	4	5
47. Talking to other African Americans, who have taken part in clinical trials.	1	2	3	4	5
48. TV shows or videotapes with African Americans in clinical trials.	1	2	3	4	5

49. Other suggestions: (please specify)_____

_____

_____

_____

SECTION VII

This section asks for some general information about you. **Please note that all information is confidential.** Your answers to the following questions will provide useful and valuable information for this study. Please **check only one** appropriate choice.

50. **What is your gender?**

1. MALE ☐
2. FEMALE ☐

51. **What is your approximate age?**

1. 18-25 years ☐
2. 26-35 years ☐
3. 36-45 years ☐
4. 46-55 years ☐
5. 56-65 years ☐
6. 66 years and over ☐

52. **What is your marital status?**

1. Married ☐
2. Divorced/Separated ☐
3. Never married ☐
4. Widowed ☐

53. **Education (check the highest level completed)**

1. Grades 0-8 ☐
2. Some High School ☐
3. High School diploma/GED ☐
4. 1-3 years college, business or technical school ☐
5. College degree ☐
6. Post graduate degree ☐

54. **What is your present employment status?**

1. Employed full time (at least 36.5 hrs/week) ☐
2. Employed part-time (at least 20hrs/week) ☐
3. Retired ☐
4. Unemployed ☐
5. Medical disability ☐

55. **What is your approximate household income?**

1. Less than $10,000 per year ☐
2. $10,000 - $19,999 per year ☐
3. $20,000 - $29,999 per year ☐
4. $30,000 - $39,999 per year ☐
5. $40,000 - $49,999 per year ☐
6. $50,000 - $59,999 per year ☐
7. $70,000 and above ☐

56. **Approximately how far do you live from the Pennington Center?** (Check the shortest distance that applies).

1. Within 3 miles of the research center ☐
2. Within 7 miles of the research center ☐
3. Within 15 miles of the research center ☐
4. Within 20 miles of the research center ☐
5. More than 20 miles from the research center ☐

57. **Approximately how far is your place of employment from the Pennington Center?** (Check the shortest distance that applies).

1. At the research center ☐
2. Within 3 miles of the research center ☐
3. Within 7 miles of the research center ☐
4. Within 15 miles of the research center ☐
5. Within 20 miles of the research center ☐
6. More than 20 miles from the research center ☐

58. **In general, would you say your health is:**

1. Excellent ☐
2. Very Good ☐
3. Good ☐
4. Fair ☐
5. Poor ☐

Thank you for taking the time to complete the questionnaire!

Please seal this questionnaire in the self-addressed stamped envelope provided and return by: October 16, 2000.

APPENDIX C
MODIFIED QUESTIONNAIRE APPROVAL

Subject: questionnaire

Dear Betty:
I have forwarded on Louise's response to you. My name is mispelled--it should read Donna McLean. I will forward a copy on to you once we receive some copies. Good luck with your research. Keep us posted we want to hear your comments of your experience.

Donna

---------- Forwarded by Donna McLean/UA/Nursing on 09/29/2000 04:53 PM ----------

"Louise Jensen" <louise.jensen@ualberta.ca> on 09/27/2000 02:16:07 PM

To: donna.mclean@ualberta.ca
cc:
Subject: questionnaire

Hi Donna:

The modified version of the PPCR is fine with me. (Note that they spell your name correct). The article is supposed to be coming out Vol 12, No 1 in Canadian Journal of Cardiovascular Nursing for them to reference. However, I do not know the page number yet. Tell Betty that you will send her a reprint as soon as you get them.

Louise

APPENDIX D
PARTICIPANT RESPONSES

Question 24: Other Advantages

1. Learn about medicine and body. (9 responses)
2. Meeting others. (3 responses)
3. Don't know enough about this to make positive statements.
4. Lose weight, medical exam.
5. Aid research by being available.

Question 31: Other Disadvantages

1. Dates and times can't be changed or rescheduled, inconvenient. (10 responses)
2. Forcing someone to overeat to maintain a specific weight; many studies are too long. (5 responses).
3. Trip to clinic. (4 responses)
4. Not getting free medicine for other condition.
5. No benefits if in control group.

Question 37: Primary Reason Decided Not to Participate

1. Busy schedule. (4 responses)
2. Illness in family.
3. Was not selected.*
4. Didn't lose weight.

*Each study has a different criteria; consequently, it's possible to be eligible (selected) for one study and not be eligible for another.

Question 42: Other Influences on Your Decision to Participate or Not

1. Having family history of disease. (17 responses)
2. I wanted to find out what research was about.
3. Unemployed (needed money); wanted to help people by doing study.

