

DEVELOPMENT OF A MINORITY RESEARCH RECRUITMENT DATABASE:  
ASSESSING FACTORS ASSOCIATED WITH WILLINGNESS OF AFRICAN AMERICANS  
TO ENROLL

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The Center for Minority Health (CMH) within the University of Pittsburgh has the mission to eliminate racial health disparities by 2010. One community-based intervention focuses on family health histories. Family health histories, or pedigrees, have been shown to be effective tools for identifying individuals at risk for common diseases who may benefit from increased screening or other risk reduction behaviors. Genetic counseling graduate students provide individuals with information pertaining to the importance of family history information in reducing the risk of chronic disease. Students travel to various locations in the African American community where they collect individuals' family health histories. Individuals who participate have the opportunity to enroll in the Minority Research Recruitment Database from which they can be contacted regarding research for which they may qualify. This is the Center's effort to increase minority recruitment. This has public health relevance given that minorities are often under-represented in research and it is thought that increasing minority recruitment will aid in elimination of racial health disparities. This study was developed to characterize individuals who elected to enroll in the database and compare them to those who declined enrollment. Factors for comparison include demographics, recruitment variables, opinions regarding research, health care, personal health, and family history. Factors were assessed for 126

participants of which approximately 80% enrolled in the database and 20% declined. Analysis revealed that those more likely to participate in the database were female, without health insurance, more likely to respond to monetary incentives, more likely to talk to their physician about concerns for developing a disease, and less likely to have previously refused participation in a clinical trial. These results indicate that women are more likely than men to seek health information that pertains to their family history, incentives act as a motivation for individuals to enroll in this database, and issues of distrust may still act as a barrier to research participation for African Americans.

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## **BACKGROUND**

The Center for Minority Health (CMH) created The Minority Research Recruitment Database in the spring of 2004. The database stores family history information collected from individuals in the African American community. The information is used to identify and contact minorities who may qualify for clinical research trials with the aim of increasing minority recruitment in research. This study aims to compare various characteristics between individuals who elect to enroll in this database and those who decline enrollment. Characteristics to be compared include demographics, recruitment variables, attitudes and beliefs towards research, health care information, personal health status, and family history.

This research was conducted by the Center for Minority Health within the University of Pittsburgh, Graduate School of Public Health. CMH was created in 1994 and has been under the leadership of Dr. Stephen B. Thomas since 2000. The vision of the Center is to eliminate racial and ethnic disparities in health by the year 2010. The work conducted within CMH includes health promotion and disease prevention activities, community-based research, health education and lay-health-advisory training, and information dissemination related to cultural competency, health communication, and health literacy. In addition, seven national health disparity priority areas have been identified and are the focus of many of the Center's efforts. These priority areas include: cancer screening and management, cardiovascular disease, diabetes, HIV infection and AIDS, immunizations (adult and child), infant mortality, and mental health.

## INTRODUCTION

The Center for Minority Health (CMH) has a mission to eliminate racial and ethnic health disparities. Racial and ethnic disparities, according to the Department of Health and Human Services' Office of Health Disparities, can be defined as a disproportionate burden of disease, injury, death, and disability within racial and ethnic minorities. [1] One specific aim is to provide family history risk assessments to the African American population of Pittsburgh, Pennsylvania. Individuals may also have their family health history entered into a computer database that provides them access to clinical trials for which they may enroll. This approach is based upon the hypothesis that individuals who complete family health histories will demonstrate an increase in knowledge about family history and how it relates to disease and will be more willing to participate in clinical research.

In the following section, a literature review provides an overview of racial and ethnic health disparities that exist both on a national and local level. Additionally, the review will describe the history of African Americans' participation in clinical trials and the utility of family health histories.

### **Racial and Ethnic Health Disparities**

As early as 1906, W.E.B. Du Bois authored *The Health and Physique of the Negro American*, one of the first known documents that focused on health disparities between black and whites. [2, 3] Still today in the 21<sup>st</sup> century, African Americans and other minorities are disproportionately

burdened by many chronic diseases when compared to whites, both on a national level and a local level in Pittsburgh, Pennsylvania. This has a significant impact on our country considering that almost 25% of individuals are classified as minorities, according to the 2000 U.S. census. Within that 25%, about 12.3% reported being African American, which translates to almost 35 million individuals. At a local level, 12.4% of Allegheny County's population self identified as African American, translating to almost 160,000 people as of the year 2000. [4]

The U.S. Department of Health and Human Services publishes data on trends in the health of Americans called Health, United States. In 2002, the four leading causes of death for African Americans were heart disease, cancer, stroke, and diabetes. Examining these four diseases in detail, the differences in mortality rates, incidence rates, and survival rates between African Americans and whites are significant. The age-adjusted death rate for heart disease in 2002 was 371.0 (deaths per 100,000 resident population) for Black males in comparison to 294.1 for white males and 263.2 for Black females in comparison to 192.1 for white females (See Table 1). The age adjusted death rate for cancer in 2002 was 319.6 (deaths per 100,000 resident population) for Black males in comparison to 235.2 for white males and 190.3 for Black females versus 162.4 for white females (See Table 1). In regards to cancer rates in 2000, Blacks reported 506.2 new cases of cancer per 100,000 in the population versus whites who reported 469.7 new cases per 100,000 individuals. Also, five-year survival rates for all sites of cancer in 1992-1999 were lower in African Americans in comparison to whites: 53.3% versus 64.4% respectively. Stroke death rates in 2002 were 81.7 (deaths per 100,000 resident population) for Black males compared to 54.2 for white males and 71.8 for Black females in comparison to 53.4 for white females (See Table 1). Finally, in 1999-2000, 14.7% of the African-American population had diabetes in

comparison to 7.4% of the white population, almost double the incidence. As is evident by these recent statistics, health disparities between African Americans and Caucasians continue to exist within our country and encompass the diseases that most commonly affect the African American population. [5]

**Table 1- Age-adjusted Death Rates in 2002 (deaths per 100,000 resident population)**

Disease	Black Males	White Males	Black Females	White Females
Heart Disease	371.0	294.1	263.2	192.1
Cancer	319.6	235.2	190.3	162.4
Stroke	81.7	54.2	71.8	53.4

Evidence suggests that health care disparities between African-American and Caucasian populations exist in Pennsylvania as well. Pennsylvania, as a whole, received a state health ranking of 25th in the country by the United Health Foundation in their 2004 report. This ranking is determined by combining individual measures of personal behaviors, community environment, and health policies with the resultant health outcomes into a comprehensive report of the health of a state. In addition, a variety of measures within this report look at health disparities within each individual state. For instance, in Pennsylvania, the years of potential life lost (YPLL) before age 75 is 6,826 years per 100,000 people for whites in comparison to 14,525 years per 100,000 people for blacks. Another instance of health disparity uncovered in this report involves pregnant women receiving adequate prenatal care. Nearly 74.4% of pregnant Caucasian women receive adequate care in comparison to 57.2% of pregnant African American

women. These are just two of many challenges that this report raises for the state of Pennsylvania. [6]

Reports have also been written about the health status of Allegheny County (Pittsburgh). In 2003, the University Center for Social and Urban Research published, *The State of Aging and Health in Pittsburgh and Allegheny County: May 2003*. This study surveyed 5,000 individuals over the age of 65 and reports on individuals' self-assessments of health. According to this report, large health disparities exist between blacks and whites in the prevalence of hypertension, diabetes, stroke, and cancer within Allegheny County. The percentages of affected elderly blacks in comparison to affected elderly whites show evidence of health disparities: 66.8% vs. 48.3% for hypertension, 11.2% vs. 9.6% for stroke, 27.7% vs. 16.6% for diabetes, and 5.6% vs. 4.5% for all cancers. [7] As previously mentioned, these are some of the leading causes of morbidity and mortality for African American's across the country.

In January of 2002, the Urban League of Pittsburgh and the University Center for Social and Urban Research released "The Black Papers", a report that looked at the health status of African Americans of all ages in Allegheny County. The four leading causes of death of blacks in Allegheny County were determined to be heart disease, cancer, stroke, and diabetes, the same leading causes of death for this population at a national level. African American females, ages 44-54, and African American males, ages 35-44, have three times the death rates for heart disease in comparison to whites. The prostate cancer death rate is more than three times greater for African American males ages 65-74 in comparison to white males of the same age. Overall cancer rates are 1.9 times greater for Blacks in men ages 45-54. Diabetes death rates are about

double for Blacks in comparison to whites, for both men and women. Stroke death rates for African Americans are about 1.5 times that of Caucasians ages 65-74. These health disparities within the Pittsburgh area reflect what is seen at both a state and national level. [8]

Racial and ethnic health disparities are evident in both national and local statistics. Many reasons have been postulated as to why blacks experience a disproportionate burden of morbidity and mortality when compared to whites. African Americans tend to be of lower socioeconomic status, which is closely linked to poor health status. In addition, blacks tend to have a greater exposure to psychosocial risk factors (such as unemployment and stress) as well as environmental risk factors (such as diet and high risk behaviors). Finally, blacks are less likely to have health insurance, less likely to receive medical care, more likely to receive medical care of poorer quality, less likely to have access to continuous care, and less likely to have access to preventative care. [8, 9] These are just some of the possible factors contributing to the nationwide problem that has generated the urgency reflected in the national efforts to eliminate racial and ethnic health disparities.

Recent federal legislation was passed entitled the Minority Health and Health Disparities Research and Education Act of 2000. This Act called for the NIH to create the National Center on Minority Health and Health Disparities (NCMHD). Its mission is to conduct and support research, training, and dissemination of information with respect to health disparities suffered by minority populations. [10] The NCMHD has funded several “Centers of Excellence” focused on the elimination of health disparities. The Center for Minority Health at the University of Pittsburgh is one of these national sites.



## **African Americans and Participation in Clinical Trials**

One of the recommendations for elimination of health disparities is to increase minority participation in clinical research. Minorities have historically been underrepresented in clinical trials. [10, 11] The majority of studies fail to collect data on race and ethnicity or fail to report it. When this data is collected, it is often apparent that the proportion of minorities participating is underrepresented. There are some areas of research in which the enrollment rate is especially lacking. Cancer research, AIDS clinical trials, women's health clinical trials, and psychiatric research have an especially low participation rate of ethnic minorities. [11]

The low minority participation in clinical research is a problem given the wide range of health disparities. As discussed previously, minorities have a higher prevalence of chronic conditions such as diabetes, certain cancers, and cardiovascular disease. In addition, conditions exist, such as breast cancer, in which the incidence is lower within minority populations but the rates of morbidity and mortality are significantly higher. [11] By including ethnic minorities in clinical research, we are giving individuals access to new and high-quality health care, increasing our ability to generalize research, learning of any potential difference in the pathophysiology of the disease, and checking for any race-related differences in treatment responses. [11, 12] Over sampling of certain racial subgroups may be the only way to assure adequate representation in clinical trials. [12] There is both promise and hope that by increasing minority participation in clinical research, science will discover the pathway to eliminate health disparities.

Recently, race-related differences in drug responses have been reported in pharmaceutical trials. Responses to drugs can be affected by differences in absorption, metabolism, distribution, excretion, and in the presence of other drugs. In some cases, these differences have been related to demographic characteristics, such as race. [13] While such findings may be controversial, it suggests that diverse study populations may be important in the development of new medications. As early as 1929, differences in drug responses were reported between blacks and whites. One of the more recent studies has shown that African American hypertensive patients repeatedly do not respond as well to antihypertensive  $\beta$ -blockers in comparison to white patients. Data suggest that race/ethnicity is a factor that should be considered when conducting and analyzing clinical drug trials. Differences among groups suggest the need for active recruitment of diverse populations so that adequate information on drug response and efficacy can be obtained. [14]

A study by Svensson (1989) looked at 50 drug clinical trials to examine the representation of African Americans. Overall, 55% of drug studies included blacks. About 13 of the 50 involved antihypertensive drugs. Of these, only 8 included African American participants and only 1 actually attempted to determine if there was a racial difference in drug response. Several suggestions have been made to improve our understanding of racial differences in drug responses: 1) All clinical trials should attempt to describe the racial composition of their study population; 2) Pharmaceutical manufacturers should attempt to increase enrollment of blacks in their clinical drug trails; 3) Specific studies should be conducted to examine the influence of race on drug response in order to assess the effectiveness or safety of new drugs in members of

minority groups. [15] The absence of this information will only limit the ability of patients to benefit from drug therapies. [14]

It is important during drug development to include participants who represent the broad range of patients who will eventually receive the drug, including people of both genders, representatives of major racial/ethnic groups, and patients with a wide range of disease severity. [13, 15] The FDA has modified the guidelines over the years to ensure the safety and efficacy of drugs by adequately studying them in individuals who represent the full range of patients who will receive them upon marketing. The 1998 Guidelines for the Format and Content of the Clinical and Statistical Drug Applications requires that “analyses of effectiveness and safety data for important demographic subgroups, including race, be included in NDAs and that enrollment of subjects in clinical studies for drug and biological products be tabulated by important demographic subgroups in investigational new drug annual reports.” [13]

The FDA is not the only organization working towards diversifying study populations in clinical trials. In a national effort to increase minority recruitment, the NIH passed the Revitalization Act of 1993 in which guidelines were established to include women and minorities in research involving human subjects, including clinical trials. These guidelines went into effect on March 9<sup>th</sup>, 1994, and stated that the NIH “*must* 1) ensure that women and members of minorities and their subpopulations are included in all human subject research; 2) for Phase III clinical trails, ensure that woman and minorities and their subpopulations must be included such that vast analyses of differences in intervention effect can be accomplished; 3) not allow cost as an acceptable reason for excluding these groups; and 4) initiate programs and support outreach

efforts to recruit these groups into clinical studies.” [10, 16] These guidelines were later amended in October of 2001 and incorporated four points: 1) the definition of clinical research was updated to patient-oriented research [research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects]; patient-oriented research includes mechanisms of human disease, therapeutic interventions, clinical trials, development of new technologies, epidemiologic and behavioral studies, outcomes research, and health services research; 2) racial and ethnic categories were updated in order to comply with the new standards issued by the Office of Management and Budget; the NIH is required to use these definitions to allow comparisons to other federal databases, especially the census and national health databases; 3) language governing NIH-defined Phase III clinical trials was clarified in order to be consistent with the mandate for the inclusion of women and minorities as subjects in clinical research; the amended policy provides additional guidance on the analyses and reporting of analyses of sex/gender, racial/ethnic, and relevant subpopulation differences in intervention effects for NIH-defined Phase III clinical trials; and 4) roles and responsibilities of NIH staff and the extramural community were updated with regard to the implementation of the NIH policy on the inclusion of women and minorities as subjects in clinical research. [10, 17] To date, no further changes have been made to this policy.

Despite detailed and increasing regulations to protect research participants, a large portion of the American population, particularly the African American population, continues to distrust physicians, medicine, and research. [18] Research has sought to provide explanations for the limited involvement in medical research. In addition to the distrust of the scientific community,

other reasons addressed in the literature include socioeconomic constraints, language and literacy barriers, misunderstanding of research, fear of deportation, lack of access to medical care, physician concerns about referring patients, an inability to recruit minorities into such studies, as well as researcher and physician biases. [11, 19, 20]

Distrust of the scientific research community by ethnic minorities, especially blacks, is deeply rooted in American history and stems from past mistreatment. For example, the history of slavery set the backdrop for distrust of authority figures and government leaders. Blacks also tend to distrust the American health care system and health care providers in general. African Americans tend to have more preventable hospitalizations and undergo fewer important diagnostic and therapeutic procedures. Studies have shown an overall lower level of trust and satisfaction of physicians by ethnic minorities. [11] Finally, African Americans have a long history of being abused as research subjects, dating back to the time of slavery when they were used for medical experimentation. One of the most blatant examples of research abuse was the Tuskegee Syphilis Study (1932-1972) in which poor black men were denied informed consent, were told procedures were therapeutic when in truth they were diagnostic, and were not given treatment for syphilis when it became available in the 1950's. This study is one of the more well-known examples of ethical misconduct in the context of clinical research, but other examples exist in which researchers failed to provide informed consent, withheld important information, changed the protocol without consulting individuals, and did not provide appropriate follow-up care. [11, 18, 20, 21] Given this history, it is understandable that African Americans and other ethnic minorities express distrust for the research community.

