

**ASSESSING THE PERCEPTIONS OF AFRICAN AMERICANS TOWARD GENETICS
AND GENETICS RESEARCH**

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The Center for Minority Health at the University of Pittsburgh aims to eliminate racial and ethnic health disparities especially in the areas of diabetes and hypertension. One avenue for eliminating racial and ethnic health disparities is through biomedical and public health research. The CMH strives to increase African American participation in research through community outreach programs including the Healthy Black Family Project. The HBFP is a community based intervention created to promote health and prevent disease through lifestyle behavior change in the African American community in Pittsburgh. The present study recruited individuals from the HBFP for focus groups to assess the perceptions of African Americans in the Pittsburgh area toward genetics and genetics research. Specifically, the study sought to characterize the willingness of African Americans to donate DNA for research examining the roles of genes and environment in disease development. The CMH is interested in this research because it has been suggested that uncovering the genetic and environmental contributions to common diseases such as diabetes and hypertension may help illuminate causes of racial and ethnic health disparities and allow for more effective strategies for prevention and treatment.

Transcripts from four focus groups attended by 43 people were read and coded using thematic analysis. Findings suggest participants are acutely aware of potential negative consequences of donating genetic material however, cautious optimism was expressed when discussing benefits of research. Additionally, the results suggest that researchers must actively

work to build trust with potential research participants to increase willingness to participate. The findings also suggest a strong association of the term genetics with family history, a limited understanding of the biological aspects of genetics, and a sensationalized view of genetics research. These last three issues may be addressed through a genetics education outreach program. This study is relevant to the field of public health because it provides researchers with direction in their effort to better characterize the willingness of African Americans to donate DNA for genetics research.

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1.0 BACKGROUND

The Center for Minority Health at the University of Pittsburgh, which was created in 1994 and has been under the leadership of Dr. Stephen B. Thomas since 2000, strives to “improve the health and wellbeing of racial and ethnic minority populations by eliminating health disparities as defined in the Healthy People 2010.” To this end, the Center for Minority Health has developed initiatives to engage the community in partnerships intended to increase the participation of minority populations in biomedical and public health research. An additional goal of these partnerships is to translate scientific research findings into disease prevention interventions at the local, regional, and national level.

One community based intervention launched by the Center for Minority Health is the Healthy Black Family Project (HBFP). The HBFP is a set of health promotion interventions with a primary goal of preventing diabetes and hypertension in targeted communities in the City of Pittsburgh. One component of the HBFP is the Family Health History initiative which was established to increase awareness of the role of family history in disease risk. Individuals completing their family health history are offered the opportunity to participate in surveys assessing their perception of risk for chronic conditions including diabetes, hypertension, heart disease, and cancer. Previous research conducted by Vinaya Murthy in 2005 investigated risk perception before and after the family health history session for two conditions, colorectal cancer and cardiovascular disease, to evaluate changes in accuracy of risk. [41] Murthy concluded the

family health history effectively identifies individuals at increased risk for chronic conditions and can promote accurate risk perceptions. [41] Murthy suggested that accurate risk perceptions may lead participants to engage in healthy behavior modifications that could have an impact on racial and ethnic health disparities. [41] Beth Dudley conducted a study in 2006 with HBFP members that assessed the ability of a family health history session to encourage participants to increase their physical activity. [42] The physical activity habits of participants were collected before and after a family health history session to determine whether or not individuals increased their physical activity after a family health history session. Data was also collected from individuals who had completed a Health Risk Assessment with a HBFP health coach but not a family health history session for comparison. Data demonstrated that individuals who complete a family health history session are more likely to increase their physical activity than individuals who complete a Health Risk Assessment. [42] Dudley suggested results of this study provide further support of the effectiveness of the family health history session as an intervention in modifying health behavior. [42] Based on the success of the initiative demonstrated by the research of both Murthy and Dudley, the CMH has continued to provide the Family Health History as a component of the HBFP to increase awareness of family history in disease risk and provide participants with an accurate assessment of disease risk to aid in lifestyle behavior change.