Question 49: Other Ideas/Suggestions

1. More advertising in African American periodicals, TV commercials with African Americans, post newsletters in African American communities. (9 responses)

2. Provide location for information and trial closer to individuals; have sites through out city instead of one location. (3 responses)

3. Flexible (longer) clinic hours: need to capitalize on first appointment because if people have to wait 2 weeks or so to see a doctor to receive medication- then they have lost their momentum/desire for losing weight or whatever reason for wanting to participate in the study. (3 responses)

4. Let African Americans know how this can help them and their family. (2 responses)

5. Informational meeting about clinical trial presented by African American physician. (2 responses)

6. To show how different foods react to humans as medicine for health and growth for longlife.

7. Publish results.

8. Provide transportation.

9. Meet with health center; occupational therapy; outpatient therapy.

10. Reveal side effects.

11. Physician needs to have excellent interpersonal skills.

12. Hard for participants to change or transition into documentation part of a study; seems to be a headache for the participant but needed for study. This needs to be explained more so persons can accept this responsibility more willingly so that you can get accurate and not made up data.

APPENDIX E
NONPARTICIPANT RESPONSES

Question 24: Other Advantages

1. Knowledge obtained is beneficial. (11 responses)
2. If clinical trial helps find a cure for a particular disease. (5 responses)
3. Study more on sickle cell. (2 responses)
4. Providing the proper information; discussing the Phase I, II, III, IV trial results and expected outcomes. Clients need to know all expectations and consequences.
5. New treatment not always an advantage.
6. Low-income families need more help.
7. Staff is trustworthy.
8. Getting a cash stipend for completing lengthy questionnaires.

Question 31: Other Disadvantages

1. Risk to your health. (11 responses)
2. Getting to clinic. (7 responses)
3. Time consuming; inconvenient. (4 responses)
4. Overcoming past atrocities where African Americans were deliberately infected (i.e. syphilis virus). (3 responses)
5. Not knowing if you are receiving treatment or sugar pill. (3 responses)
6. Uncertainty of integrity of researchers/study.
7. Religious convictions.

Question 37: Primary Reason Decided Not to Participate

1. Disqualification; eligibility criteria for the study. (11 responses)
2. Hours of participation were during work hours. (9 responses)
3. No transportation.
4. Friend talked me out of it.

Question 42: Other Influences

1. Never asked to participate. (12 responses)
2. Did not fit profile. (12 responses)
3. To learn about health problem I had.
4. Financial need.
5. To help in scientific research.

Question 49: Other Ideas/Suggestions

1. Research about the test not just from African Americans but whomever has participated. (6 responses)

2. Congregations; ask East Baton Rouge (EBR) Ministers Association to participate; have prominent African Americans of EBR community to do public service announcements; take clinical trials to churches, contact schools for volunteers. (3 responses)

3. Provide list of side effects. (3 responses)

4. Endorsements from patients' Primary Care Physician (PCP) would lend credibility to the trial. (2 responses)

5. Transportation, child care during screening visit, later appointments so that won't have to miss work. (2 responses)

6. Talking to people who had good experiences with the trials; give all information to participants. (2 responses)

7. More TV commercials about clinic's mission. (2 responses)

8. Explain how participation in clinical trials can possibly help you in prevention of a disease.

9. Not having to be present daily to eat meals; meet for labs on weekends only; have blood drawn at nearest hospital.

VITA

The author was born in Orrville, Alabama, on September 6, 1952. She is the only child of Eliza Hardin. She is married to Mr. Roy Kennedy and has two beautiful children, Tiffany and Troy. She grew up in Mobile, Alabama, and graduated Valedictorian from Williamson High School in 1970.

The author received a Norton Biology Scholarship from Miles College, Birmingham, Alabama, and graduated with a bachelor of arts degree in biology/chemistry in May 1973. After graduation, the author moved back home to Mobile, Alabama, and began training to become a Branch Manager of FinanceAmerica Corporation. Her training transferred her back to Birmingham, Alabama, as an Associate Manager, and finally, promoted and transferred to Baton Rouge, Louisiana, as a Branch Manager on July 18, 1979.

After 15 years in the finance industry which had begun to fail, the author enrolled at Southern University in January 1990 and received the degree of Master of Public Administration in May 1992. Upon graduation, the author worked at the Office of Public Health, Chronic Disease Control, in New Orleans, Louisiana, for 9 months. She is currently employed at the Pennington Biomedical Research Center as a Research Recruiter for the past 8 years, has published 4 manuscripts, and recently received a $5,000 contract to recruit volunteers for Focus Groups giving her the privilege of serving as Principal Investigator.

Upon graduation with the degree of Doctor of Philosophy, she plans to continue on at the Pennington Biomedical Research Center as a researcher, recruiter, community activist, and ultimately, to teach in higher education.

DOCTORAL EXAMINATION AND DISSERTATION REPORT

Candidate: Betty Monroe Kennedy

Major Field: Vocational Education

Title of Dissertation: Obstacles in Recruiting African Americans for Clinical Trials

Approved:

Major Professor and Chairman

Dean of the Graduate School

EXAMINING COMMITTEE:

Date of Examination:

June 27, 2001