A number of studies have been conducted to examine the current attitudes of minorities towards medical research. [11, 18] Studies find that minorities are afraid of being treated like “guinea pigs”. These studies find that many African Americans think of research as unethical and that scientists are untrustworthy. In addition, African Americans are more likely to think that researchers conceal information from participants and have little respect for participants in comparison to whites. Overall, these results suggest that minorities harbor a general distrust of research and the research community. [7, 11]

In addition to clinical researchers, physicians are also distrusted by many African Americans. One study examined differences in distrust of physicians by race. A national telephone questionnaire was conducted with a population of over 900 black (59%) and white (41%) participants. African Americans were more likely than whites not to trust that their physician would fully explain research participation (41.7% vs. 23.4%); less likely to believe that they could freely ask their physician questions (15.2% vs. 7.6%); more likely to disagree that their physician would not ask them to participate in the research if the physician thought there was harm (37.2% vs. 19.7%); more likely to state that they thought their physicians sometimes exposed them to unnecessary risks (45.5% vs. 34.8%); more likely to believe that someone like them would be used as a “guinea pig” without his or her consent (79.2% vs. 51.9%); more likely to believe that physicians often prescribed medication as a way of experimenting on people without consent (62.8% vs. 38.4%); and more likely to think that their physicians had given them treatment as part of an experiment without their permission (24.5% vs. 8.3%). These important differences by race in aspects of trusting physicians may influence reluctance to participate in clinical research. [18]

In light of the overwhelming evidence that distrust is a major barrier to minority recruitment, many organizations have worked to rebuild trust with minority populations. For example, the Resource Centers on Minority Aging Research (RCMAR) reported being successful in building trust within the African American community. The researchers visited churches and spoke about their hopes of working together and how participation could benefit members of the community. They worked closely with well-respected leaders within the community. Once they had their trust, these well-respected leaders endorsed the studies and talked to their congregations about the benefits of joining the study. The researchers also built trust by helping with and participating in social events and providing clinical services within the community, thus developing a reciprocal partnership. As a result of the relationships built, there was an increase in participation by minorities in several research studies. In addition, they were able to maintain trust by sharing the research results. Following RCMAR's success, they published recommendations that can be adopted by other researchers for building trust and enhancing recruitment efforts (See Figure 1). [11, 19]

<b>RCMAR's Recommendations:</b>
1. Develop relationships with trusted community members, leaders, and community-based efforts
2. Recognize and incorporate the community's cultural standards and health concerns
3. Apply university resources during times of critical need
4. Participate in the political process regarding health concerns
5. Employ researchers and staff reflective of the community
6. Practice beneficence
7. Include community members in research development when possible
8. Communicate research outcomes to study participants and their communities
9. Provide incentives and reimbursements for participation
10. Use appropriate language
11. Elicit opinions from ethnic adults about their health priorities and solutions for overcoming participation barriers
12. Teach researchers cross-cultural sensitivity
13. Disseminate "best practices" for research recruitment and retention in academic forums

**Figure 1- RCMAR's Recommendations for Building Trust and Enhancing Recruitment [11]**

Following these guidelines will assist researchers in rebuilding trust and enhancing recruitment efforts. However, rebuilding trust is not the sole solution. Despite all of the research that finds trust to be a major barrier in minority recruitment, it would be misleading to suggest that it is the only barrier to participation in clinical trials. Several authors suggest that the attitudes of researchers and physicians act as barriers towards minority recruitment. Some researchers may limit minority recruitment due to a belief that minorities have lower rates of compliance and higher rates of attrition. Some researchers claim that including minorities or women in their studies lower the statistical power of their study. Others have low recruitment because they fail to establish research clinics in minority institutions. Another barrier mentioned by researchers is that there is limited funding that can be spent on actively recruiting minorities. [20] This evidence suggests that we need to not only work with the target populations to increase recruitment, but also work with the physicians and researchers who are also potentially introducing barriers.

Recruitment in the African American community needs to be an ongoing process of engagement, dialogue, and feedback. [18] A conference was held at Tuskegee in 1996 at which members of the local African American community met with community leaders, researchers, and health care providers to discuss minority recruitment issues. The conference was set up in the format of presentations, focus groups, and interviews. The African American community participants indicated during their focus group that they would be more likely to take part in research if they felt it was beneficial to their family or community and if it was supported by the church. Barriers to participation included time commitments, the collection of blood samples, the use of radiation, distrust, lack of information, and bad past experiences. They recommended solutions



to include workshops to provide more information about clinical trials, community education, utilizing churches, and using fraternities and sororities in recruitment efforts. The community leader interviews conducted during the conference identified barriers to minority recruitment as well, which included the perception that insurance will not cover clinical trials, complexity of consent forms and the research trials, and distrust of the healthcare system. The recommended strategies towards overcoming these barriers included making the project more accessible to participants, writing easy-to-read consent forms, scheduling study activities during nonworking hours, and using recruiters known within the study community. Finally, health care provider interviews revealed reasons for not referring minorities to clinical trials such as skepticism about the capability of low-income minorities to participate; concerns that their patients would be randomized to a control group; and fear that their patients would be “stolen away.” They proposed solutions to these problems including the development of educational programs for community physicians and the involvement of providers in prevention trials. At the conclusion of this conference, two themes emerged. The first theme involved the critical need to involve the community in the research process from the beginning. The second theme was the importance of researchers and community members having open dialogue. [22]

A similar study was conducted by Freimuth et. al. (2001). This study consisted of seven focus groups with 60 African Americans in 4 cities across the United States. This study was designed to examine knowledge and attitudes towards medical research as well as knowledge of the Tuskegee Syphilis Study. The study showed that participants had a limited understanding of various aspects of research and concluded that the presence of misconceptions may have an impact on participation. For example, few of the participants could clearly define common

research terms, such as confidentiality, informed consent, placebo, clinical trial, protocol, and randomization. Participants indicated that they had difficulty giving informed consent due to the complexity of the research. Few participants had ever participated in research and participants had trouble making the distinction between treatment, prevention, and research. In addition, several participants questioned the likelihood that African Americans would benefit from research. Upon completion of the study, it was concluded that a crucial first step in increasing minority recruitment is educating the public to have a clear understanding of research, its terms and procedures, and its many purposes. [20]

The extensive research conducted on the topic of minority participation in clinical trials indicates that increasing minority recruitment is not going to be an easy task. African American participants need to have a better understanding of research in general. More attention must be given to building trust between blacks and researchers as well as with the health care community. Also, racial biases in attitudes and opinions of researchers that act as barriers towards recruitment need to be addressed. Most importantly, all of these issues need to be openly discussed between the African American community, the research community, and the health care community in order to achieve a solution to the problem of minority recruitment.

### **Family History and Public Health**

As previously discussed, African Americans and other minorities are at an increased risk for developing common chronic diseases, such as heart disease, diabetes and cancer. According to the American Heart Association, these conditions are among the leading causes of morbidity and

mortality in the United States and other developed countries. [23] In addition, causes for these diseases are multifactorial, meaning that they are the result of multiple gene and environmental interactions. [24, 25] While these interactions are complex and still not completely understood, the family health history is a valuable tool that is able to capture the relationship between genetic susceptibilities, common behaviors, and shared environment. [24, 26, 27]

One of the most effective tools for recognizing an individual's risk for diseases with a genetic component is the analysis of his or her family health history, or pedigree. [25] The pedigree has long been a critical element in clinical genetics visit. It aids in making a diagnosis, determining risk, and assessing the need for patient education and providing psychosocial support. [25, 28] Genetic medicine has recently entered the realm of primary care. [25] It is estimated that 45% of families have a positive family history of one or more common chronic disease. [29] The family health history has been shown to predict the risk of many of these conditions, including heart disease [24, 27, 29, 30], colon cancer [24, 30], breast cancer [24, 30], ovarian cancer [24, 30], osteoporosis [24, 27], asthma [24, 27, 30], adult-onset diabetes mellitus [24, 27, 30, 31], and suicide[24]. Also, early cardiovascular-related events, such as coronary heart disease, stroke, hypertension, and diabetes, occur more frequently in families with a positive history of cardiovascular disease. [27] In general, a family history of a common, chronic disease is associated with relative risks ranging from 2 to 5 times greater than those of the general population. [23, 27] Therefore, the family health history has the potential to be a cost-effective, population-based screening tool for genetic risk of common diseases.[25]

Assessment of family history has been used in a few instances as a public health screening tool for a specific disease. One such example in the literature involves using family history as a population-based screening tool to identify individuals and families who were at high risk for cardiovascular disease (CVD). Two general approaches to primary prevention of CVD have been proposed: population-wide health promotion and targeted intervention in high-risk groups. Population-based educational programs have been instrumental in reducing CVD incidence. In addition, prevention methods have consisted of targeting high-risk individuals who can be offered more intensive intervention than the general population. A high school-based Health Family Tree Study in Utah successfully used family history to evaluate risk of CVD. Overall, 14% of Utah families had a positive family history of CVD. However, these families accounted for 72% of all early heart disease events and 48% of events at any age. These results demonstrate that early events of heart disease cluster in families with a positive family history and that these families might benefit from rigorous intervention. [29]

The potential usefulness of the family health history has also been demonstrated in the case of identifying individuals who are high-risk for diabetes. It has been suggested that a large percentage (33%-50%) of individuals with Type 2 diabetes are undiagnosed and untreated, translating to about 8 million people. Furthermore, many people with diabetes will already have complications associated with the disease prior to the time of diagnosis. There is a need to identify individuals at high risk for developing the disease and encourage behavior modification that could result in disease prevention. [32] Knowler et. al (2002) performed a study on 3234 non-diabetic individuals in which people were randomly assigned to one of three groups: placebo, metformin (850mg, 2x a day), or lifestyle modification (consisting of weight-loss and

increased physical activity.) The lifestyle intervention reduced the incidence by 58% whereas the metformin reduced the incidence by 31%. [33] Results of this and other similar studies have lead the American Diabetes Association to issue a position statement that states that lifestyle modifications including healthy diet, increased physical activity, or pharmacologic interventions can significantly decrease the incidence of diabetes in high-risk groups. This evidence suggests that it is possible to delay the onset of diabetes.[32] Therefore, it is essential to identify high-risk individuals who would benefit from targeted interventions.

Family history has been shown to be a key tool in identifying individuals at risk for developing diabetes. There is a two-fold to six-fold increased risk for Type 2 diabetes when there is a family history. The risk is found to be elevated across various study designs and ethnic groups. It has been suggested that once individuals are aware of the increased risk, they are more likely to partake in risk-reduction behaviors. [32] One study of 1112 participants found that individuals with a positive family history (39%) were 45% more likely to report having a diabetes screening in the past year over individuals without a family history (61%). [34] This evidence indicates that family history information can be useful in identifying individuals at high risk for disease who then may be more likely to participate in appropriate interventions.

Research suggests that family history by itself is most useful for predicting disease when multiple family members are affected, when family members are closely related, and when individuals are diagnosed with early-onset disease. [27] Research has aimed to identify the accuracy of family history information reported by individuals. In a case-control study, the authors reported that histories of first-degree relatives were validated using death certificates,

physician records, and hospital records. In the 174 cases examined, the sensitivity, positive predictive value, and specificity were 67.3%, 70.5%, and 96.5% respectively. The lower sensitivity values indicate some under-reporting of disease in relatives. [23] Another study examined the accuracy of patient reports of a family history of cancer. The accuracy of cancer-site identification by the participant was 83.7%, and about 71% in first and second-degree relatives. [23] Overall, these studies suggest that a positive family history report can generally be used with a high degree of accuracy.

Family history information can be a valuable tool in disease prevention. However, collection and interpretation of this information is rarely used in public health practice or preventative medicine as a means to assess disease risk and design methods for early detection and preventive strategies. [27-29] Henderson and Scheuner (1998) performed a study that examined 15 primary care physicians to determine how family history information was collected and recorded during regular primary care visits. The study found that of all the patients that reported a positive family history for at least one common disease, the physician only recorded the family health history 36% of the time. [27] A study by Acheson (2000) found that physicians only discuss family history information about half of the time during new patient visits. This percentage decreased to 22% in established patient visits. When physicians did take the time to discuss family history information, the average duration of the discussion was less than 2.5 minutes. When the physician's charts were reviewed, only 11% contained some sort of family health history. [27, 35] It appears that family history information is lacking as a routine screening tool in primary care settings.

A variety of reasons have been proposed to explain why family history information has not been used effectively by health professionals. For example, Guttmacher believes that clinicians commonly underestimate the immense value of family history information. Many physicians find it difficult to find the time to obtain, organize, and analyze family history information. [24] Also, many physicians report that they have had little training in genetics, they feel uncomfortable providing genetic counseling, and are wary of interpreting genetic test results. [23, 25] In a study that looked at traits of physicians who utilized family history information, physicians with fewer years of practice were more likely to take family health histories. Also, physicians with greater knowledge of genetics were more likely to provide risk assessments based upon family history information. Finally, physicians who had a higher rate of preventive service delivery were more likely to discuss and record family history information. [35]

A study conducted by Suchard et. al. (1999) examined the attitudes of 339 general practitioners to determine their use of family health histories. Approximately 60% of practitioners agreed or strongly agreed that they should be involved with screenings for common diseases. However, only 29% of respondents reported that they were adequately prepared to take a family health history. This shows that while health professionals may understand the utility of family health histories, there is a drastic need for educating health professionals and helping them to feel comfortable in recording and interpreting family history information. However, it is promising that 78% of respondents wanted to learn more about genetic screenings. [36]

While physicians may or may not recognize the benefit of family history information, the general public tends to think that it is useful. A recent questionnaire of over 4000 individuals was

conducted to analyze public opinion on family history information. The authors reported that 73% of individuals felt that knowledge of family history information was very important and an additional 24% of people felt that this information was somewhat important. Despite this, only 30% of respondents indicated that they had actually collected family history information. [24]

It appears that the general public and physicians would both benefit from family history information in health promotion and disease prevention. Failure to recognize a positive family history could lead to detrimental health effects. For example, many women are unaware that a family history of breast/ovarian cancer in their father's family may warrant increased cancer screenings. If their physician never takes their family health history, women may not be involved in proper surveillance. [24] Individuals who have a genetic susceptibility to a condition such as hereditary breast and ovarian cancer can often benefit from enhanced screening protocols that involve more intense screening methods, beginning at earlier ages, and occurring more frequently. [23, 26] For example, women at greater risk for breast and ovarian cancer are recommended to have annual mammograms beginning as early as 25 in comparison to the general population's recommendation of beginning at age 40. They are also recommended to have monthly self breast exams starting at ages 18-21 and semiannual clinical breast exams starting at ages 25-35. In order to reduce their ovarian cancer risk, screening tests such as semi-annual CA-125 blood tests and semi-annual transvaginal ultrasounds are also available. These ovarian screening tests are not routinely offered to the general population. [37]

Screenings are not the only way for high-risk individuals to reduce their risk. Many conditions have behavior-modification strategies that have been demonstrated to prevent disease or delay



onset. [24, 26] For example, the risk for developing diabetes or coronary artery disease can be decreased by making modifications in lifestyle behaviors and diet. When a clinician is unaware of a positive family history for one of these conditions, relevant behavior modifications may never be recommended and may never take place. [24] Some individuals may benefit from chemoprevention, or taking medications that lower their risk. A physician would not recognize the need to prescribe these medications without knowing that their patients are at risk. Finally, some family histories may direct a physician to refer the patient to a specialist that can best manage a patient's risk for a particular condition. [26] Noting a family history early could allow a patient to benefit from the expertise of a specialist who could educate the patient about possible preventative measures. There are compelling reasons to routinely collect family history information for each individual patient.

Measures need to be taken to increase the effectiveness and use of the family health history. The first step is to educate both the public and health care professionals about the value of the family health history. In addition, a method for collecting and analyzing this information that makes the task easy and time-efficient for the clinician is needed. [24] Once an individual is identified as being at increased risk, the clinician would have the opportunity to counsel a patient about lifestyle changes and screening techniques for risk reduction. While each individual reacts differently upon learning about his or her risk, some studies suggest that individuals are more likely to comply with preventive recommendations once they have this information. [25] Prevention efforts that would be cost-prohibitive in the general population could prove to be cost-effective when they are targeted towards high-risk individuals. [27]

The U.S. Surgeon General has developed a Family History Initiative with the goal to increase awareness of the importance of family history and to provide a tool that collects and organizes family history information. Thanksgiving Day has been designated as the annual National Family History Day in order to increase communication about family health issues among family members. A web-based tool ([www.hhs.gov/familyhistory](http://www.hhs.gov/familyhistory)) that allows individuals to organize and store their family history information is available. In addition, individuals can easily access this information and update their family health histories over time as their situation changes. This tool also highlights conditions in which known medical recommendation exist. These conditions include breast cancer, ovarian cancer, colon cancer, stroke, diabetes, and coronary artery disease. [24]

People should be encouraged to collect family history information. Having families put together this information can enhance their awareness of shared disease risk and can provide an opportunity for family-based lifestyle changes. Encouraging individuals to collect family history information may prove to be a beneficial public health prevention tool. [29]

Until we have genetic tests that identify susceptibility genes and a way to measure environmental exposures, family history information that reflects both genetic and environmental factors may be an effective means for predicting risk for future disease. [27] A comprehensive family health history that includes information regarding common, chronic disease of adulthood should be an integral component of any disease prevention program. This technique is a comprehensive and generally accurate method for risk stratification for many preventable conditions that impact a large percentage of the general population as well as the African American population.

Individuals identified in this manner have the most to gain from targeted preventive interventions. [23]

Family history information can be recorded graphically in the form of a family health history, or pedigree, which is a quick visual tool for incorporating and interpreting medical information. Key information recorded for each individual in a pedigree includes age, age of death, cause of death, siblings (denote if half or full), children (note if with separate partners), parents and grandparents, aunts, uncles, cousins, age at diagnosis, ethnic background for all grandparents, and consanguinity. [26, 38] It is important to record this information so that both the presence of a family history that confers risk and a family history that does not can be noted. In addition, this graphical form of a health history shows the exact relationship of relatives and can be critical in making a diagnosis or assessing risk. A pedigree can also be used as a visual tool for assessing the medical, emotional, and social impact of a disorder on the patient and the entire family. In addition, a pedigree is a valuable tool for patient education because it is a visual representation of their entire family. These are just some of the many benefits of a pedigree that make it an ideal method for identifying individuals at risk for common disease and helping individuals to understand their risk (See Figure 2). [38]

There is a clear role for public health professionals to incorporate family health histories into community outreach activities. As previously discussed, the systematic use of family health histories in public health and preventative medicine is largely neglected. [39] It is possible that if family health histories made their way into general practice, general practitioners could utilize the benefits of a family health history and provide genetic screenings for common diseases.