Individuals who participate in the Family Health History initiative also have the opportunity to enroll in the Minority Research Recruitment Database. The MRRD was created in the spring of 2004 to identify and contact individuals with an interest in participating in research studies. Kristen Vogel conducted a study in 2005 to characterize individuals who elected to participate in the database and compare them to those who declined enrollment. Vogel

found that individuals more likely to participate in the database were female, more likely to respond to monetary incentives, more likely to talk to their physician about concerns for developing a disease, less likely to have previously refused participation in a clinical trial and have no health insurance. Since Vogel's study researchers have continued to enroll participants in the MRRD.

The Minority Research Recruitment Database was utilized in the present study to recruit participants for focus groups designed to assess the perceptions of African Americans toward genetics and genetic research. Specifically, the present study was conducted to explore the views of African Americans toward prospective studies which involve the collection of DNA for the investigation of the genetic and environmental contributors to common disease. CMH's relationship with the African American community in Pittsburgh through the Healthy Black Family Project creates a partnership with the potential to organize a population based study collecting DNA to investigate the genetic and environmental contributors to disease. Prior to establishing this type of study, researchers within the Center for Minority Health felt it was important to hear the opinions of the community on the donation of DNA for genetic studies therefore this exploratory study was initiated.

1.1 INTRODUCTION

The Center for Minority Health is interested in the willingness of African Americans to participate in large population based studies collecting DNA for the study of the genetic and environmental contributors to common disease because these studies have the potential to uncover the causes of racial and ethnic health disparities. By determining the genetic and environmental contributors to conditions that disproportionately affect African Americans such as diabetes and hypertension, researchers may be able to devise new methods of prevention and treatment for these conditions. A primary goal of the Center for Minority Health is the elimination of racial and ethnic health disparities and the development of targeted interventions based on data from population studies will help the Center translate scientific research findings into disease prevention interventions within the City of Pittsburgh. There is limited information in the literature about the opinions of African Americans on genetic research and specifically the willingness to donate DNA for genetics research.

In the following section, a literature review provides an overview of the role of genetics in complex conditions such as diabetes, proposed methods of studying the roles of genes and the environment in disease development, and existing racial and ethnic health disparities. Additionally, the review will detail the history of African-American participation in biomedical and public health research, opinions of African-Americans' toward genetics and genetic research, and the use of qualitative research methods in public health research.

1.1.1 Genetics and Complex Disease

The majority of the leading causes of death in the United States are common chronic conditions including heart disease, cancer, stroke and diabetes. [1] These diseases are known as multi-factorial conditions because they are determined by combinations of multiple genes and their interactions with the environment. Multi-factorial conditions do not demonstrate a clear pattern of inheritance however they tend to segregate within families and display a higher degree of similarity between identical twins which supports a genetic component. Studies of risk based on family history of complex disease including diabetes and cardiovascular disease indicate that individuals with affected first- and second-degree relatives are at increased risk to develop these complex conditions. [29,30,31] Although it is widely accepted that most common conditions are complex diseases due to both genetic and environmental factors, little is known about how the interactions between these factors contribute to disease development. [2] Epidemiological research has identified risk factors that contribute to common disease while genetic research is working to identify genetic variants associated with common disease. [2] Researchers recognize that except in rare cases, genetic variants and environmental and behavioral risk factors do not act alone to cause common chronic diseases such as diabetes, cardiovascular disease, and cancer. Instead genetic variants or predispositions may increase the chance an individual will develop a chronic disease when combined with certain environmental exposures and lifestyle factors. Additionally, in the absence of certain environmental exposures and behaviors an individual with a genetic susceptibility may not develop disease.

It has been suggested that if the contributions of genes and environment to disease development are considered separately without consideration of their interaction it will incorrectly estimate the proportion of disease explained by genes, the environment and their joint

effect. [2] Investigating differences in environmental exposures and lifestyle behaviors between individuals with a disease susceptibility variant who develop the disease and individuals with a disease susceptibility variant who do not develop the disease may provide valuable information about which environmental exposures and/or lifestyle behaviors contribute to disease risk.[2] Understanding complex gene-environment interactions may provide the opportunity for individuals to engage in preventive strategies if a disease susceptibility variant is identified or personalized treatment of the disease if diagnosed. [2]

The task of exposing the gene-environment interactions leading to common disease is not straight forward. However, knowledge of the human genome sequence and increasing information about the function of the genome provide a starting point for research investigating gene-environment interactions. [2,3] In order to accurately assess the role of gene-environment interactions in disease development the information collected on both genetic and environmental factors needs to be precise. [2] The ability of these studies to provide information that may be incorporated into public-health and clinical practice depends on reproducibility in two or more studies. [2] Various study designs have been proposed to ensure that high-quality information on environmental and lifestyle factors such as diet or smoking is combined with biological samples in research designed to assess and confirm gene-environment interactions. [2]

1.1.2 Prospective Cohort Study of Genes and Environment

In May of 2004, *Nature* published an article authored by Francis S. Collins, Director of the National Human Genome Research Institute (NHGRI), highlighting the importance of establishing a US prospective cohort study of genes and environment. [4] Subsequently the

NHGRI published a paper titled “Design Considerations for a Potential United States Population-Based Cohort to Determine the Relationships among Genes, Environment, and Health: Recommendations of an Expert Panel” which proposed a prospective cohort study design for the US study. The purpose of such a study is to collect biological, health, and exposure information in a representative sample of the population prior to disease onset in an effort to identify the genetic and environmental factors that contribute to health, common disease, and response to treatment. [2,4] A prospective study which gathers information prior to the development of disease has been proposed to minimize the problems of selection and recall bias in case-control studies. [2] Participants would provide DNA samples and exposure information prior to disease diagnosis and follow-up for development of specified endpoints would take place for years, perhaps decades. [2] The term biobank has been used to describe this type of study that would allow researchers to withdraw samples of genetic material along with information on environmental and lifestyle factors.

A prospective cohort study or biobank would use knowledge of the human genome sequence and its current function to improve understanding of how genetic and environmental factors interact to cause common disease. [3] The purpose of a prospective study of genes and environment is to understand how genetic predispositions and environmental exposures and lifestyle factors interact to contribute to an individual’s risk for disease. [4] The objective of this research is to understand the complex contribution of genes, the environment, and gene-gene and gene-environment interactions to disease development. [3] Once these complex relationships are established, strategies for modifying the effects of genetic susceptibilities by avoiding the harmful environmental exposure or lifestyle factors can be developed to reduce the burden of disease. [4]

Although several countries including Iceland, Estonia, the United Kingdom, Germany, Canada and Japan are establishing protocols for or have established large-scale cohort studies or Biobanks, one of the reasons Collins suggested the United States consider a national study is the studies from other countries would not adequately represent the US population.[3,4] The NHGRI paper proposes the US cohort study recruit a minimum of 500,000 people representing the diverse US population at different stages of the life-cycle. [4,5] These individuals would undergo a baseline evaluation to characterize their current health and identify cases of pre-existing disease. [5] Although the information to be included in the initial data collection is currently under review, it would most likely include information that could best assess current health status, disease risk, exposure status, and genetic make-up. [5] Samples of biologic material including DNA would be a requirement for inclusion into the study. [5] Study participants would undergo periodic follow-up to identify outcomes of interest such as incident disease, measure new exposures and disease presentations, measure changes in health and exposure status, and establish a more complete data pool. [5] Disease outcome would be assessed using hospital records, outpatient records, and other databases containing medical information. [5]

Challenges in conducting a prospective study include the substantial cost to recruit and retain participants and difficulties assessing new cases of disease, identifying causes of death, and collecting detailed exposure information for the many environmental exposures that may be related to multiple diseases. Follow-up to assess disease outcome may be complicated in the US because there is no system of centralized electronic medical records. [4] Other issues addressed by authors discussing the merits of a prospective cohort study include challenges related to maintaining participant confidentiality, providing informed consent, the return of genetic results,

the costs of additional testing and clinical care, and the risk to insurance or employment status from research participation. [4,6]