### Uses of a Pedigree [38]:

- Developing a differential diagnosis
- Identifying genetic and environmental risk factors for disease
- Establishing a pattern of inheritance for genetic counseling and risk assessment
- Identifying medical risks for other relatives
- Deciding an approach to genetic testing
- Planning medical management, prevention, and surveillance
- Assessing reproductive options
- Developing patient rapport and trust
- Recording a snapshot of family's health-related experiences
- Seeing family dynamics: sources of conflict or support
- Patient education; clarifying misconceptions

**Figure 2- Uses of a Pedigree**

Their roles could include making initial contact with concerned patients, taking family health histories to assess risk, referring patients for genetic testing and counseling, and providing patients with information about their personal risk. [36] The benefits of family history information led to the development of the Healthy Black Family Project within the University of Pittsburgh's Center for Minority Health.

The Center for Minority Health has incorporated the family health history into community outreach programs focused on African Americans. One issue that is not widely found in the literature is the importance of taking family history information in a culturally appropriate manner when screening for common disease. Culture, in general, shapes the way each of us thinks and as a result, culture is deeply ingrained in many belief systems, including beliefs dealing with health. [40] Therefore, ethnocultural considerations must be taken into account when using family history information as a population-based screening and prevention tool. Since African Americans are at increased risk for common diseases, they are an important population to consider when developing these family history tools. Culturally appropriate tools

needs to take into account cultural variation by disease susceptibility, healthcare access, disease definition, risk estimation, and lifestyle behaviors. [32]

The Center for Minority Health and the Healthy Black Family Project aim to reach out to the African American community in a culturally-competent fashion to provide individuals with knowledge that emerges from their family health history. In addition to the benefit of having this knowledge, individuals have the opportunity to have their family health history entered into a research database and to be sent information about clinical trials.

The present study aims to characterize individuals who completed a family health history and describe factors associated with a willingness to enroll in the Minority Research Recruitment Database.

## METHODS AND PROCEDURES

### Healthy Black Family Project

The Healthy Black Family Project (HBFP) is a comprehensive community-based intervention designed to promote health and prevent disease. The HBFP is focused on a geographic area called the Health Empowerment Zone (HEZ): East End neighborhoods, including – East Hills, East Liberty, Homewood North, Homewood South, Homewood West, Larimer, Lincoln Larimer, and Wilkinsburg (See Figure 3). These areas of Pittsburgh have an average of 79.1% African American residents and an average of 25.7% of residents living below the federal poverty line. The Family Health History is one of the innovative methods used to engage the community.

Zip Code	Neighborhoods
15147	<b>Penn Hills</b>
15206	<b>Lincoln, Lemington, Belmar, East Liberty, Larimer, Garfield</b>
15207	<b>Glen Hazel</b>
15208	<b>Point Breeze North, Homewood South, Homewood North, Homewood West</b>
15213	<b>Terrace Village, Upper Hill</b>
15219	<b>Crawford Roberts, Terrace Village, Middle Hill, Bedford Dwellings, Upper Hill</b>
15221	<b>Homewood North, East Hills, Wilkinsburg</b>
<b>15224</b>	<b>Garfield</b>

Figure 3- The Health Empowerment Zone: Zip Codes and Neighborhoods

## **Family Health History Initiative**

The Family Health History component of the HBFP sends genetic counseling graduate students from the University of Pittsburgh, Graduate School of Public Health, Department of Human Genetics, to African American churches, retirement centers, health/community fairs, and barbershops/salons within the HEZ. Interested individuals are able to inquire about the family health history process at the HBFP information table. Students then meet with individuals for a one-on-one session, lasting from 30 minutes to one hour. The individual's detailed family health history, or pedigree, is recoded by hand. Once the pedigree is complete, the student provides a general risk assessment, often focusing on common, chronic diseases that the individual may be at increased risk for developing, based upon their family health history. The student then provides the individual with information on relevant behavior modifications that may reduce their risk. The student also emphasizes the importance of sharing this information with other family members and with his or her physician. After the one-on-one family health history session, the student uses the hand-drawn family health history to create a computer-generated version of the pedigree using Progeny® software. This document is sent to the participant along with targeted health education materials and a certificate of appreciation (See Appendix F).

## **The Minority Research Recruitment Database**

Individuals who complete their family health history are given the opportunity to enroll in The Minority Research Recruitment Database, created by the Center for Minority Health as one effort to increase minority recruitment into clinical research trials. By giving informed consent and enrolling into the database, the individual's pedigree is stored in Progeny®. As CMH becomes

aware of a clinical study that is currently recruiting individuals, the database is queried for people who may meet the inclusion criteria. Individuals who are identified are then sent information about the details of the study along with the investigator's contact information. Contact information is kept entirely within the database and is at no time released to any study investigators.

### **Assessing African American's Response to Family Health Histories**

The purpose of this study was to assess the response of African Americans to Family Health Histories. This study was funded by a grant to Stephen B. Thomas from the National Institutes of Health: National Center on Minority Health and Health Disparities, and received approval by the University of Pittsburgh Institutional Board of Review (IRB) in May of 2004 (See Appendix B). The specific aims of the study were to: 1) describe the extent to which individuals with a family history of a particular condition demonstrate higher levels of awareness regarding their increased risk compared to individuals without a family history of that condition, 2) describe the extent to which knowledge of a personalized family health history shapes "information seeking" and other behaviors associated with health promotion and disease prevention, 3) describe the extent to which knowledge of a personalized family health history, including review of the pedigree, shapes willingness to participate in research, and 4) compare and contrast demographics, recruitment variables, health care information, family health, personal health status, and opinions about research between individuals who agree to enroll in the Minority Research Recruitment Database to individuals who decline participation.



The overall study was organized into two smaller studies designed to serve as Master's thesis projects for two graduate students. This thesis will focus on the 4<sup>th</sup> specific aim related to willingness to enroll in the database.

## **Procedure**

All individuals who agreed to a family health history session were offered the opportunity to participate in this study. If they expressed interest, the student reviewed the informed consent with the participant, explaining the aims, process, risks, and benefits of the study. If participants remained interested, they signed the informed consent. Also, they were asked if they were interested in enrolling in the Minority Research Recruitment Database. The database was explained to be a method in which their family health history would be stored and queried and that they may be contacted with information about clinical trials for which they may qualify, based upon family history information. If individuals were interested in enrolling, they signed the portion of the consent form that enrolled them into the database.

Once the consent process was complete, they were asked to answer the pre-questionnaire. This questionnaire consisted of demographic questions and questions about risk perception (See Appendix C). Once they completed the initial questionnaire, the student took their family health history, eliciting as many generations as possible based upon the participant's memory. Once the family health history was completed and a risk assessment was provided to the participant, they were asked to complete the post-questionnaire. This questionnaire consisted of risk perception questions, questions about individuals' opinions on research, and questions about a research

recruitment database (See Appendix D). Finally, individuals were asked to give permission to be contacted in one month to have a short follow-up phone interview (See Appendix E).

### **Pre- and Post- Questionnaires**

The questions used for this study included the demographic questions from the pre-questionnaire and the questions about attitudes and beliefs towards research, the research recruitment database, and post-session risk perception. The majority of demographic questions and all of the questions about research opinions came directly from a study completed by S. B. Thomas, et. al [41]. This study assessed the influence of demographic variables on willingness to participate in a medical research study. The results of this study were directly reported to the Centers for Disease Control and Prevention (CDC). In addition, the results of this study were reported in the Archives of Internal Medicine in 2002. [18] In regards to the remaining questions used in this study, they were created through the collaborative efforts of the Healthy Black Family research team.

#### Pre-questionnaire – Section 1: General Information

Section 1 of the pre-questionnaire asked respondents to disclose demographic information and health care information. Respondents were asked about their age, gender, race/ethnicity, total household income, level of education, knowledge of genetics, description of their general health, whether they have a primary health care provider, whether they have had difficulty going to a physician due to cost, health insurance status, whether they are currently concerned about developing a condition, to rate their worry for developing that condition, and whether they have spoken with a health professional about their concern for developing that condition.

### Post-questionnaire – Section 1: Risk Perception

Section 1 of the post-questionnaire asked individuals to rate their risk (Low, Moderate, and High) for the following conditions: breast cancer, ovarian cancer (females only), colon cancer, prostate cancer (males only), cardiovascular disease, lung cancer, diabetes, Alzheimer's disease, and hypertension. In addition, they were asked to rate their risk in comparison to individuals of the same gender and age as them for the same conditions mentioned above. They rated their comparative risk on a scale from 1 (much lower) to 5 (much higher).

### Post-questionnaire – Section 2: Opinions on Research

Section 2 of the post-questionnaire asked participants a variety of different questions regarding their opinions on research as well as their opinions on a database comparable to the Minority Research Recruitment Database. They were asked how important they felt medical research was, if they have ever participated in medical research, whether they have ever declined an opportunity to participate in medical research, and their general attitude towards medical research that uses human subjects. They were then asked how the following factors would affect the likelihood that they would agree to participate in clinical research: free medical care, \$500, and free medicine. They were then asked how much they felt the following groups of individuals benefit from medical research: scientists, their community, their family and friends, and them (as individuals). The last group of questions on the post-questionnaire asked individuals to think about a database such as the Minority Research Recruitment Database and to indicate if they would have interest in entering such a database (Note: This is not where individuals enrolled in the database – they could only enroll by giving consent during the

informed consent process). If individuals indicated that they were interested, they were asked to answer a question in which they gave their expectations for such a database. Individuals who were not interested in enrollment were asked to answer a question in which they gave reasons for declining. Finally, participants were asked to describe their overall experience of having their family health history taken.

### **Pedigree Analysis**

In the American Journal of Medical Genetics, Scheuner et al. (1997) established general guidelines for risk stratification for many common diseases, based upon family history information. These guidelines use number of affected relatives, degree of relatedness, and age of onset to place individuals at average (population) risk, moderate risk, or high risk. These guidelines apply to heart disease, stroke, diabetes, colon cancer, prostate cancer, breast cancer, ovarian cancer, and endometrial cancer [23] (See Figure 2 below). Using these criteria, each pedigree was analyzed for all of these conditions and each individual was placed at average, moderate, or high risk, based upon their family health history. Personal history was not used for risk stratification but was ascertained for heart disease, stroke, diabetes, colon cancer, breast cancer, ovarian cancer, endometrial cancer, Alzheimer's disease, hypertension, mental illness, and substance abuse (including alcoholism). We also examined each family for Alzheimer's disease and hypertension using Scheuner's stratification guidelines. We defined premature age of onset Alzheimer's disease to be  $\leq 65$  (given information identified on the Alzheimer's Association's website at <http://www.alz.org/Resources/FactSheets/FSonset.pdf>) and premature hypertension to be  $\leq 50$  (no distinct guideline was identified so we chose 50 to be conservative).

We also noted whether any individual reported having two or more 1<sup>st</sup> or 2<sup>nd</sup> degree relatives with mental illness of any kind or substance abuse (including alcoholism). Each pedigree was analyzed independently by two genetic counseling students. Once each pedigree was analyzed for personal history and family history, the two counseling students compared results. Any discrepancies were reanalyzed by three genetic counseling students in order to establish an agreed upon conclusion.

Guidelines for Risk Stratification [23]		
High Risk	Moderate Risk	Average Risk
<ol style="list-style-type: none"> <li>1. Premature disease* in a 1<sup>st</sup> degree relative</li> <li>2. Premature disease* in a 2<sup>nd</sup> degree relative (coronary artery disease only)</li> <li>3. Two affected 1<sup>st</sup> degree relatives</li> <li>4. A 1<sup>st</sup> degree relative with late/unknown onset of disease and an affected 2<sup>nd</sup> degree relative with premature disease* from the same lineage</li> <li>5. Two 2<sup>nd</sup> degree maternal or paternal relatives with at least one having premature onset of disease*</li> <li>6. Three or more affected maternal or paternal relatives</li> <li>7. The presence of a “moderate risk” family history on both sides of the pedigree</li> </ol>	<ol style="list-style-type: none"> <li>1. A 1<sup>st</sup> degree relative with late or unknown disease onset</li> <li>2. Two 2<sup>nd</sup> degree relatives from the same lineage with late or unknown disease onset</li> </ol>	<ol style="list-style-type: none"> <li>1. No affected relatives</li> <li>2. Only one affected 2<sup>nd</sup> degree relative from one of both sides of the pedigree</li> <li>3. No known family history</li> <li>4. Adopted individual with unknown family history</li> </ol>
<p>*Premature disease: coronary artery disease onset <math>\leq 55</math> yrs in males, <math>\leq 65</math> yrs in females; stroke, noninsulin-dependent diabetes, colon and prostate cancer onset <math>\leq 50</math> yrs; breast, ovarian, and endometrial cancer onset premenopausal or <math>\leq 50</math> yrs.</p>		

**Figure 4 - Scheuner’s General Guidelines for Risk Stratification**

## **Extrapolated Data**

A portion of data used for analysis were collected through pedigree analysis. It was determined which individuals reported suffering from at least one chronic condition as well as how many conditions each individual reported having. It was also determined which individuals were considered high-risk for at least one condition, based upon their family health history. In addition, the number of high-risk conditions, based upon their family health history, was tabulated for each individual. Similarly, data were collected on which individuals perceived themselves at high risk on the questionnaire for at least one condition. The number of conditions for which they considered themselves to be at high-risk was also tabulated. Finally, a comparison was made between individuals' perceived risk from the questionnaire to their actual risk based upon their family health history. By making this comparison, the number of conditions that each individual over-estimated their risk, under-estimated their risk, and accurately estimated their risk was determined. These data were entered into an Excel spreadsheet for the first phase of the data analysis.

## **Data Analysis**

Each pre- and post-questionnaire was entered into an online version of the questionnaire using QuestionnaireSolutions<sup>®</sup>. The questionnaire data were then exported into an Excel<sup>®</sup> file. All of the data in excel were checked against the original questionnaires to correct for any errors made in entering the responses into the online version of the questionnaire. The family history risk information and the personal history information (from the pedigree analysis) were then added into the spreadsheet.

Once all of the data were entered into the spreadsheet, it was decided that only data on African American participants would be analyzed. Non-African American individuals were excluded due to their small representation of the total study population (4 individuals out of 130). The participants were then divided into two groups: those who elected to enroll in the database and those who declined enrollment. Once they were divided into their respective groups, the data were tabulated using Excel. R<sup>®</sup> Statistical Package [42] was used to complete Binomial tests of proportions [43-45] and Fisher's exact tests [46, 47] to determine significant differences between the group of individuals who enrolled in the database and those who declined enrollment.

Whenever the analysis involved two variables (i.e. male vs. female), a binomial test of proportions was used. This statistical analysis compares observed proportions using binomial probability for expectation. [43-45]

$$Z = \frac{|p_2 - p_1|}{\left(\frac{p_1q_1}{n_1} + \frac{p_2q_2}{n_2}\right)^{1/2}}$$

Whenever the analysis involved three or more variables (i.e. average risk vs. moderate risk vs. high risk), a Fisher's exact test was used. This statistical analysis consists of evaluating the probability of the observation table and comparing it to the probability for all other simulated tables with similar marginal counts. [46, 47]

$$Pr = \frac{(n1!)(n2!)(n1!)(n2!)}{(n..!)(n11!)(n12!)(n21!)(n22!)}$$

## **RESULTS**

During this study, 175 individuals completed their family health history with a genetic counseling student. Of these individuals, a total of 126 (72%) African Americans agreed to complete the pre- and post-questionnaire during their family health history session. For each participant, extensive information was collected on multiple generations within the family. Information was collected on a total of 4491 individuals. The average pedigree size was 36 individuals. The most common conditions reported included hypertension, diabetes, cancers, heart disease, stroke, mental illness, and substance abuse.

Among the 126 participants who participated in the study, 100 (79.4%) elected to enroll in the Minority Research Recruitment Database and 26 (20.6%) declined enrollment. Data analysis compared selected variables between individuals who enrolled in the database to those who declined enrollment. Information compared included demographics, recruitment variables, health care, attitudes and beliefs regarding research, personal health status, and family history.

### **Demographics of the Study Population**

Demographic information collected included the participants' gender, age, race/ethnicity, income level, and education. These data were collected to ascertain any possible significant differences in demographics between the individuals who enrolled in the database and those who declined enrollment. In addition to this information, individuals were asked to rate their knowledge of genetics.



Basic demographic characteristics were analyzed for all study participants. There was a significant difference between the gender distribution in the participants who elected to be enrolled in the database and the individuals who declined enrollment (See Table 5 in Appendix A). Men were more likely to decline enrollment when compared to women ( $P=.038$ ). The distribution of race/ethnicity, age, income level, education, and knowledge of genetics were not significantly different between individuals who enrolled in the database and those who did not (See Table 2 and Tables 6-10 in Appendix A).

### **Participant's Family Health History Session**

Each participant completed a family health history session. There were three different genetic counseling students who conducted the sessions and there were a variety of locations for participant recruitment. Both of these variables were examined to detect possible correlations with the participants' willingness to enroll in the database. In addition, each participant was asked on the questionnaire to describe their experience of having their family health history completed as being enjoyable, informative, uncomfortable, and/or no opinion, and to choose all answers that applied.