The challenges presented by a prospective cohort study have been identified through public discussion involving experts in epidemiology, genetics, environmental science, ethics, public health, economics, and public policy however, to date the general public has not been included in these discussions. Recently it was announced that the American public will be able to voice their opinions on a prospective cohort study because the success of a prospective cohort study depends on the willingness of the American people to participate in such research. In September of 2006, the National Human Genome Research Institute gave the Genetics and Public Policy Center of the Berman Bioethics Institute at Johns Hopkins University \$2 million dollars to conduct a series of focus groups to assess public perception of research collecting DNA for the investigation of how genes and the environment affect human health. [7] Of particular interest is public opinion on issues of patient privacy and informed consent. [7]

It is particularly important to engage minority groups in these discussions because the ability to address racial and ethnic health disparities which is stated as an objective of a prospective study will depend on their participation in these studies. African Americans and other minority groups in the United States including Latinos and Native Americans bear a disproportionate burden of disease, injury, death, and disability related to common diseases such as cancer, cardiovascular disease, and diabetes. A prospective cohort study including individuals from these populations may provide information about targeted interventions that could reduce disease burden and may address the goal of eliminating racial and ethnic health disparities. [3]

1.1.3 Racial and Ethnic Health Disparities

Racial and ethnic health disparities, defined as differences between racial and ethnic groups in burden of disease, injury, death and disability, have been a focus of public health observation and study for over 100 years. [8,9,10] The disproportionate burden of common disease experienced by African Americans and other US minority groups compared to non-Hispanic whites persist despite efforts to eliminate racial and ethnic health disparities. The persistence of racial and ethnic health disparities will have a significant impact on the future health of America because the groups currently experiencing poorer health status are expected to grow as a proportion of the total US population. [11] According to the 2000 U.S. census, approximately 13% of the US population or 36.4 million persons identified themselves as Black or African American. [10] Projections from the Census Bureau indicate there will be more than 50 million African Americans in the US by the year 2035. [12]

According to health statistics published by the U.S. Department of Health and Human Services the four leading causes of death for Blacks or African Americans in 2004 were heart disease, cancer, stroke and diabetes. [12,13] Although the top three causes of death are the same for Blacks or African Americans and non-Hispanic Whites, the risk factors and incidence, morbidity, and mortality rates for these chronic diseases are often greater among Blacks than Whites. [10] In 2003, African American men were 30% more likely to die from heart disease as compared to non-Hispanic white men. The age-adjusted death rate from heart disease in 2003 for Black males was 364.3 (per 100,000) compared to 286.9 (per 100,000) for non-Hispanic white males. African American women were 1.4 times more likely than non-Hispanic white women to die from heart disease. The age-adjusted death rate from heart disease in 2003 for Black females was 253.8 (per 100,000) compared to 187.1 (per 100,000) for non-Hispanic white

females. African Americans were 1.5 times more likely as non-Hispanic whites to have high blood pressure which is a risk factor for heart disease.

African Americans have the highest mortality rate of any racial and ethnic group for all cancers combined and for most major cancers. In 2003, African American men reported 634.6 new cases of cancer per 100,000 compared to 543.9 new cases of cancer per 100,000 for non-Hispanic white men. In 2003, African American men were 1.6 times as likely to have new cases prostate cancer, compared to non-Hispanic white men and 2 times as likely to have new cases of stomach cancer as non-Hispanic white men. African American men had lower 5-year cancer survival rates for lung and pancreatic cancer as compared to non-Hispanic white men. In 2003, African American men were 2.4 times more likely than non-Hispanic white men to die from prostate cancer. African American women were 10% less likely to have been diagnosed with breast cancer however they were 36% more likely to die from breast cancer compared to non-Hispanic white women. Additionally in 2003, African American women were 2.3 times as likely to have been diagnosed with stomach cancer, and they were 2.2 times as likely to die from stomach cancer, as compared to non-Hispanic white women. As of a 2004 National Health Interview Survey, 11.2 % of African Americans 18 and over had diabetes compared to 6.1% of non-Hispanic whites 18 and over. African American adults were 2.1 times more likely than non-Hispanic white adults to have been diagnosed with diabetes and 2.1 times as likely to die from diabetes. In 2002, African American men were 2.1 times as likely to start treatment for end-stage renal disease related to diabetes compared to non-Hispanic white men. Additionally, African Americans were 1.6 times more likely to undergo lower extremity amputation due to diabetes than non-Hispanic whites. African American adults are 30% more likely than non-Hispanic white adults to have a stroke and 50% more likely to die from a stroke than non-