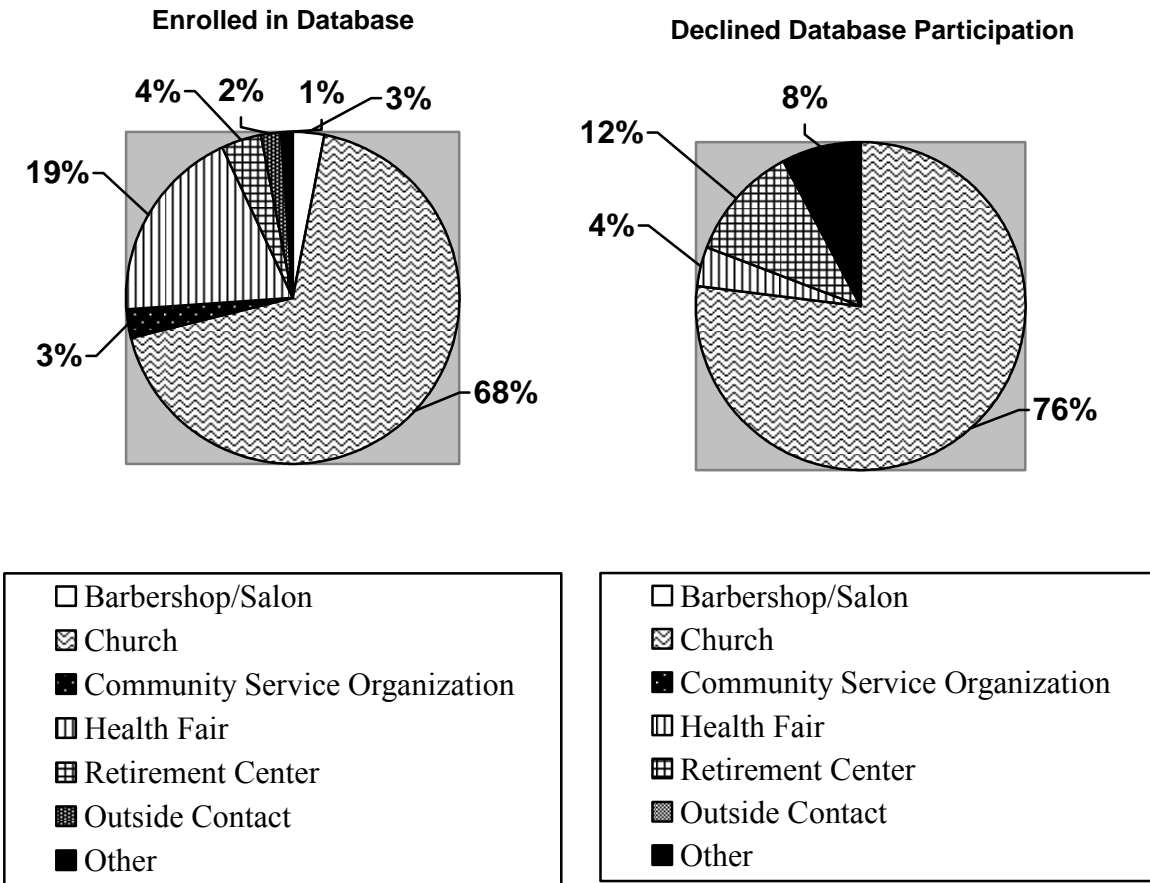
The participant's likeliness to enroll in the database was not correlated with the student who completed the family health history session (See Table 11 in Appendix A). However, there did appear to be a correlation between enrollment in the database and location of recruitment. While the majority of individuals from both groups were recruited in a church, there was a much wider

**Table 2 - Comparisons of Proportions for Demographic Information**

Demographic Variable	Enrolled in Database % (n)	Declined Enrollment % (n)
Age		
18-35	13% (13)	15.4% (4)
36-50	41% (41)	38.5% (10)
51-65	33% (33)	34.6% (9)
66+	13% (13)	11.5% (3)
Gender*		
Female	82% (82)	65.4% (17)
Male	18% (18)	34.6% (9)
Race		
African American Only	91% (91)	92.3% (24)
African American and Other	9% (9)	7.7% (2)
Income Level		
<\$10,000	4.1% (4)	8% (2)
\$10,001-\$20,000	17.5% (17)	16% (4)
\$20,001-\$35,000	25.8% (25)	20% (5)
\$35,001-\$50,000	18.6% (18)	16% (4)
\$40,001-\$75,000	13.4% (13)	16% (4)
>\$75,001	20.6% (20)	24% (6)
Education		
8th Grade or Less	0% (0)	3.8% (1)
Some High School	5% (5)	0% (0)
Completed High School	14% (14)	3.8% (1)
1-3 Years College	40% (40)	46.2% (12)
4+ Years of College	23% (23)	23.1% (6)
Graduate School	18% (18)	23.1% (6)
Knowledge of Genetics		
Poor	19% (19)	15.4% (4)
Fair	42% (42)	26.9% (7)
Good	27% (27)	26.9% (7)
Very Good	10% (10)	19.2% (5)
Excellent	2% (2)	7.7% (2)

\* Comparison of gender distribution showed a significant difference (P=.038)

variety of recruitment sites for the individuals who enrolled in the database (See Figure 5). While this correlation existed, it did not reach statistical significance ( $P=0.088$ ) (See Table 13 in Appendix A).



**Figure 5 - Comparison of Recruitment Locations**

Finally, when each individual was asked to describe their experience, there was not a significant difference between those who enrolled in the database and those declined enrollment (See Tables 13-16 in Appendix A). However, it was noteworthy that of the total participants, 63.5% rated the experience as enjoyable, 71.4% rated the experience as informative, 3.2% rated the experience as “neutral”, and no one rated the experience as being uncomfortable.

## **Participants' Opinions about Research**

The questionnaire addressed individuals' opinions on different aspects of research. Given that the aim of the database is to make individuals more aware of clinical research studies and potentially increase minority recruitment, it was hypothesized that there would be a significant difference in the attitudes and beliefs regarding research between those who enrolled in the database when compared to those who declined enrollment.

Questions were asked on the post-questionnaire to determine whether participants were in favor of medical research and if they had a past history of participating in research. All of the participants from both groups responded that they found medical research either very important or somewhat important. The individuals in the database were slightly more likely to say that they found medical research very important, although the difference did not reach statistical significance ( $P=0.084$ ) (See Table 17 in Appendix A). In addition, the majority of individuals in both groups reported that they found research *involving humans* either very favorable or somewhat favorable and there was not a statistically significant difference between the individuals who elected to enroll and those who declined (See Table 18 in Appendix A). Out of all participants ( $n=125$ ), only 35 (28%) individuals had ever previously participated in a clinical trial. There was no significant difference in the participation rate between individuals enrolled in the database and those who declined enrollment (See Table 19 in Appendix A). However, there was a significant difference between the two groups when they were asked to report a past history of refusing to participate in a clinical study ( $P=0.044$ ). Individuals who declined

enrollment in the database were more likely to have a history of refusing participation in a clinical study (See Table 20 in Appendix A).

Questions within the post-questionnaire were asked to determine how various incentives (money, free medication, and free health care) impacted the likelihood that an individual would want to participate in research. Each incentive was examined by comparing the proportion of individuals who responded that an incentive would make them more likely to participate to the number of individuals who responded otherwise. More than half (55.2%) of total individuals who answered these questions (n=125) responded that \$500 would make them more likely to participate in research. In addition, the individuals enrolled in the database who responded (n=99) were significantly more likely to state that they would be more likely participate in clinical research when \$500 (P=0.028) was offered as an incentive, in comparison to those individuals who did not enroll in the database (n=26) (See Table 3 and Table 21 in Appendix A). Approximately 53.6% of total individuals who responded (n=125) reported that free health care would increase the likelihood that they would participate in research. It appears as though the incentive of free health care may also appeal more to the individuals in the database when compared to the individuals who declined enrollment, although the difference between the two groups did not reach statistical significance (P=0.072) (See Table 3 and Table 22 in Appendix A). In regards to the incentive of free medication, 44% of total individuals reported that free medication would make them more likely to participate in research. However, unlike the other incentives discussed, there was not a significant difference in individuals' opinions on the effect of free medication between the two groups. (See Table 3 and Table 23 in Appendix A).

**Table 3 – Comparisons of Proportions for Effects of Incentives on Research Participation**

Incentive	Enrolled in Database % (n)	Declined Database % (n)
\$500*		
More likely to Participate	59.6% (59)	38.5% (10)
Other Response <sub>1</sub>	40.4% (40)	61.5% (16)
Free Health Care		
More likely to Participate	57.6% (57)	38.5% (10)
Other Response <sub>1</sub>	42.4% (42)	61.5% (16)
Free Medication		
More likely to Participate	45.5% (45)	38.5% (10)
Other Response <sub>1</sub>	54.5% (54)	61.5% (16)

1-Other Responses: less likely to participate, no effect on participation, or uncertain of effect

\*Comparison of the effect of \$500 showed a significant difference (P=0.028)

Participants were asked on the post-questionnaire to describe the benefit that they felt different groups (e.g. scientists, community, family/friends, and themselves) received as a result of clinical research. Virtually all of the participants felt that scientists benefit a great deal from clinical research. Responses varied when it came to the benefit to the community, family/friends, or themselves; although the majority still felt that these groups benefited a great deal from clinical research. In addition, there were no statistically significant differences in these opinions between the individuals who elected to enroll in the database and those individuals who declined enrollment (See Tables 24-27 in Appendix A).

Individuals were also asked to consider a database such as the Minority Research Recruitment Database and to either provide expectations for such a database when they were interested in enrolling or to provide reasons why they would not be interested in enrolling. Paradoxically, some individuals who enrolled in the database gave reasons for why they would not be interested in such a database and individuals who declined enrollment gave expectations for such a database. Looking at responses from all participants, 103 of the 126 individuals provided expectations for such a database. Of these individuals, 70% reported that they expected

information on clinical studies for which they were eligible, 46.6% reported that they expected information on *all* clinical studies, 30.1% reported that they expected superior care by participating in studies, 19.4% reported that they expected incentives for participating in studies, and 7.8% gave additional expectations for a database such as the Minority Research Recruitment Database. Such additional expectations included getting information pertaining to the health of them and their families and getting the results of the studies. The remaining 23 individuals gave reasons why they would not be interested in such a database. Of these individuals, 52.2% said that were not interested in any sort of database, 30.4% indicated that they did not want to disclose their contact information, 26.1% reported that they were not interested in research, 8.7% stated that they did not want to be part of anything that was related to their family health history, and 21.7% gave additional reasons as to why they would not be interested in a database such as the Minority Research Recruitment Database. Additional reasons included time constraints, transportation constraints, and distrust of the research community.

### **Participants' Health Care**

On the pre-questionnaire, individuals gave information about their health care, including information about insurance coverage, their physician, and whether they communicated their concern about disease development with their physician. In regards to insurance coverage, participants in the database were significantly less likely to have insurance coverage in comparison to individuals who declined enrollment ( $P=0.041$ ) (See Table 28 in Appendix A). However, both groups were equally likely to respond that they were unable to see a physician due to cost over the past year (See Table 30 in Appendix A). In regards to a primary care

physician (PCP), the majority of individuals had one or more PCP and there was not a significant difference between the two groups (See Table 31 in Appendix A).

Individuals were asked whether or not they were currently concerned about developing a chronic disease, how concerned they were, and whether or not they had talked to their physician about that concern. Approximately 81.7% of total individuals were currently concerned and there was not a significant difference between those who enrolled in the database and those who declined enrollment (See Table 31 in Appendix A). In addition, there was no difference between the two groups as to how they ranked their worry on a scale from 1-5 (1 being low and 5 being high). For the most part, individuals in both groups ranked their worry between a 1 and 3 (See Table 32 in Appendix A). When it came to communicating this concern to a physician, those who enrolled in the database were significantly more likely to have talked to their doctor about their worries in comparison to those individuals who declined enrollment ( $P=0.029$ ) (See Figure 6 and Table 34 in Appendix A). This comparison excluded one individual who was uncertain whether or not she had expressed her concern with a physician.

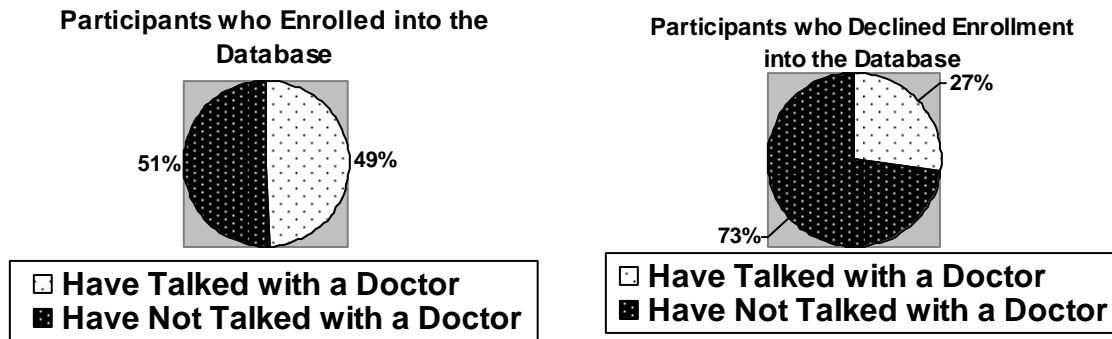


Figure 6 – History of Talking to a Physician about Concern for Developing a Condition



## **Participant's Personal Health Information**

In the pre-questionnaire, each individual was asked to rate their overall health. In addition, during the family health history session, participants were asked to report any personal history of health problems. Comparisons were made between the individuals who enrolled in the database and individuals who declined enrollment to detect any trends that existed between personal medical history and enrollment into the database.

Each participant was asked on the pre-questionnaire to rate their health on a five-level scale, from poor to excellent. There was a bell-curved distribution of responses. The average worry rating for individuals who enrolled in the database was 2.6 in comparison to an average worry rating of 2.7 for individuals who declined enrollment in the database. This difference was not statistically significant (See Table 34 in Appendix A).

During the health history sessions, individuals were asked to describe any personal history of health problems. The following conditions were then analyzed between the two comparison groups: heart disease, stroke, diabetes, colon cancer, prostate cancer, ovarian cancer, endometrial cancer, breast cancer, Alzheimer's disease, hypertension, substance abuse, and mental illness. These are the same conditions for which each pedigree was analyzed. The overall disease incidence was relatively low. The most prevalent conditions included hypertension (n=43), diabetes (n=14), and prostate cancer (n=3). There was not a significant difference in disease prevalence for any of the conditions between the individuals who enrolled in the database and those who declined enrollment (See Table 4 and Tables 35-46 in Appendix A). In addition to looking at each disease independently, the diseases were combined together to see whether the

presence of *any* condition was correlated with enrollment. Once again, the presence of *any* condition was not correlated with the enrollment into the database (See Table 47 in Appendix A). Finally, the number of conditions that each individual reported was tabulated to discern any significant difference between the two groups. A difference was not found between the number of conditions reported and whether or not the individual enrolled in the Minority Research Recruitment Database (See Table 48 in Appendix A).

**Table 4 – Prevalence of Common Diseases for our Study Participants (Probands)**

Condition	Affected Enrolled % (n)	Affected Declined % (n)	Affected Total % (n)
Heart Disease	2% (2)	3.8% (1)	2.4% (3)
Stroke	1% (1)	3.8% (1)	1.6% (2)
Diabetes	9% (9)	19.2% (5)	11.1% (14)
Colon Cancer	0% (0)	3.8% (1)	0.8%, (1)
Prostate Cancer <sub>1</sub>	16.7% (3)	0% (0)	11.1% (3)
Ovarian Cancer <sub>2</sub>	0% (0)	0% (0)	0% (0)
Endometrial Cancer <sub>2</sub>	0% (0)	0% (0)	0% (0)
Breast Cancer	2% (2)	3.8% (1)	2.4% (3)
Alzheimer’s Disease	0% (0)	3.8% (1)	0.8%, (1)
Hypertension	33% (33)	38.5% (10)	34.1% (43)
Substance Abuse	3% (3)	3.8% (1)	3.2% (4)
Mental Illness	7% (7)	3.8% (1)	6.3% (8)

1- Prostate Cancer was evaluated for men only

2 - Ovarian Cancer and Endometrial Cancer were evaluated for women only

### **Participant’s Family History Information**

Within the pre-questionnaire, each individual was asked a few questions regarding family history information. Following the family health history session, they were also queried on the post-

questionnaire to estimate their risk for a select group of chronic conditions as well as compare their risk to other individuals of the population who are of the same gender and age. Also, information about each individual's family was recorded on the pedigree and was later analyzed to place individuals in objective risk categories for a list of common diseases [23]. All of this family history information was then compared between the individuals who enrolled into the database and those who declined enrollment to ascertain any possible difference between the two groups.

Analyzed responses from the pre-questionnaire revealed that 44.4% of the total participants (n=126) think that family history always contributes to disease risk and another 45.2% of individuals reported that family history sometimes contributes to disease risk. Only 10.3% reported that family history never contributes to disease risk or were unsure of its contribution. There was not a significant difference in opinions between individuals enrolled in the database and those who declined enrollment (See Table 49 in Appendix A). In addition, all individuals were asked whether or not they thought they had a family history of a chronic condition. As a group, 78.6% of total individuals (n=126) responded that they thought they had a positive family history. There was no significant difference in responses between the two groups (See Table 50 in Appendix A).

Within Section 1 of the post-questionnaire, each individual was asked to rate their risk (low, moderate, or high) for a list of common diseases: breast cancer, ovarian cancer (females only), prostate cancer (males only), colon cancer, lung cancer, heart disease, diabetes, Alzheimer's disease, and hypertension. Individuals in both groups tended to find themselves at low risk for

breast cancer, ovarian cancer, colon cancer, lung cancer, and Alzheimer's disease. Individuals tended to have a more equal distribution of responses for prostate cancer, diabetes, and heart disease. Also, the majority of total individuals perceived themselves to be high risk for hypertension. When the group of individuals who enrolled in the database was compared to the groups of individuals who declined enrollment, no significant differences were found in risk perception for each individual disease (See Tables 51-59 in Appendix A). In addition, the number of conditions for which each individual perceived themselves to be high-risk was tabulated. The proportion of individuals who perceived themselves to be high risk for at least one condition was not significantly different between those who enrolled in the database and those who declined enrollment (See Table 60 in Appendix A). The number of conditions that individuals perceived themselves to be high risk for did not differ significantly between the two groups (See Table 61 in Appendix A).

On the post-questionnaire, each individual was asked to compare their risk for a particular chronic disease to other individuals in the general population of the same gender and of the same age. They rated their risk as either much lower, somewhat lower, the same, somewhat higher, much higher, or uncertain. The list of conditions was the same list of conditions for which they had to rate their own risk. For the majority of conditions, individuals rated their risk as much lower or somewhat lower than the general population. The exceptions were hypertension, diabetes, heart disease, and prostate cancer. For these conditions, there was a wider distribution of responses. As with the questions on risk perception, there was not a significant difference in risk comparison between the individuals who enrolled in the database and those who declined enrollment (See Tables 62-70 in Appendix A).

Finally, each pedigree's family history information was analyzed to place individuals in objective risk categories for a variety of chronic conditions using Scheuner's Guidelines for Risk Stratification [23]. Then, for each condition, the proportion of individuals at each risk level was compared between the individuals in the database and those not in the database. None of the conditions had statistically significant differences in risk distributions between the two comparison groups (See Table 5 and Tables 71-82 in Appendix A).

For each individual's family health history, all of the conditions were analyzed together to see if they were considered to be high-risk for at least one condition. Of total individuals (n=126), 73% were high risk for at least one common disease and there was not a significant difference between the individuals who elected to be entered in the database and those who declined (See Table 83 in Appendix A). Also, the number of conditions for which each individual was considered to be high-risk was tabulated. The majority of individuals were at high risk for 0, 1, or 2 conditions. There was not a statistically significant difference in the comparison of the number of high-risk conditions between the two groups (See Table 85 in Appendix A).

Lastly, the tendency of individuals to under-estimate, over-estimate, or accurately estimate their risk was analyzed. This was done by comparing actual risk (using Scheuner's Risk Stratification Guidelines [23] ) to perceived risk (based upon participant's responses on the post-questionnaires). The number of conditions where individuals over-estimated their risk ranged from 0-6, although the majority of individuals (84.9%) only over-estimated their risk on 0-3

**Table 5- Comparison of Proportion of Individuals' At Risk for Common Disease based upon Family History using Sheuner's Risk Stratification**

Condition	Enrolled (n=100) % (n)	Declined (n=26) % (n)	Total (n=126) % (n)
Heart Disease			
Average Risk	40% (40)	42.3% (11)	40.5% (51)
Moderate Risk	20% (20)	7.7% (2)	17.5% (22)
High Risk	40% (40)	50% (13)	42% (53)
Stroke			
Average Risk	75% (75)	84.6% (22)	77% (97)
Moderate Risk	19% (19)	7.7% (2)	16.7% (21)
High Risk	6% (6)	7.7% (2)	6.3% (8)
Diabetes			
Average Risk	47% (47)	61.5% (16)	50% (63)
Moderate Risk	21% (21)	15.4% (4)	19.8% (25)
High Risk	32% (32)	23.1% (6)	30.2% (38)
Colon Cancer			
Average Risk	95% (95)	88.5% (23)	93.7% (118)
Moderate Risk	4% (4)	11.5% (3)	5.6% (7)
High Risk	1% (1)	0% (0)	0.8% (1)
Prostate Cancer <sub>1</sub>			
Average Risk	83.3% (15)	100% (9)	88.9% (24)
Moderate Risk	16.7% (3)	0% (0)	11.1% (3)
High Risk	0% (0)	0% (0)	0% (0)
Ovarian Cancer <sub>2</sub>			
Average Risk	96.3% (79)	94.1% (16)	96% (95)
Moderate Risk	0% (0)	5.9% (1)	1% (1)
High Risk	3.7% (3)	0% (0)	3% (3)
Endometrial Cancer <sub>2</sub>			
Average Risk	98.8% (81)	94.1% (16)	98% (97)
Moderate Risk	0% (0)	0% (0)	0% (0)
High Risk	1.2% (1)	5.9% (1)	2% (2)
Breast Cancer			
Average Risk	87% (87)	88.5% (23)	87.3% (110)
Moderate Risk	7% (7)	3.8% (1)	6.3% (8)
High Risk	6% (6)	7.7% (2)	6.3% (8)
Alzheimer's Disease			
Average Risk	93% (93)	96.2% (25)	93.7% (118)
Moderate Risk	5% (5)	0% (0)	4% (5)
High Risk	2% (2)	3.8% (1)	2.4% (3)
Hypertension			
Average Risk	33% (33)	30.8% (8)	32.5% (41)
Moderate Risk	16% (16)	30.8% (8)	19% (24)
High Risk	51% (51)	38.5% (10)	48.4% (61)
Substance Abuse			
0-1 Relatives	78% (78)	76.9% (20)	77.8% (98)
2+ Relatives	22% (22)	23.1% (6)	22.2% (28)
Mental Illness			
0-1 Relatives	93% (93)	96.2% (25)	93.7% (118)
2+ Relatives	7% (7)	3.8% (1)	6.3% (8)

1- Prostate Cancer was evaluated for men only

2 – Ovarian Cancer and Endometrial Cancer were evaluated for women only

conditions. There was not a significant difference in the number of over-estimated conditions between the individuals who chose to enroll in the database and those who declined enrollment (See Table 85 in Appendix A). The number of conditions that individuals under-estimated their risk ranged from 0-5, although the majority of individuals (96%) only under-estimated their risk on 0-2 conditions. Once again, there was not a significant difference between the comparison groups (See Table 86 in Appendix A). Finally, the number of conditions that individuals accurately estimate their risk ranged from 0-7, although the majority of individuals (80.2%) were accurate in 2-6 conditions. There was not a significant difference in accurate risk estimation between the individuals who enrolled in the database and those who declined enrollment (See Table 87 in Appendix A).

## **DISCUSSION**

Overall, it appears as though the use of family health histories for dissemination of information on clinical research was effective for this project. The majority (79.4%) of individuals (n=126) who completed their family health history elected to enroll into the Minority Research Recruitment Database. It is possible that as individuals continue to enroll in the database, more studies will be identified for which they may be eligible. To date, clinical trial information has been sent to eight individuals: studies on breast cancer, prostate cancer, and Crone's Disease. Additional research can be completed to determine the effectiveness of the database in increasing minority recruitment once information has been sent to a greater number of participants.

In addition, in less than one year, 175 individuals were able to complete family health histories. Since the completion of this study, a variety of other groups have shown interest in participating in this initiative. This study provides evidence that the Family Health History Initiative appeals to the African American population of Pittsburgh and that a health screening service is being provided to a group of individuals who have been shown to be underserved and suffer from health disparities.

### **Demographics of the Study Population**

Demographic characteristics were compared between the individuals who enrolled in the database and those who declined enrollment. With the exception of gender, demographics did not differ between the two groups. For this project, women were more likely to complete their



family health histories and complete the questionnaires in comparison to men. This may be a consequence of the nature of this study as it deals with health information and the family. Women play a key role in health care seeking behavior, for both themselves and their family members. In general, they are more experienced and knowledgeable health care consumers in comparison to men. [48] Another possible explanation for the gender difference is that women simply outnumbered men in many of the locations of recruitment. Therefore, future recruitment sites should be focused on locations where there is a greater proportion of men. Additionally, it may be possible that the differences in gender participation are a reflection of less interest by the male population. Perhaps men are not as aware of health issues within their family and therefore, were not as interested in participating.

At a recent gathering of individuals who completed their family health histories, we asked African American men to give reasons as to why they felt there was such a low participation rate by African American men. Many men suggested that it was an issue of male pride. One man stated that when most men get sick, they continue their daily lives and do not want to talk about it. Another man alluded to the fact that men want to be seen as strong individuals and so they do not want to discuss issues that may make them appear otherwise. Future research should listen to what these and other men have to say about barriers for family health history participation and attempt to provide a local public health message that encourages men to talk about health and disease and emphasize why they, as men, would benefit from talking about their health and the health of their families. In addition, to determine the appeal of this project to the male population, a study could analyze the total number of men and women at each recruitment site and then determine the number of each gender who refuse participation, who show initial interest

but do not complete the family health history process, who actually complete their family health history, and who actually enroll in the Minority Research Recruitment Database.

### **Recruitment Variables**

A few variables from each individual's family health history session were analyzed to look for any uncontrolled external factors that may have influenced an individual's decision to enroll in the database. It was determined that the location of recruitment and the student performing the health history session did not appear to influence an individual's decision towards enrollment. In addition, when individuals were asked to describe their family health history session, virtually all individuals described it as either informative, enjoyable, or both. No one described it as uncomfortable and only a few individuals had a neutral opinion about this experience. It is encouraging to learn that no one had a bad experience with the family health history sessions. It is possible to consider that the overall high enrollment rate into the database may reflect the high percentage of individuals who had an enjoyable and/or informative experience.

### **Participants' Opinions about Research**

Participants responded to various questions about their attitudes and beliefs regarding research. Individuals who enrolled in the database were significantly more likely to respond that monetary incentives would increase their likelihood of research participation. This finding is consistent with other research studies. Cunny and Miller (1994), for example, found that financial compensation was the primary motivation for participation in a clinical drug study. [49, 50] Similarly, in a study of 440 participants, 53.3% of individuals indicated that they participated as

a result of financial motives. [51] This suggests that monetary incentives may enhance research recruitment in general, and therefore, it is possible that the hope of receiving monetary rewards has influenced individuals to enroll in the database. This may have ethical implications, however. While some ethicists argue that some level of inducement is necessary to prompt recruitment, other ethicists are concerned that monetary incentives lead individuals to expose themselves to risk in a study for which they would not participate in otherwise. [50] Of similar ethical concern is the fact that individuals who enrolled in the database appeared to be more likely to report that free health care would increase the likelihood for participation in research. Cassileth, et. al. (1982) showed that 52% of individuals reported that their main reason for participation was the opportunity for best medical care. [49] Given that 13% of individuals who enrolled in the database do not have health insurance, it is of concern that individuals may use the database as a substitution for health care. To address this issue, the Center for Minority Health is continually locating resources for low-cost health insurance. Finally, it was interesting to see that individuals were less likely to report that free medication would increase the likelihood to participate in clinical trials, in comparison to the other two incentives. Medications are potentially hazardous to one's health, unlike free health care or monetary incentives. This potential risk may be why individuals are less likely to be attracted to such an incentive. Future research could examine the attitudes of participants towards various incentives and could address the ethical dilemmas that incentives pose in clinical trials.

Despite the fact that individuals in the database are more likely to be participate in research when given incentives, it is important to emphasize that a significant percentage (40-42%) of individuals in the database report that monetary incentives and free health care do not make them

more likely to participate in research. Many of these individuals may have an altruistic motive behind their decision to enroll in the database. Future studies may wish to explore participants' motives for enrolling in the Minority Research Recruitment Database.

Another finding regarding attitudes towards research was the similar proportion of previous participation in a clinical trial among individuals who enrolled and those who declined enrollment. In contrast, a greater proportion of individuals who declined participation in the database have a past history of declining participation in clinical research. These two findings suggest that some individuals in the declined group may have participated in research at one point but have since decided to decline participation. In the future, it would be interesting to have individuals describe their research experiences and try to uncover reasons for declining participation. Corbie-Smith et. al conducted a study in which they developed an index of distrust that could be used to evaluate individuals' levels of distrust of the research community. This distrust index is based upon seven questions from a questionnaire about attitudes and beliefs regarding research [18]. Some of the questions used in the present study were taken from the questionnaire used in Corbie-Smith's study; however none of the questions came from the index of distrust. It would be interesting to use this index of distrust with future participants and measure the correlation between distrust and declining enrollment in the database.

Individuals were also asked within the questionnaire to consider a database such as the Minority Research Recruitment Database and to either give expectations for such a database or to give reasons for not having interest. As stated previously, this is not where individuals actually enrolled in the database, rather a theoretical database that serves the same purpose as the

Minority Research Recruitment Database. These questions were created to directly assess reasons for enrolling in the database and reasons for declining enrollment. Interestingly enough, some individuals who actually enrolled in the database by signing the informed consent form indicated on the survey that they were not interested and gave reasons for not having interest. Similarly, several individuals who declined enrollment into the database during the consent process indicated on the survey that they would be interested in a database like the Minority Research Recruitment Database and gave their expectations. This could possibly suggest that people did not completely understand these particular questions, they misunderstood what they were doing when they signed the informed consent form that enrolled them into the database, or that they liked the idea of the database in theory but were not interested when it came time to actually enroll. Never the less, it was interesting to see the expectations given for the database. Most people indicated that they expected to receive information on some or all clinical trials. This suggests that these individuals understood the purpose of the database. In addition, individuals indicated that they expected incentives (including superior healthcare), which reinforces the aforementioned findings regarding how incentives may have influenced individuals' decisions to enroll. Finally, it was interesting to see the reasons for declining the database. Surprisingly, the majority of people did not respond that they declined due to lack of interest with research. Rather, most people were just not interested in enrolling in a database or disclosing their contact information. This suggests that some participants who declined enrollment may still be interested in participating in research but are not interested in the Minority Research Recruitment Database. Future studies may involve conducting focus groups with the individuals who declined enrollment in the database in hopes of further clarifying their attitudes towards research. If they appear to have any interest in participating in research, it

would be beneficial to have these individuals help identify other ideas for the dissemination of information on clinical research trials.

### **Participants' Health Care**

Results revealed that individuals without health insurance were more likely to enroll in the database. This may help clarify why some individuals, both those who enrolled in the database and those who declined enrollment, stated that incentives such as free health care and free medication would make them more likely to participate in research. As mentioned previously, it is of ethical concern that individuals may participate in research as a means of obtaining health care. [49] There are other programs available in the Pittsburgh area, such as Primary Care Health Services, Inc, that are superior choices for individuals seeking no-cost or low-cost health care. It is important to make individuals aware of these other health care options so that clinical studies are not used as a substitute for necessary medical care.

Individuals who enrolled in the database were more likely to have spoken with a physician in the past year about their concern for developing a disease. It is possible that these individuals have a more trusting relationship with their physician. The literature suggests that trust and distrust of physicians and other health care providers are linked to trust and distrust of researchers as well [18]. Therefore, it could be hypothesized that individuals who have talked with their physicians about these concerns have not only more trust in their physicians than the individuals who declined, but that they are more trusting of researchers. The possibility that those individuals who decline enrollment have a lack of trust in researchers is plausible based on other studies that have documented the lack of trust as being one of the largest barriers to minority participation in

research [11, 18]. Once again, these results require additional study to further evaluate the issues of trust and distrust in potential participants. For example, individuals' levels of trust could be objectively analyzed using the aforementioned distrust index scale.

### **Participants' Personal Health Status**

Participant's personal health status (i.e. affected with specific conditions) was compared between individuals who enrolled in the database and those who declined enrollment. There was no correlation between being affected with a condition and enrolling in the database. In addition, the number of conditions that an individual had was not correlated with enrollment in the database. It is possible that the limited sample size and the relatively small number of individuals who are currently affected by disease may be a limitation in this analysis. Perhaps as the study population grows, we will be able to say more definitively whether or not personal health influences individuals' interest in research and the database.

### **Participants Family Health Information**

Each individual's family health history was examined to determine if factors within one's family history influenced their likelihood to enroll in the database. We did not find that being at risk for a particular condition based upon family history information was linked to enrollment into the database. In addition, having a family history of substance abuse or mental health did not effect enrollment in the study. However, it is possible that individuals were reluctant to report family history of these conditions. Perhaps, individuals are not reporting a family history of substance abuse or mental health and yet it is deterring their choice to enroll in the database.

It is possible that some individuals were unfamiliar with their risk or inaccurately estimated their risk for developing certain diseases based on family history and for this reason, risk perception and its influence on enrollment was examined. It was hypothesized that individuals who considered their risk to be high would be more likely to enroll. There was no correlation between perceived risk and inclination to enroll. In addition, we determined individuals' tendency to underestimate or overestimate their risk by comparing their actual risk to their perceived risk. Additionally, individuals who overestimated their risk were not more likely to enroll. In fact, it appears that no aspect of family history was correlated with the decision to enroll in the Minority Research Recruitment Database. Once again, however, this may be a result of a limited sample size and the fact that some conditions were relatively uncommon in our study population, making it difficult to find significant differences.

### **Limitations of this Study**

It was quite an accomplishment to recruit 126 individuals in less than one year's time. In addition, it was very pleasing to see that of these 126 individuals, 100 enrolled in the database. This enrollment rate was virtually 80%, far exceeding the expectations of the project. However, as a result of the majority of participants enrolling in the study, the sample size of individuals who declined was relatively small. This small sample size was especially limiting when a question had a large variety of possible responses. The larger the number of possible responses for a question, the smaller the number of individuals per response group and the more difficult it is to find significance when comparing groups. Therefore, in order to make the study more statistically robust, it is necessary to continue recruitment.



In addition to a relatively limited sample size, the number of men who participated was quite small. This makes it more difficult to generalize many of these results to both men and women. Future studies should focus on going to recruitment sites where more men are present.

Another limitation to this study was the total number of statistical tests conducted on a large set of data. Since the use of family history information to enroll individuals into recruitment database is virtually unprecedented, it was difficult to make specific hypotheses. Rather, we made a large number of comparisons to see what factors warrant further, more specific investigation. Consequently, it is difficult to assess the robustness of the significance identified with the current results. It is possible that through multiple testing, some of the significant differences were found just by chance.

This was an exploratory study in which each variable was analyzed separately, without looking at any multivariate analyses to see variable interactions. It is possible that some variables are correlated with one another and the interaction between variables may be a confounding factor. Further analysis of any one or two single significant variables may help to clarify the significant findings of the others.