Hispanic white adults. The age adjusted death rate for stroke in 2003 for African American males was 81.7 per 100,000 compared to 54.2 per non-Hispanic white males. The age adjusted death rate for stroke in 2003 for African American females was 71.8 per 100,000 compared to 53.4 per non-Hispanic white females. [13]

These health statistics illustrate the persistence of racial and ethnic health disparities despite efforts to achieve the national health objectives set for the year 2010. [11] Research has suggested there are many factors that contribute to racial and ethnic health disparities including socioeconomic factors, lifestyle behaviors, social environment and access to preventive health-care services. Given the existing racial and ethnic health disparities and the growing number of individuals from minority populations in the U.S. it is imperative to address these disparities on many levels.

1.1.4 African American Participation in Research

One avenue for addressing health disparities is biomedical research. Historically, individuals who bear a disproportionate burden of disease including African Americans are underrepresented in biomedical research. The NIH published guidelines in the 1990's and updated these guidelines in the year 2000 mandating the inclusion of women and minorities in research. These guidelines titled the NIH Revitalization Act of 1993 were established to better understand disparities in health and to improve generalizability of research findings by ensuring the active recruitment of women and minorities into clinical research. [15] These guidelines stated that in addition to continuing to include women and minorities in all NIH-supported biomedical and behavioral research involving human subjects, the NIH must: 1. ensure that

women and minorities and their subpopulation are included in all human subject research, 2. ensure that for all Phase III clinical trials women and minorities and their subpopulations must be included such that valid 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 for outreach efforts to recruit these groups into clinical studies. [32]

Despite efforts to increase African American participation in clinical and public health research, participation remains low for many different reasons. Data on participation rates from a variety of biomedical studies suggest that African Americans are especially difficult to recruit. [17] Additionally, authors, including Freimuth et al (2001), have documented multiple barriers to participation in research including broader health care system issues, characteristics of potential participants, public knowledge, perceptions, and attitudes toward researchers and research and behaviors and attitudes of providers and researchers. [17] Lack of knowledge of research, differential access to health care, mistrust, fear of exploitation and the Tuskegee Syphilis Study have also been identified as barriers to participation in research. [17]

The literature provides many references to the Tuskegee Syphilis Study as a crucial contributing factor to the distrust expressed by many African Americans toward medical and public health research. Gamble (1997) suggests the Tuskegee Syphilis Study has emerged as the most prominent example of medical racism because it encompasses all the potential abuses by the medical community that are feared by the African American community. [16] The Tuskegee Study of Untreated Syphilis in the Negro Male was conducted by the U.S. Public Health Service from 1932 to 1972 in Macon County, Alabama. This study which lasted approximately 40 years is the longest non-therapeutic study in medical history. Three hundred and ninety-nine African American men were used as subjects and 201 African American men served as controls in this

study to follow the natural history of syphilis. Participants were not told they had syphilis and were denied penicillin treatment once it became the standard of care in the 1940's. An estimated 28 to 100 men died as a result of syphilis. [33]

Revelation of the Tuskegee Study exposed research misconduct on the part of the US government against African American men contributing to theories that there is a governmental plot to eliminate African Americans and the belief that researchers value the lives of African Americans less than Whites. [16] Although the Tuskegee Syphilis Study is viewed as the prototypical example of research misconduct against African Americans, fears about exploitation can be traced to the use of slaves and free Black people as subjects for dissection and medical experimentation before the Civil War. [16] Gamble (1997) suggests that the Tuskegee Syphilis Study continues to cast a shadow on efforts to improve the health status of African Americans but it is not the sole reason for African American distrust of the medical establishment. Instead African American distrust of the medical and public health communities may be a result of broader issues of racism. [16]