Another limitation to this research involved the study population itself. The individuals who answered the questionnaires were not chosen at random, but rather were a self-selected group of individuals who were highly motivated to take the time to complete their family health histories. Therefore, it is difficult to generalize these results to the entire African American community in

Pittsburgh. For example, these individuals might already have enough trust in the research community to participate in this study. Therefore, their views of research may differ significantly from the general African American population.

### **Additional Indications for Future Studies**

Because this initiative is relatively unstudied and warrants further exploration, there are additional studies that might be conducted in the future, some of which have already been mentioned. To follow are just a few additional ideas for future research.

Increasing the sample size and repeating the analysis would further enhance this study. This would involve increasing not only the total sample size, but also the representation of men. As the overall sample size increased, the number of declined individuals would most likely increase as well, thus making for a more significant overall comparison. In addition, some of the questions with the wider range of responses may result in significant results once the study population has reached an appropriate size.

Multivariate analyses should be run on the dataset. A logistic regression analysis would allow the significant variables to be compared to determine how the variables are interacting and to identify whether any one or two variables are driving the other variables towards significance. By performing a multivariate analysis, results could be adjusted appropriately and the issues of multiple testing or multiple variable interactions could be addressed.

Creation of a questionnaire that examines attitudes and beliefs about research is suggested. This instrument could compare individuals who complete their family health history and individuals who do not have interest in completing their family health history. This would assist with interpretation of the research beliefs of the study population and help further explain the differences between those who enroll in the database and those who decline. It would also be interesting to compare demographic information between those individuals who do not show interest in the family health histories, those who sign up but never complete the process, those who sign up and complete their family health history, and those who sign up, complete their family health history, and enroll in the database.

Recruitment of non-African-American participants could determine whether any of the significant findings are unique to the African American population. Additional research could then explore possible reasons for any differences that exist in the African American population. Similarly, by conducting this study at other sites, it would be possible to assess whether the opinions of African Americans in Pittsburgh represented the opinions of African Americans elsewhere.

Additional analysis could be performed from the data collected on the one-month follow-up. It could be determined how many individuals actually shared the information with their physicians or families. It would be ideal to conduct further research on these participants to examine if the family health history lead to behavior modification towards healthier lifestyles and disease prevention.

Finally, once the Center for Minority Health begins to send more information on clinical research trials, it may be possible to contact participants and analyze which individuals actually contacted the study coordinators and actually enrolled in clinical research studies. This would ultimately determine the impact and effectiveness of family health histories in increasing minority recruitment in clinical research trials.

## EPILOGUE

When coming to the Center for Minority Health (CMH) almost two years ago, I did not realize what lay ahead. I was coming from a white, middleclass, suburban town, having never experienced life within the African American community. My first experience with CMH was in a black barbershop in which I was supposed to talk to individuals about the importance of knowing family history information. To be honest, I was very intimidated. After all, I was not used to being the “minority” within a setting. I felt that I was very out of place and that everyone surrounding me was thinking the exact same thing. Following this event, I was questioning my decision to work for CMH.

I decided to just give myself time to adjust to a new environment. As I began to spend more time in the black community, being the “minority” became less of an issue. It is almost as if racial lines began to disappear. I felt that as I became more comfortable in my setting, participants began to feel more comfortable with me. For example, there was one particular black church that we often frequented to complete family health histories. After a couple of months, I had past participants coming up to me before and after services, giving updates on their lives as if we were old friends. I felt as though I had become part of their community.

When I am asked what I learned from this research, I do not recall my analysis of participants in the database. Rather, I speak of what I have learned while being in the black community. I have learned to be a more culturally-sensitive, culturally-competent health professional. In my opinion, this is not something easily learned, yet it is something that is extremely important in becoming a good genetic counselor.

## **APPENDIX A**

### **Tables of Results**

## Demographics of the Study Population

**Table 5- Gender Distribution**

	Males	Females
Participants Enrolled in the Database	18	82
Participants who Declined Enrollment	9	17
Total	27	99

P=0.038 (Binomial Test of Proportions)

**Table 6- Race/Ethnicity Distribution**

	African American Only	African American and Other
Participants Enrolled in the Database	91	9
Participants who Declined Enrollment	24	2
Total	115	11

P=1.000 (Binomial Test of Proportions)

**Table 7- Age Distribution**

	18-35	36-50	51-65	66+
Participants Enrolled in the Database	13	41	33	13
Participants who Declined Enrollment	4	10	9	3
Total	17	51	42	16

P=0.982 (Fisher's Exact Test)

**Table 8- Income Level Distribution**

	<\$10,000	\$10,001-\$20,000	\$20,001-\$35,000	\$35,001-\$50,000	\$50,001-\$75,000	\$75,001+
Participants Enrolled in the Database	4	17	25	18	13	20
Participants who Declined Enrollment	2	4	5	4	4	6
Total	6	21	30	22	17	26

P=0.932 (Fisher's Exact Test)

**Table 9- Education Level Distribution**

	Grade 8 or Less	Some High School	Completed High School	1-3 years College/ Technical School	4+ years of College	Graduate School
Participants Enrolled in the Database	0	5	14	40	23	18
Participants who Declined Enrollment	1	0	1	12	6	6
Total	1	5	15	52	29	24

P=0.282 (Fisher's Exact Test)

**Table 10- Ranking of Personal Knowledge of Genetics**

	Poor	Fair	Good	Very Good	Excellent
Participants Enrolled in the Database	19	42	27	10	2
Participants who Declined Enrollment	4	7	7	5	2
Total	23	49	34	15	4

P=0.249 (Fisher's Exact Test)



## Participants' Family Health History Session

**Table 11- Counseling Student Performing the Family Health History Session**

	Kristen Vogel	Vinaya Murthy	Beth Dudley
Participants Enrolled in the Database	36	49	15
Participants who Declined Enrollment	13	10	3
Total	49	59	18

P= 0.448 (Fisher's Exact Test)

**Table 12- Location of Recruitment**

	Barbershop/ Salon	Church	Community Service Org.	Health Fair	Retirement Center	Outside Contact	Other
Participants Enrolled in the Database	3	68	3	19	4	2	1
Participants who Declined Enrollment	0	20	0	1	3	0	2
Total	3	88	3	20	7	2	3

P=0.088 (Fisher's Exact Test)

**Table 13- Had an Enjoyable Family Health History Session**

	Yes	No
Participants Enrolled in the Database	63	37
Participants who Declined Enrollment	17	9
Total	80	46

P=1.000 (Binomial Test of Proportions)

**Table 14- Had an Informative Family Health History Session**

	Yes	No
Participants Enrolled in the Database	72	28
Participants who Declined Enrollment	18	8
Total	90	36

P=0.827 (Binomial Test of Proportions)

**Table 15- Had an Uncomfortable Family Health History Session**

	Yes	No
Participants Enrolled in the Database	0	100
Participants who Declined Enrollment	0	26
Total	0	126

P=1.000 (Binomial Test of Proportions)

**Table 16- Had No Opinion about the Family Health History Session**

	Yes	No
Participants Enrolled in the Database	3	97
Participants who Declined Enrollment	1	25
Total	4	122

P=0.547 (Binomial Test of Proportions)

## Participant's Opinions about Research

**Table 17 - General Opinion on Importance of Medical Research**

	Very Important	Somewhat Important
Participants Enrolled in the Database	95	4
Participants who Declined Enrollment	23	3
Total	118	7

P=0.084 (Binomial Test of Proportions)

**Table 18- General Opinion about Clinical Research Involving Humans**

	Very Favorable	Somewhat Favorable	Neutral	Somewhat Unfavorable	Very Unfavorable	Uncertain
Participants Enrolled in the Database	53	38	3	2	0	2
Participants who Declined Enrollment	12	12	0	2	0	0
Total	65	50	3	4	0	2

P=0.169 (Fisher's Exact Test)

**Table 19- Previous History of Participating in a Clinical Trial**

	Have Participated in Clinical Trials	Have Never Participated in a Clinical Trial
Participants Enrolled in the Database	28	71
Participants who Declined Enrollment	7	19
Total	35	90

P=1.000 (Binomial Test of Proportions)

**Table 20- Past History of Declining Enrollment in a Clinical Study**

	History of Declining Enrollment	Never Declined Enrollment	Uncertain
Participants Enrolled in the Database	29	69	1
Participants who Declined Enrollment	11	13	2
Total	40	82	3

P=0.044 (Fisher's Exact Test)

**Table 21- Effect of \$500 on Clinical Research Participation**

	Less likely to Participate	More likely to Participate	No Effect on Participation	Uncertain of Effect
Participants Enrolled in the Database	7	59	20	13
Participants who Declined Enrollment	1	10	12	3
Total	8	69	32	16

P=0.066 (Fisher's Exact Test) vs. 0.028 (Binomial Test) \*

\*Two groups: Those more likely to participate vs. all other responses

**Table 22- Effect of Free Medical Care on Clinical Trial Participation**

	Less likely to Participate	More likely to Participate	No Effect on Participation	Uncertain of Effect
Participants Enrolled in the Database	6	57	32	4
Participants who Declined Enrollment	4	10	10	2
Total	10	67	42	6

P=0.151 (Fisher's Exact Test), P=0.072 (Binomial Test) \*

\*Two groups: Those more likely to participate vs. all other responses

**Table 23- Effect of Free Medication on Clinical Trial Participation**

	Less likely to Participate	More likely to Participate	No Effect on Participation	Uncertain of Effect
Participants Enrolled in the Database	10	45	34	10
Participants who Declined Enrollment	2	10	9	5
Total	12	55	43	15

P=0.623 (Fisher's Exact Test) vs. P=0.557 (Binomial test)\*

\*Two groups: Those more likely to participate vs. all other responses

**Table 24- Opinion on the Degree to which Scientists Benefit from Clinical Research**

	Great Deal	Moderate Amount	Only a Little	Not at All	Depends
Participants Enrolled in the Database	80	13	1	0	5
Participants who Declined Enrollment	23	3	0	0	0
Total	103	16	1	0	5

P=0.777 (Fisher's Exact Test)

**Table 25- Opinion on the Degree to which the Community Benefits from Clinical Research**

	Great Deal	Moderate Amount	Only a Little	Not at All	Depends
Participants Enrolled in the Database	52	29	11	0	8
Participants who Declined Enrollment	14	6	1	0	5
Total	66	35	12	0	13

P=0.31 (Fisher's Exact Test)

**Table 26- Opinion on the Degree to which Family/Friends Benefit from Clinical Research**

	Great Deal	Moderate Amount	Only a Little	Not at All	Depends
Participants Enrolled in the Database	56	24	14	1	5
Participants who Declined Enrollment	13	7	1	0	5
Total	69	31	15	1	10

P=0.123 (Fisher's Exact Test)

**Table 27- Opinion on the Degree of Personal Benefit from Clinical Research**

	Great Deal	Moderate Amount	Only a Little	Not at All	Depends
Participants Enrolled in the Database	67	20	6	1	6
Participants who Declined Enrollment	15	7	0	0	0
Total	82	27	6	1	6

P=0.316 (Fisher's Exact Test)

## Participant's Health Care

**Table 28- Insurance Coverage**

	Insurance Coverage	No Insurance Coverage
Participants Enrolled in the Database	87	13
Participants who Declined Enrollment	26	0
Total	103	13

P=0.041 (Binomial Test of Proportions)

**Table 29- Presence of Primary Care Physician (PCP)**

	No PCP	One PCP	More than One PCP
Participants Enrolled in the Database	11	59	30
Participants who Declined Enrollment	1	17	8
Total	12	76	38

P=0.637 (Fisher's Exact Test)

**Table 30- Unable to See a Physician Due to Cost in the Past Year**

	Unable due to Cost	Cost did not Interfere	Uncertain
Participants Enrolled in the Database	10	89	1
Participants who Declined Enrollment	2	24	0
Total	12	113	1

P=1.000 (Fisher's Exact Test)

**Table 31- Current Concern about Developing a Chronic Disease**

	Worried	Not Worried
Participants Enrolled in the Database	82	18
Participants who Declined Enrollment	21	5
Total	103	23

P=0.801 (Binomial Test of Proportions)

**Table 32- Level of Worry for Developing a Chronic Condition (Scale of 1-5)**

	Worry : 1	Worry : 2	Worry : 3	Worry : 4	Worry : 5
Participants Enrolled in the Database	15	31	38	5	8
Participants who Declined Enrollment	5	5	12	2	2
Total	20	36	50	7	10

P=0.738 (Fisher's Exact Test)

**Table 33- History of Talking to a Physician about Concern for Developing a Condition**

	Have Talked to a Physician	Have not Talked to a Physician	Uncertain
Participants Enrolled in the Database	49	50	1
Participants who Declined Enrollment	7	19	0
Total	56	69	1

P=0.092 (Fisher's Exact Test)\* and P=0.018 (Binomial Test of Proportions)\*\*

\*Includes uncertain individual \*\*Excludes uncertain individual



## Participant's Personal Health Information

**Table 34- General Health**

	Poor	Fair	Good	Very Good	Excellent
Participants Enrolled in the Database	2	21	54	19	4
Participants who Declined Enrollment	0	4	11	9	2
Total	2	25	65	28	6

P=0.350 (Fisher's Exact Test)

**Table 35- Personal History of Heart Disease**

	Positive History	Negative History
Participants Enrolled in the Database	2	98
Participants who Declined Enrollment	1	25
Total	3	123

P=0.409 (Binomial Test of Proportions)

**Table 36- Personal History of Stroke**

	Positive History	Negative History
Participants Enrolled in the Database	1	99
Participants who Declined Enrollment	1	25
Total	2	124

P=0.230 (Binomial Test of Proportions)

**Table 37- Personal History of Diabetes**

	Positive History	Negative History
Participants Enrolled in the Database	9	91
Participants who Declined Enrollment	5	21
Total	14	112

P=0.079 (Binomial Test of Proportions)

**Table 38- Personal History of Colon Cancer**

	Positive History	Negative History
Participants Enrolled in the Database	0	100
Participants who Declined Enrollment	1	25
Total	1	125

P=0.206 (Binomial Test of Proportions)

**Table 39- Personal History of Prostate Cancer**

	Positive History	Negative History
Participants Enrolled in the Database	3	15
Participants who Declined Enrollment	0	9
Total	3	24

P=0.372 (Binomial Test of Proportions)

**Table 40- Personal History of Breast Cancer**

	Positive History	Negative History
Participants Enrolled in the Database	2	98
Participants who Declined Enrollment	1	25
Total	3	113

P=0.230 (Binomial Test of Proportions)

**Table 41- Personal History of Ovarian Cancer**

	Positive History	Negative History
Participants Enrolled in the Database	0	82
Participants who Declined Enrollment	0	17
Total	0	99

P=1.00 (Binomial Test of Proportions)

**Table 42- Personal History of Endometrial Cancer**

	Positive History	Negative History
Participants Enrolled in the Database	0	82
Participants who Declined Enrollment	0	17
Total	0	99

P=1.00 (Binomial Test of Proportions)

**Table 43- Personal History of Alzheimer's Disease**

	Positive History	Negative History
Participants Enrolled in the Database	0	100
Participants who Declined Enrollment	1	25
Total	1	125

P=0.206 (Binomial Test of Proportions)

**Table 44- Personal History of Hypertension**

	Positive History	Negative History
Participants Enrolled in the Database	33	67
Participants who Declined Enrollment	10	16
Total	43	83

P=0.538 (Binomial Test of Proportions)

**Table 45- Personal History of Substance Abuse**

	Positive History	Negative History
Participants Enrolled in the Database	3	97
Participants who Declined Enrollment	1	25
Total	4	122

P=0.547 (Binomial Test of Proportions)

**Table 46- Personal History of Mental Illness**

	Positive History	Negative History
Participants Enrolled in the Database	7	93
Participants who Declined Enrollment	1	25
Total	8	118

P=1.000 (Binomial Test of Proportions)

**Table 47- Personal History of Any Condition**

	History of At Least One Condition	No Personal History of a Condition
Participants Enrolled in the Database	37	63
Participants who Declined Enrollment	12	14
Total	49	77

P=0.417 (Binomial Test of Proportions)

**Table 48- Number of Conditions within a Personal History**

	0	1	2	3
Participants Enrolled in the Database	63	26	9	2
Participants who Declined Enrollment	14	7	2	3
Total	77	33	11	5

P=0.210 (Fisher's Exact Test)

## Participants' Family History Information

**Table 49- Opinion on the Effect of Family History on Risk**

	Always Contributes to Risk	Sometimes Contributes to Risk	Never Contributes to Risk	Unsure
Participants Enrolled in the Database	48	42	1	9
Participants who Declined Enrollment	8	15	1	2
Total	56	57	2	11

P= 0.231 (Fisher's Exact Test)

**Table 50- Think they have a Positive Family History of a Chronic Condition**

	Positive Family History	Negative Family History	Uncertain
Participants Enrolled in the Database	79	19	2
Participants who Declined Enrollment	20	5	1
Total	99	24	3

P=0.703 (Fisher's Exact Test)

**Table 51- Perceived Breast Cancer Risk**

	Low Risk	Moderate Risk	High Risk	Don't Know Risk
Participants Enrolled in the Database	64	25	7	3
Participants who Declined Enrollment	18	4	3	0
Total	82	29	10	3

P=0.533 (Fisher's Exact Test)

**Table 52- Perceived Ovarian Cancer Risk**

	Low Risk	Moderate Risk	High Risk	Don't Know Risk
Participants Enrolled in the Database	52	23	3	3
Participants who Declined Enrollment	11	4	2	0
Total	63	27	5	3

P=0.461 (Fisher's Exact Test)