Because the Tuskegee Syphilis Study is often mentioned as a reason for African American distrust of the medical system and lack of participation in medical research, studies have been conducted to assess African American's knowledge of the Tuskegee Syphilis study compared to whites in an effort to better understand its role in race differences in mistrust of healthcare system. Freimuth et al (2001) conducted a series of focus groups to better understand African American's attitudes toward research, assess knowledge and beliefs about the Tuskegee Syphilis Study, and identify strategies to overcome barriers to participation in research. [17] Data collected during the focus groups indicate that the majority of participants were familiar with the Tuskegee Syphilis Study however most lacked specific and correct information about

the study. [17] These findings have been seen in other studies assessing knowledge of the Tuskegee Syphilis Study. [18] Freimuth et al (2001) reported that a significant number of participants incorrectly believed the men in the study had been injected with syphilis. Additionally, data indicated participants believed that the intentional deception and exploitation of the men in the Tuskegee Study was representative of other research projects involving African Americans. [17] Participants in these focus groups also referenced other examples of health conditions and mistreatment of African Americans that contribute to their distrust of the medical community. [17] Freimuth et al concluded that potential participants should be provided with accurate and factual information about the Tuskegee Study and other perceived research controversies in order to deconstruct existing myths that may impede African American participation in research. [17]

Additionally, the focus groups in the Freimuth et al study illustrated the importance of clearly and completely outlining the purpose and procedures of a research project for participants. Explicitly detailing the intent of the research may address the theme of suspicion mentioned in several focus groups. Formative research with community members conducted prior to beginning recruitment was suggested as a means of providing culturally appropriate information to potential subjects. Freimuth et al found that distrust of white researchers was a common theme in the focus groups and participants felt the issues of mistrust needed to be addressed before African Americans would be willing to participate in research. [17] This study suggests as others have previously that many African Americans distrust of the medical system may be systemic of a broader societal issue of mistrust. [16,17] Freimuth et al concluded that these broader issues are beyond the purview of biomedical and public health researchers but they can actively take steps to develop more trusting relationships within the context of research. [17]

Additional studies have found that distrust of the medical care system may have broader roots than the Tuskegee Syphilis Study. A 2003 telephone survey of 277 African-American and 101 white adults in Baltimore, Maryland conducted by Brandon et al (2005) found no differences by race in knowledge of or about the Tuskegee Syphilis Study however they found a difference in trust of the medical community based on race. Most respondents were unaware of when the study ended, the size of the study, and who conducted the study. Most respondents believed the men in the study had been given syphilis by the study team (75.3% of Blacks and 52.8% of Whites) although a larger percentage of whites (47.2%) than Blacks (24.7%) reported that the men in the study already had syphilis. When asked if this type of study could take place in 2003, 47.2% of Whites responded yes while 76.6% of Blacks responded yes. Brandon et al reported this opinion underscores the issue of racial differences in medical care trust. When the relationship between race and the incidence of the belief that a similar study could happen again, researchers found that blacks who were unaware of the study before being told about it by investigators were 21% more likely than unaware whites to believe a similar study could happen again. When the relationship between race and the incidence of the belief that a similar study could happen again, researchers found that blacks who were aware of the study were 130% more likely than aware whites to believe a similar study could happen again. These findings suggested that overall blacks were more likely to believe a similar study could happen again regardless of their awareness of the Tuskegee Syphilis Study. Various statistical models were employed to investigate the relationship between race and mistrust of the medical care system. Brandon et al concluded results from these analyses indicate that black race remained a significant predictor of mistrust in the medical system when controlling for confounding variables including demographics and awareness and knowledge of the Tuskegee Syphilis Study. Additionally

Brandon et al suggested these results may indicate that knowledge of the Tuskegee Syphilis Study is not the sole reason for race differences in mistrust of the medical care system. These differences most likely stem from broader historical and personal experiences of African Americans in the healthcare system. [18]

Distrust of medical researchers by many African Americans presents a well-documented hurdle to recruitment of African Americans into research. [16,17,18] A 2002 National telephone survey of 909 individuals was conducted by Corbie-Smith et al to examine the issues of distrust, race, and research. Five hundred and twenty-seven African Americans and 382 white individuals responded to this survey on beliefs of Americans toward their physicians and participation in clinical research. [19] Results found that African Americans were more likely than white respondents to not trust that their physician would fully explain research participation (41.7% vs. 23.4%); disagree that their physician would not ask them to participate in research if the physician thought there was harm (37.2% vs. 19.7%); state that they thought their physicians sometimes exposed them to unnecessary risks (45.5% vs. 34.8%); believe that someone like them would be used as a guinea pig without his or her consent (79.2% vs. 51.9%); believe that physicians often prescribed medication as a way of experimenting on people without consent (62.8% vs. 38.4%); believe their physicians had given them treatment as part of an experiment without their permission (24.5% vs. 8.3%). Further analysis revealed that none of the socio-demographic variables were found to substantially modify the relationship between race and distrust which indicated race remained strongly associated with a higher distrust score. [19] These findings are consistent with negative views of the health care system held by African Americans published in the literature which indicates thoughtful steps must be employed when approaching African Americans to participate in research.

Studies examining the barriers to participation in research have also included discussions with participants about the steps that could be taken to encourage participation by African Americans. Corbie-Smith et al (1999) conducted focus groups to explore the reasons for low participation in medical and public health research among African Americans. Thirty-three African American adults presenting to an urban public hospital for outpatient medical care participated in five focus groups. Data from focus groups reinforce previous research identifying lack of trust in the medical community and concerns about ethical misconduct as barriers to participation in medical research. [15] Participants feared being “guinea pigs” and expressed concern that researchers would make statements to persuade people into participating but may not keep their word. Additionally, research participants referenced the Tuskegee Syphilis Study and other historical evidence of exploitation of African Americans in medical research to validate their fear of misconduct by researchers. [15] Given the expressed barriers to participation in research, investigators engaged participants in a discussion about strategies for improving recruitment of African Americans into medical and public health research. Participants requested more education about the importance of and opportunity to participate in research. [15] Additionally, they indicated a feeling of trust would be very important in their discussion to participate in research. [15]

Freimuth et al (2001) reviewed suggested strategies for overcoming issues of distrust and increasing African American participation in research. [17] Building a relationship between researchers and the African American community was identified as an integral component in efforts to increase participation in research. Strategies to build a relationship include raising awareness through outreach programs, local churches, and community organizations; publicity campaigns targeted to African Americans; increasing awareness about studies among doctors;

using community-centered communication involving trusted individuals, and involvement and commitment of culturally-sensitive staff. [17] Other strategies include the use of incentives like financial compensation, medical care, prescription coverage, and transportation to research activities. It has been suggested that educating the African American community on the topics of clinical trials, sampling, responsibilities of the researcher and the participant and other issues involved in research would aid in recruiting African Americans into research studies. [17]

Increasing African American participation in research is essential in the quest to eliminate racial and ethnic health disparities. As described previously African Americans experience a disproportionate burden of common diseases and biomedical and public health research with African Americans is essential for addressing the underlying causes for these health disparities. Currently, there is an initiative within the biomedical and public health communities to understand the genetic or inherited susceptibilities associated with common diseases including diabetes, cardiovascular disease, and cancer. The goal is to understand how genetic susceptibilities interact with environmental and lifestyle factors to cause common disease. The ultimate goal is better prevention and treatment strategies for those who may be predisposed to certain diseases such as diabetes or heart disease. African American participation in studies on how genetic susceptibilities interact with environmental and behavioral exposures to cause common disease is essential to permit meaningful conclusions about the role of gene-environment interactions in disease development in African Americans and advance the study of health disparities. [3] Despite the breadth of research on attitudes of African Americans toward medical research, few studies have examined the attitudes of African Americans toward genetics research.