**Table 53- Perceived Colon Cancer Risk**

	Low Risk	Moderate Risk	High Risk	Don't Know Risk
Participants Enrolled in the Database	58	29	8	4
Participants who Declined Enrollment	16	9	0	0
Total	74	38	8	4

P=0.452 (Fisher's Exact Test)

**Table 54- Perceived Prostate Cancer Risk**

	Low Risk	Moderate Risk	High Risk	Don't Know Risk
Participants Enrolled in the Database	3	8	6	1
Participants who Declined Enrollment	3	5	0	0
Total	6	13	6	1

P=0.272 (Fisher's Exact Test)

**Table 55- Perceived Heart Disease Risk**

	Low Risk	Moderate Risk	High Risk	Don't Know Risk
Participants Enrolled in the Database	28	40	28	4
Participants who Declined Enrollment	10	6	10	0
Total	38	46	38	4

P = 0.283 (Fisher's Exact Test)

**Table 56- Perceived Lung Cancer Risk**

	Low Risk	Moderate Risk	High Risk	Don't Know Risk
Participants Enrolled in the Database	61	24	10	5
Participants who Declined Enrollment	18	7	1	0
Total	79	31	11	5

P=0.669 (Fisher's Exact Test)

**Table 57- Perceived Diabetes Risk**

	Low Risk	Moderate Risk	High Risk	Don't Know Risk
Participants Enrolled in the Database	30	38	29	3
Participants who Declined Enrollment	13	6	6	0
Total	43	42	35	3

P=0.225 (Fisher's Exact Test)



**Table 58- Perceived Alzheimer's Disease Risk**

	Low Risk	Moderate Risk	High Risk	Don't Know Risk
Participants Enrolled in the Database	62	20	4	14
Participants who Declined Enrollment	19	3	3	1
Total	81	23	7	15

P=0.171 (Fisher's Exact Test)

**Table 59- Perceived Hypertension Risk**

	Low Risk	Moderate Risk	High Risk	Don't Know Risk
Participants Enrolled in the Database	25	30	43	2
Participants who Declined Enrollment	6	6	13	0
Total	31	36	56	2

P=0.857 (Fisher's Exact Test)

**Table 60- Perceived to be at High Risk for At Least One Condition**

	High Risk for 1+ Condition	Not High Risk for Any Conditions
Participants Enrolled in the Database	61	39
Participants who Declined Enrollment	14	12
Total	75	51

P=0.547 (Binomial Test of Proportions)

**Table 61- Number of Conditions Perceived to be High Risk**

	0	1	2	3	4	5	6	7	8
Participants Enrolled in the Database	39	23	17	12	5	2	1	0	1
Participants who Declined Enrollment	12	5	2	3	2	1	1	0	0
Total	51	28	19	15	7	3	2	0	1

P=0.704 (Fisher's Exact Test)

**Table 62- Comparative Breast Cancer Risk**

	Much Lower Risk	Somewhat Lower Risk	Same Risk	Somewhat Higher Risk	Much Higher Risk	Uncertain
Participants Enrolled in the Database	48	25	16	7	1	1
Participants who Declined Enrollment	12	9	1	3	0	0
Total	60	34	17	10	1	1

P=0.487 (Fisher's Exact Test)

**Table 63- Comparative Ovarian Cancer Risk**

	Much Lower Risk	Somewhat Lower Risk	Same Risk	Somewhat Higher Risk	Much Higher Risk	Uncertain
Participants Enrolled in the Database	38	22	15	5	0	1
Participants who Declined Enrollment	9	6	2	0	0	0
Total	47	28	17	5	0	1

P=0.783 (Fisher's Exact Test)

**Table 64- Comparative Colon Cancer Risk**

	Much Lower Risk	Somewhat Lower Risk	Same Risk	Somewhat Higher Risk	Much Higher Risk	Uncertain
Participants Enrolled in the Database	44	27	16	10	0	3
Participants who Declined Enrollment	11	8	4	1	0	1
Total	55	35	20	11	0	4

P=0.90 (Fisher's Exact Test)

**Table 65- Comparative Prostate Cancer Risk**

	Much Lower Risk	Somewhat Lower Risk	Same Risk	Somewhat Higher Risk	Much Higher Risk	Uncertain
Participants Enrolled in the Database	5	3	6	3	0	1
Participants who Declined Enrollment	3	4	1	0	0	0
Total	8	7	7	3	0	1

P=0.320 (Fisher's Exact Test)

**Table 66- Comparative Heart Disease Risk**

	Much Lower Risk	Somewhat Lower Risk	Same Risk	Somewhat Higher Risk	Much Higher Risk	Uncertain
Participants Enrolled in the Database	20	26	31	12	7	4
Participants who Declined Enrollment	8	5	6	5	2	0
Total	28	31	37	17	9	4

P=0.645 (Fisher's Exact Test)

**Table 67- Comparative Lung Cancer Risk**

	Much Lower Risk	Somewhat Lower Risk	Same Risk	Somewhat Higher Risk	Much Higher Risk	Uncertain
Participants Enrolled in the Database	45	26	23	4	0	2
Participants who Declined Enrollment	14	3	8	1	0	0
Total	59	29	31	5	0	2

P=0.481 (Fisher's Exact Test)

**Table 68- Comparative Diabetes Risk**

	Much Lower Risk	Somewhat Lower Risk	Same Risk	Somewhat Higher Risk	Much Higher Risk	Uncertain
Participants Enrolled in the Database	25	21	27	17	6	4
Participants who Declined Enrollment	10	7	3	3	2	0
Total	35	28	30	20	8	4

P=0.397 (Fisher's Exact Test)

**Table 69- Comparative Alzheimer's Disease Risk**

	Much Lower Risk	Somewhat Lower Risk	Same Risk	Somewhat Higher Risk	Much Higher Risk	Uncertain
Participants Enrolled in the Database	48	15	17	9	0	10
Participants who Declined Enrollment	15	4	3	3	0	1
Total	63	19	20	12	0	11

P=0.831 (Fisher's Exact Test)

**Table 70- Comparative Hypertension Risk**

	Much Lower Risk	Somewhat Lower Risk	Same Risk	Somewhat Higher Risk	Much Higher Risk	Uncertain
Participants Enrolled in the Database	19	24	21	20	13	1
Participants who Declined Enrollment	5	5	5	5	5	0
Total	24	29	26	25	18	1

P=0.946 (Fisher's Exact Test)

**Table 71- Actual Risk for Heart Disease based upon Family History**

	Average Risk	Moderate Risk	High Risk
Participants Enrolled in the Database	40	20	40
Participants who Declined Enrollment	11	2	13
Total	51	22	53

P=0.335 (Fisher's Exact Test)

**Table 72- Actual Risk for Stroke based upon Family History**

	Average Risk	Moderate Risk	High Risk
Participants Enrolled in the Database	75	19	6
Participants who Declined Enrollment	22	2	2
Total	97	21	8

P=0.410 (Fisher's Exact Test)

**Table 73- Actual Risk for Diabetes based upon Family History**

	Average Risk	Moderate Risk	High Risk
Participants Enrolled in the Database	47	21	32
Participants who Declined Enrollment	16	4	6
Total	63	25	38

P=0.455 (Fisher's Exact Test)

**Table 74- Actual Risk for Colon Cancer based upon Family History**

	Average Risk	Moderate Risk	High Risk
Participants Enrolled in the Database	95	4	1
Participants who Declined Enrollment	23	3	0
Total	118	7	1

P=0.331 (Fisher's Exact Test)

**Table 75- Actual Risk for Prostate Cancer based upon Family History**

	Average Risk	Moderate Risk	High Risk
Participants Enrolled in the Database	15	3	0
Participants who Declined Enrollment	9	0	0
Total	24	3	0

P=0.529 (Fisher's Exact Test)

**Table 76- Actual Risk for Breast Cancer based upon Family History**

	Average Risk	Moderate Risk	High Risk
Participants Enrolled in the Database	87	7	6
Participants who Declined Enrollment	23	1	2
Total	110	8	8

P=0.893 (Fisher's Exact Test)

**Table 77- Actual Risk for Ovarian Cancer based upon Family History**

	Average Risk	Moderate Risk	High Risk
Participants Enrolled in the Database	79	0	3
Participants who Declined Enrollment	16	1	0
Total	95	1	3

P=0.235 (Fisher's Exact Test)

**Table 78- Actual Risk for Endometrial Cancer based upon Family History**

	Average Risk	Moderate Risk	High Risk
Participants Enrolled in the Database	81	0	1
Participants who Declined Enrollment	16	0	1
Total	97	0	2

P=0.315 (Fisher's Exact Test)

**Table 79- Actual Risk for Alzheimer’s Disease based upon Family History**

	Average Risk	Moderate Risk	High Risk
Participants Enrolled in the Database	93	5	2
Participants who Declined Enrollment	25	0	1
Total	118	5	3

P=0.480 (Fisher’s Exact Test)

**Table 80- Actual Risk for Hypertension based upon Family History**

	Average Risk	Moderate Risk	High Risk
Participants Enrolled in the Database	33	16	51
Participants who Declined Enrollment	8	8	10
Total	41	24	61

P=0.217 (Fisher’s Exact Test)

**Table 81- Family History of Substance Abuse**

	2+ Relatives (1° or 2°) with Substance Abuse	0-1 Relatives (1° or 2°) with Substance Abuse
Participants Enrolled in the Database	22	78
Participants who Declined Enrollment	6	20
Total	28	98

P=0.816 (Binomial Test of Proportions)



**Table 82- Family History of Mental Illness**

	2+ Relatives (1° or 2°) with Mental Illness	0-1 Relatives (1° or 2°) with Mental Illness
Participants Enrolled in the Database	7	93
Participants who Declined Enrollment	1	25
Total	8	118

P=1.000 (Binomial Test of Proportions)

**Table 83- At High Risk for At Least One Condition Based upon Family History**

	Positive History	Negative History
Participants Enrolled in the Database	75	25
Participants who Declined Enrollment	17	9
Total	92	34

P=0.261 (Binomial Test of Proportions)

**Table 84- Number of Conditions At High Risk For Based upon Family History**

	0	1	2	3	4	5
Participants Enrolled in the Database	25	31	28	10	5	1
Participants who Declined Enrollment	9	4	8	5	0	0
Total	34	35	36	15	5	1

P=0.357 (Fisher's Exact Test)

**Table 85- Number of Conditions in Which Risk was Over-Estimated**

	0	1	2	3	4	5	6
Participants Enrolled in the Database	28	22	10	26	6	4	4
Participants who Declined Enrollment	8	5	4	4	3	2	0
Total	36	27	14	30	9	6	4

P=0.644 (Fisher's Exact Test)

**Table 86- Number of Conditions in Which Risk was Under-Estimated**

	0	1	2	3	4	5
Participants Enrolled in the Database	48	30	16	5	0	1
Participants who Declined Enrollment	16	5	5	0	0	0
Total	64	35	21	5	0	1

P=0.595 (Fisher's Exact Test)

**Table 87- Number of Conditions in Which Risk was Accurately Estimated**

	0	1	2	3	4	5	6	7
Participants Enrolled in the Database	2	11	13	10	22	21	14	7
Participants who Declined Enrollment	0	1	2	6	4	7	2	4
Total	2	12	15	16	26	28	16	11

P=0.613 (Fisher's Exact Test)

## **APPENDIX B**

### **University of Pittsburgh Institutional Board of Review (IRB) Approval**



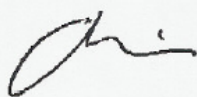
# University of Pittsburgh

## Institutional Review Board

3500 Fifth Avenue  
Ground Level  
Pittsburgh, PA 15213  
(412) 383-1480  
(412) 383-1146 (fax)

**MEMORANDUM:**

TO: Stephen B. Thomas, Ph.D.

FROM: Christopher Ryan, Ph.D., Vice Chair 

DATE: May 4, 2004

SUBJECT: IRB#: 0403125 HEALTHY BLACK FAMILY PROJECT: Assessing African Americans' Response to Family Health Histories

The above-referenced proposal has received expedited review and approval from the Institutional Review Board under 45 CFR 46.110 (7).

Please note that the advertisement that was submitted for review has been approved as written.

If applicable, please include the following information in the upper right-hand corner of all pages of the consent form:

Approval Date: 05/03/2004  
 Renewal Date: 05/02/2005  
 University of Pittsburgh  
 Institutional Review Board  
 IRB# 0403125

Adverse events which occur during the course of the research study must be reported to the IRB Office. Please call the IRB Adverse Event Coordinator at 412-383-1145 for the current policy and forms.

The protocol and consent forms, along with a brief progress report must be resubmitted at least one month prior to the expiration date noted above for annual renewal as required by FWA00006790 (University of Pittsburgh), FWA00006735 (University of Pittsburgh Medical Center) and FWA00006600 (Children's Hospital of Pittsburgh).

Please be advised that your research study may be audited periodically by the University of Pittsburgh Research Conduct and Compliance Office.

CR:ky

Figure 7- IRB Approval Letter

## **APPENDIX C**

### **Study Pre-Questionnaire**

## Pre-questionnaire

An important aim of genetic counseling is to provide risk information so that individuals and families can make better informed decisions about their health and that of their families. The purpose of this questionnaire is to explore your perceptions of risk for developing certain health conditions. We want to understand whether family health histories (i.e., sharing information about diseases in your family) can help provide you with a more accurate assessment of your risk for developing particular health conditions.

If there is a question that you do not feel comfortable answering, you can skip it and continue on. Please answer the following questions to the best of your ability. **DO NOT PROVIDE ANY NAMES OF FAMILY MEMBERS.** The questionnaire should take approximately 10 minutes. Thank you for your time.

### Section 1: General Information

1) What is your age?

\_\_\_ \_\_\_ age in years

2) What is your gender?

1 Male

2 Female

3) Are you Hispanic or Latino?

1 Yes

2 No

3 Don't know

3a) Which one or more of the following would you say is your race? **(Check all that apply)**

1 White

2 Black or African American

3 Asian

4 Native Hawaiian or Other Pacific Islander

5 American Indian, Alaska Native

6 Other [specify] \_\_\_\_\_

4) What was the total household income from all sources last year?

1 Less than \$10,000

2 Between \$10,000 and \$20,000

3 Between \$20,001 and \$35,000

4 Between \$35,001 and \$50,000

5 Between \$50,001 and \$75,000

6 Greater than \$75,000

5) What is the highest grade or year of school you completed?

1 Grades 8 or less (Elementary)

2 Grades 9 through 11 (Some high school)

3 Grade 12 or GED (High school graduate)

4 College 1 year to 3 years (Some college or technical school)

5 College 4 years or more (College graduate or post-graduate)

6 Graduate level (Masters or PhD)

6) How would you rate your knowledge on genetics?

- 1 Excellent
- 2 Very good
- 3 Good
- 4 Fair
- 5 Poor

7) How would you describe your general health?

- 1 Excellent
- 2 Very good
- 3 Good
- 4 Fair
- 5 Poor

8) Do you have one person you think of as your personal doctor or health care provider?

- 1 Yes, only one
- 2 More than one
- 3 No
- 4 Don't know / Not sure

9) Was there a time in the past 12 months when you needed to see a doctor but could not because of the cost?

- 1 Yes
- 2 No
- 3 Don't know / Not sure

10) Do you have any kind of health care coverage, including health insurance, prepaid plans such as HMOs, or government plans such as Medicare?

- 1 Yes
- 2 No
- 3 Don't know / Not sure

**Section 2: Risk Perception**

11) Have you ever talked to a doctor or nurse about your concerns for developing a disease?

- 1 Yes Please describe: \_\_\_\_\_
- 2 No
- 3 Don't know / Not sure

12) In your opinion, how often do you believe each of the following factors increases (or contributes to) an individual's chance or risk for developing a disease such as diabetes, heart disease, and cancer? **(Please respond for each item listed)**

1=Never      2= Sometimes      3=Always      4=Don't know / Not sure

- Smoking \_\_\_\_\_
- Having a poor diet \_\_\_\_\_
- Lack of exercise \_\_\_\_\_
- Family history (other family members with a disease) \_\_\_\_\_

13) What do you think the chances are of a healthy woman the same age as you to develop the following health conditions sometime in her life? **(Please respond for each condition listed)**  
1=Low (<10%)    2=Moderate (10-50%)    3=High (>50%)    4=Don't know / Not sure

Breast cancer \_\_\_\_\_  
Ovarian cancer \_\_\_\_\_  
Colon cancer \_\_\_\_\_  
Cardiovascular disease \_\_\_\_\_  
Lung cancer \_\_\_\_\_  
Diabetes \_\_\_\_\_  
Alzheimer's disease \_\_\_\_\_  
Hypertension \_\_\_\_\_

14) What do you think the chances are of a healthy man the same age as you to develop the following health conditions sometime in his life? **(Please respond for each condition listed)**  
1=Low (<10%)    2=Moderate (10-50%)    3=High (>50%)    4=Don't know / Not sure

Breast cancer \_\_\_\_\_  
Colon cancer \_\_\_\_\_  
Prostate cancer \_\_\_\_\_  
Cardiovascular disease \_\_\_\_\_  
Lung cancer \_\_\_\_\_  
Diabetes \_\_\_\_\_  
Alzheimer's disease \_\_\_\_\_  
Hypertension \_\_\_\_\_

15) Have you ever been concerned or worried about your chances for developing any of these health conditions?  
1 Yes  
2 No

15a) If yes, which one(s)? \_\_\_\_\_  
Please describe: \_\_\_\_\_

16) On a scale from 1 (not worried) – 5 (extremely worried), how would you rate your concern about developing any of the above health condition(s)? \_\_\_\_\_

17) Do you have a blood relative (mother, father, sister, brother, uncle, aunt, grandmother, grandfather) who had or has a health condition that you are concerned about developing sometime in your life?  
1 Yes  
2 No  
3 Don't know / Not sure

17a) If yes, who and what was the health condition? **\*DO NOT INCLUDE NAMES OF FAMILY MEMBERS, ONLY THE RELATIONSHIP TO YOU**  
\_\_\_\_\_  
\_\_\_\_\_



18) Have you ever talked to a health provider about your concern for developing that particular health condition?

- 1 Yes
- 2 No
- 3 Don't know / Not sure

19) At this time, what do you think your chances are of developing any of the following health conditions sometime in your life? **(Please respond for each condition listed)**

1=Low (<10%)      2=Moderate (10-50%)      3=High (>50%)      4=Don't know / Not sure

- Breast cancer \_\_\_\_\_
- Ovarian cancer (Women Only) \_\_\_\_\_
- Colon cancer \_\_\_\_\_
- Prostate cancer (Men Only) \_\_\_\_\_
- Cardiovascular disease \_\_\_\_\_
- Lung cancer \_\_\_\_\_
- Diabetes \_\_\_\_\_
- Alzheimer's disease \_\_\_\_\_
- Hypertension \_\_\_\_\_

20) At this time, what do you think your chances are of developing any of the following health conditions someday, compared with most individuals your age? **(Please respond for each condition listed)**

1=Much lower      2=Somewhat lower      3=Same      4=Somewhat higher  
5=Much higher      6=Don't know / Not sure

- Breast cancer \_\_\_\_\_
- Ovarian cancer (Women Only) \_\_\_\_\_
- Colon cancer \_\_\_\_\_
- Prostate cancer (Men Only) \_\_\_\_\_
- Cardiovascular disease \_\_\_\_\_
- Lung cancer \_\_\_\_\_
- Diabetes \_\_\_\_\_
- Alzheimer's disease \_\_\_\_\_
- Hypertension \_\_\_\_\_

Thank you very much for your help with our questionnaire. We would appreciate any comments/feedback about your experience.

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## **APPENDIX D**

### **Study Post-Questionnaire**

## Post-questionnaire

We hope that you enjoyed having your family health history done. We would like to ask you a few more questions about risk to see if the family health history session changed your ideas about what conditions you might be at risk for. In addition, this post-session questionnaire is looking at your opinions regarding participating in research.

If there is a question that you do not feel comfortable answering, you can skip it and continue on. Please answer the following questions to the best of your ability. **DO NOT PROVIDE ANY NAMES OF FAMILY MEMBERS.** The questionnaire should take approximately 10 minutes. We would like to thank you in advance for your willingness to participate in this study.

### Section 1: Risk Perception

1) Based on your family health history, what do you think your chances are of developing any of the following health conditions sometime in your life?

**(Please respond for each condition listed)**

1=Low (<10%)      2=Moderate (10-50%)      3=High (>50%)      4=Don't know / Not sure

Breast cancer	_____
Ovarian cancer (Women Only)	_____
Colon cancer	_____
Prostate cancer (Men Only)	_____
Cardiovascular disease	_____
Lung cancer	_____
Diabetes	_____
Alzheimer's disease	_____
Hypertension	_____

2) Based on your family health history, what do you think your chances are of developing any of the following health conditions someday, compared with most individuals your age?

**(Please respond for each condition listed)**

1=Much lower      2=Somewhat lower      3=Same      4=Somewhat higher  
5=Much higher      6=Don't know / Not sure

Breast cancer	_____
Ovarian cancer (Women Only)	_____
Colon cancer	_____
Prostate cancer (Men Only)	_____
Cardiovascular disease	_____
Lung cancer	_____
Diabetes	_____
Alzheimer's disease	_____
Hypertension	_____

### Section 2: Opinions on Research

3) How important do you feel that medical research is?

- 1 Very important
- 2 Somewhat important
- 3 Not very important
- 4 Not important at all
- 5 Don't know

4) Have you ever participated as a subject in any medical research studies?

- 1 Yes
- 2 No
- 3 Don't know

5) Have you ever been offered the chance to participate in a medical research study and decided not to participate?

- 1 Yes
- 2 No
- 3 Don't know

6) If you were to describe your general attitude towards medical research involving people, would you say that you feel?

- 1 Very favorable
- 2 Somewhat favorable
- 3 Somewhat unfavorable
- 4 Very unfavorable
- 5 Neither favorable nor unfavorable
- 6 Don't know

7) Would the offer of free medical care make you more likely or less likely to agree to participate in research?

- 1 More likely
- 2 Less likely
- 3 No effect
- 4 Don't know

8) Would the offer of \$500 make you more likely or less likely to agree to participate in research?

- 1 More likely
- 2 Less likely
- 3 Have no effect
- 4 Don't know

9) Would the offer of free medicine make you more likely or less likely to agree to participate in research?

- 1 More likely
- 2 Less likely
- 3 Have no effect
- 4 Don't know

10) How much do you think scientists benefit from medical research?

- 1 A great deal
- 2 A moderate amount
- 3 Only a little
- 4 Not at all
- 5 Depends

11) How much do you think your community benefits from medical research?

- 1 A great deal
- 2 A moderate amount
- 3 Only a little
- 4 Not at all
- 5 Depends

12) How much do you think your family and friends benefit from medical research?

- 1 A great deal
- 2 A moderate amount
- 3 Only a little
- 4 Not at all
- 5 Depends

13) How much do you think you benefit from medical research?

- 1 A great deal
- 2 A moderate amount
- 3 Only a little
- 4 Not at all
- 5 Depends

14) Do you have an interest in having your name in a database that would allow you to receive information about clinical research studies related to your family health history?

**NOTE: Answering YES to this question DOES NOT enter you into any database nor does it sign you up to receive any information.**

- 1 Yes
- 2 No

14a) If you answered yes, what are your expectations? **(Please circle all that apply)**

- 1 I expect to receive information about *all* of the latest research studies.
- 2 I expect to receive information about studies that I am eligible for.
- 3 I expect to be rewarded for participating in research (paid, free health care, etc.)
- 4 I expect to get the best health care available.
- 5 Other: \_\_\_\_\_

14b) If you answered no, what are your primary reasons? **(Please circle all that apply)**

- 1 I am not interested in participating in research.
- 2 I am not interested in anything tied to my family/my genetics.
- 3 I do not want to be part of a database.
- 4 I do not want to disclose my contact information.
- 5 Other: \_\_\_\_\_

15) How would you describe your experience with having your family health history taken? **(Please circle all that apply)**

- 1 Enjoyable
- 2 Informative
- 3 Uncomfortable/Unpleasant
- 4 Neutral/No opinion

## **APPENDIX E**

### **1-Month Telephone Follow-Up**

1-Month Telephone Follow-Up

Date: \_\_\_\_\_

Person Making Phone Call: \_\_\_\_\_

INTERVIEWER: ASK TO SPEAK WITH THE INDIVIDUAL WHO GAVE US HIS OR HER NAME AND TELEPHONE NUMBER. IF YOU ARE TOLD THAT THE PERSON IS NOT HOME, SCHEDULE A CALL-BACK. WHEN YOU ARE SPEAKING WITH THE INDIVIDUAL, READ...

Hi, my name is \_\_\_\_\_ and I am a genetic counseling student from The University of Pittsburgh with the Center for Minority Health. About a month ago, you completed a questionnaire and had your family health history completed at \_\_\_\_\_. As you may recall, you agreed to let us contact you for a follow-up questionnaire. I just have a couple of brief questions to ask you. It should take about five minutes. Is it okay to proceed with the questions?

- 1) After having your family health history done, how did it make you feel?
  
  
  
  
  
  
  
  
  
  
- 2) Did you tell any one about having your family health history drawn out?
  
  
  
  
  
  
  
  
  
  
- 3) **(IF THE PERSON SAYS YES TO #2)** Who did you tell and what did you tell them?
  
  
  
  
  
  
  
  
  
  
- 4) Has anything about your family health history changed since we met?
  
  
  
  
  
  
  
  
  
  
- 5) Did you add (that or) anything else you may have remembered to your family health history?

6) Did you look over the materials/information we sent you with your family health history?

7) **(IF THE PERSON SAYS YES TO #6)** Did you find them helpful?

8) Would you like any additional information?

9) Have you seen a health care professional since you had your family health history done?

10) **(IF THE PERSON SAYS YES TO #9)** Did you share your family health history with the health care professional?

11) **(IF THE PERSON SAYS YES TO #10)** What did he or she say about it?



12) Do you have any plans to share your family health history with your family in the next six months?

13) Do you plan to share your family health history with a health care professional (i.e., doctor, nurse, pharmacist, physician assistant, or genetic counselor) in the next six months?

14) Have you made any lifestyle changes (diet/exercise/smoking/increased screening) since we did your family health history?

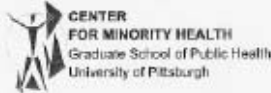
15) **(IF THE PERSON SAYS NO TO #14)** Do you want to or are you planning on making any changes?

16) **(IF THE PERSON SAYS YES TO #15)** What do you find to be the barriers for you to making changes?

17) **(IF THE PERSON SAYS YES TO #15)** Do you think support groups or classes would help you make the changes you want to?

## **APPENDIX F**

### **Sample of Materials Sent to Family Health History Participants**



## CERTIFICATE OF APPRECIATION

Presented to

**Sample**

*For completing a family health history session to better understand the role that family history plays in disease prevention and the health of your family.*



**Stephen B. Thomas, PhD**  
Director, CMH

**Vinaya Murthy, MPH**  
Genetic Counseling Student, CMH

**Beth Dudley, BS**  
Genetic Counseling Student, CMH

**Kristen Vogel, BA**  
Genetic Counseling Student, CMH

**Figure 8- Certificate of Appreciation Sent to All Family Health History Participants**

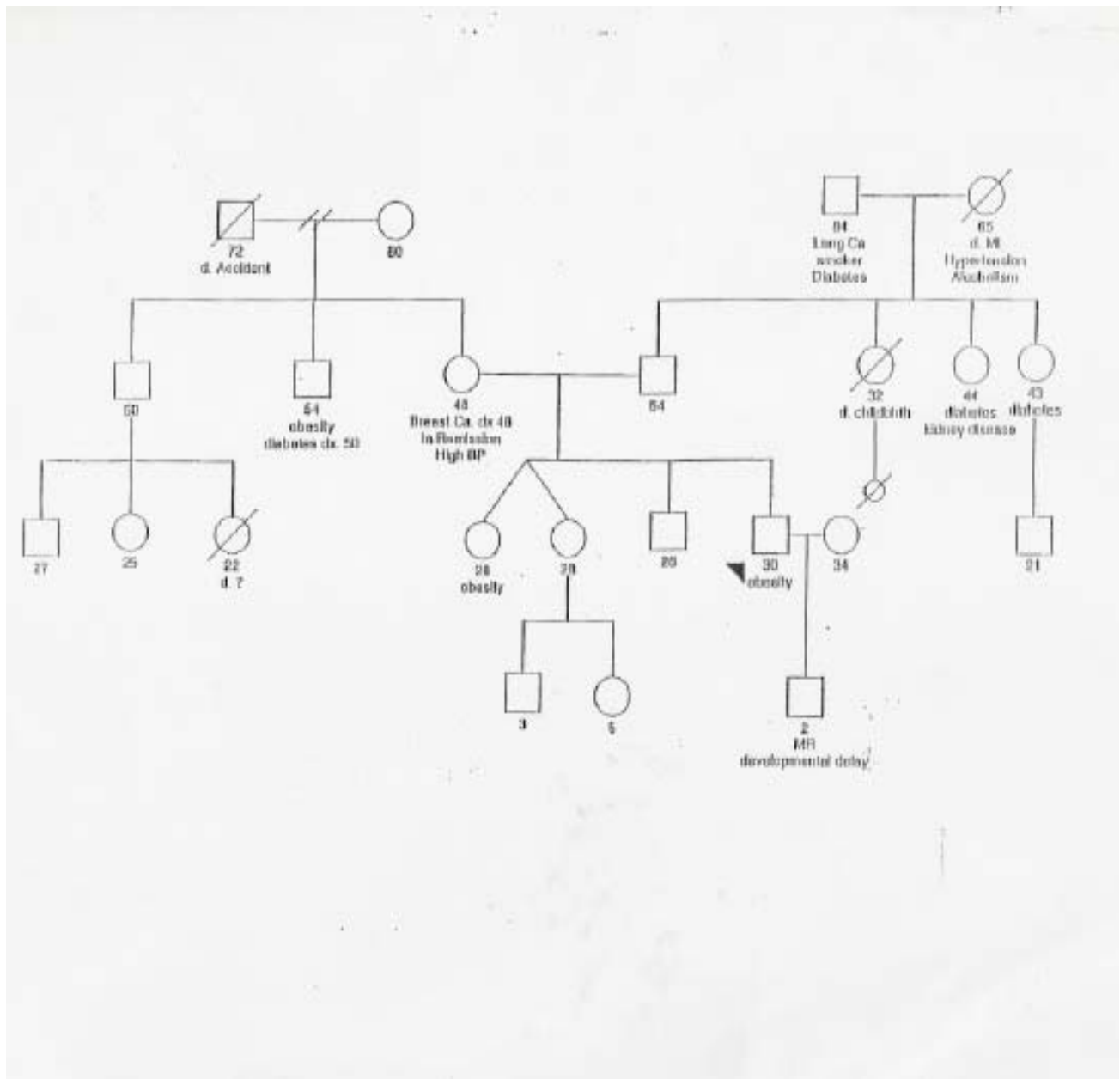
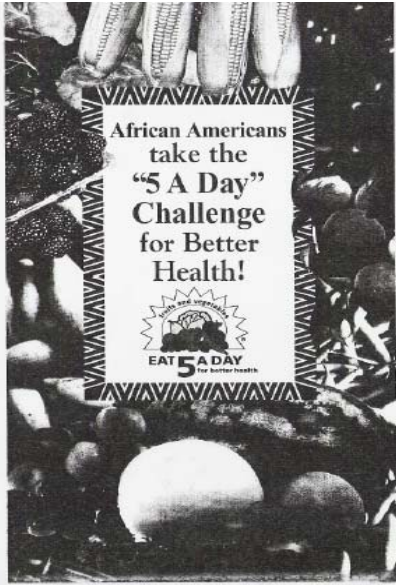


Figure 9- Sample Computer-Generated Family Health History Using Progeny Software



African Americans are at high risk for serious diseases like cancer, diabetes and stroke. Many people can avoid these diseases by making simple diet, health and lifestyle changes.

That's right! You can start making these changes **RIGHT NOW** by taking the "5 A Day" Challenge. That means eating any mix of five servings of fruits and vegetables everyday, like three vegetables and two fruits. Fruits and vegetables are an important part of a healthy diet. They are low in fat, and good sources of vitamins, minerals, and fiber.

Read on to learn how people are making changes in their lives to look better, feel better and live longer. Learn how YOU can do it too!



### WHY Take The "5 A Day" Challenge



"I almost died on my job from a stroke. My pressure was high. I ate greasy food every day, and I wasn't willing to change my ways. When I woke up in the hospital and didn't have any feeling on my left side, I knew I had to make some changes. It took me nine months to get back on my feet. Now I get regular check-ups, try to exercise, eat plenty of fruits and vegetables and cut out the grease. Believe me, these changes have made a difference in my life!"

"I've known Joe for a long time. When he had a stroke on the job, it shook me up. I learned from my doctor that Black men have more strokes than anyone else. I'm young, but I know the things I do now will help me to be healthier later on. I learned a lot from Joe and my doctor and I'm making changes."

Here are some fast and easy tips to help you meet the "5 A Day" Challenge!

**BREAKFAST**

- Drink a glass of juice.
- Add fruit to your waffles or pancakes.
- Add fruit to your hot or cold cereal.

**LUNCH**

- Have vegetable soup or a salad.
- Eat a piece of fruit like an apple, banana or a peach.
- Add lettuce and tomatoes to your sandwich.

**SNACK**

- Snack on grapes or raisins instead of candy.
- Have a bowl of your favorite fruits.

**DINNER**

- Eat beans cooked with non-fatty seasonings.
- Add fresh, sliced tomatoes or cucumbers to your dinner.
- Add vegetables to your rice or casserole.

To make sure you get "5 A Day" follow the serving guide below.

A serving is:

- 1 medium fruit or 1/2 cup of small or cut-up fruit
- 3/4 cup of 100% fruit juice
- 1/4 cup of dried fruit
- 1/2 cup of raw or cooked vegetables
- 1 cup raw leafy vegetables (lettuce, spinach)
- 1/2 cup cooked beans or peas (black-eyed peas, lima beans)

1/4 CUP 1/2 CUP 3/4 CUP 1 CUP

For more information on nutrition and diet, or to learn more about chronic diseases, contact your local health department, your doctor or the organizations listed below.

National Cancer Institute ..... 1-800-4-CANCER (1-800-422-6237)  
 American Cancer Society ..... 1-800-AICIS-2345 (1-800-227-2345)  
 American Heart Association ..... 1-800-AHA-USA1 (1-800-242-8711)  
 American Diabetes Association ..... 1-800-DIABETES (1-800-342-2383)  
 American Lung Association ..... 1-800-LUNG-USA (1-800-556-4672)

D H E C  
 HEALTHY PEOPLE 2000  
 A National Program of the  
 U.S. Department of Health and Human Services  
 Office of Minority Health, Division of Community Health  
 Program provided by South Carolina Department of Agriculture, National Cancer Institute, and CDC, Anthropology & Photography Center, U. South Carolina, 1998  
 Sponsored by the National Cancer Institute and the Center for Disease Control and Prevention

Figure 10- Sample Patient Education Material

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