1.1.5 Attitudes of African Americans toward Genetics and Genetics Research

Little is known about the awareness of and attitudes toward genetics in minority populations including African Americans. Catz et al conducted a series of eight focus groups in the winter of 2002 and 2003 to better understand the attitudes and beliefs toward genetics and genetic testing in minority populations. [22] They found that focus group participants had limited understanding about genetics and genetic testing however they expressed an interest in learning more information about these topics. [22] Attitudes about genetic testing could be separated into two distinct categories: genetic testing is beneficial because it may aid in disease prevention and management and genetic testing is both good and bad because it may be used for prevention but it can be used unethically and may cause heightened anxiety if tests diagnose a condition. When data from the focus groups were examined on the basis of racial category it revealed that Latino and Chinese participants generally expressed positive attitudes toward genetic research and genetic testing. Results reported the most common advantage was the possibility to prevent disease. Overall, African Americans and Non-Hispanic white participants expressed more concerns about genetic research and genetic testing. Fears voiced during the focus groups included concerns about insurability and discrimination if predictive testing revealed a predisposition to disease, concerns about who would have access to the information and concerns about the ethical dilemmas posed by genetic technology. Focus group participants expressed generally positive responses toward carrier testing especially for the preventive aspects and that it did not involve testing of infants or children. [22] Although results of focus groups cannot necessarily be applied to the general population this research examined the views of genetics with participants from diverse populations that are often underrepresented in research and for which little information is known about their attitudes toward genetics. Attitudes

expressed during these focus groups demonstrate a need for genetics education in minority populations to increase awareness and potentially access to medical services including genetics. Understanding the perceptions of minority populations including African Americans toward genetic testing and genetic research is essential to ensuring they are involved in genetics research when so desired and benefit from advances in genetic technology.

Research has indicated that African Americans including those with a significant science background have a relatively positive view of genetic testing as a preventive strategy but this positive view is balanced by concern that the information may be used in a discriminatory manner. A 2001 study by Laskey et al was conducted to examine the attitudes of African Americans toward genetic testing and screening. The study included a questionnaire which consisted of questions on genetic testing, population screening, prenatal testing, discrimination, confidentiality issues, abortion, and uses of genetic test results was available to 97 premedical students participating in a minority program for those interested in a health career at Case Western Reserve University School of Medicine during their orientation session. Seventy-two respondents were African American, seven were Hispanic and eighteen reported other. A modified version of the questionnaire was distributed at the end of their 8-week program. The second survey was similar to the first but included sections that asked if respondents' attitudes had changed and to list their major concerns and benefits of testing. Sixty-six participants filled out the first questionnaire (71% African American). Results from the initial survey indicated the majority of students strongly agreed that genetic testing should be used for preventive care (95%), that it should be used for pre-symptomatic detection of disease (88%), that it should be widely available to patients (83%) and that it should be used to influence one's health (74%). Additionally, results indicated that 68% expressed concern that genetic testing would lead to

discrimination and 51% thought that genetic testing would make abortions more common. Results demonstrate that the number of respondents concerned that discrimination would become more common rose from 68% to 80% and concerns regarding eugenics increased from 37% to 67% between the initial survey and the post-survey. The questionnaires were anonymous therefore comparison among participants was not possible. Only 29% of African American students were in favor of carrier screening for high risk groups compared to 40% of non-African American minority students. A statistically significantly higher percentage of non-African American students desired to know their own genetic make-up in both the initial (89% vs. 49%) and post questionnaire (84% vs. 55%). Laskey et al concluded the data from this study demonstrate that African American premedical students have a positive view of genetic testing for prevention of disease and for pre-symptomatic testing however they are concerned about how the information will be used by patients and others. Furthermore, the concerns expressed by the respondents in the post-questionnaire demonstrated that concerns were increased by exposure to genetics education. [20] Laskey et al propose that the African American students' views on carrier screening may be related to the broader issues of distrust within the African American community toward the healthcare community. They suggest further research is needed to explore African Americans opinions on genetic testing and genetic research. [20]

A few studies have been conducted to better understand African Americans' perceptions toward genetic testing. A study by Singer, Antonucci, and Van Hoewyk (2004) examined the attitudes about genetic technology and the potential barriers to genetic testing held by three ethnic-racial groups: African Americans, non-Hispanic Whites, and Latinos. Singer et al attempted to recruit a large enough sample to permit separate analysis of these groups. Singer et al concluded results of their study indicated that African American and Latino respondents were

more open to both prenatal and adult genetic testing than White respondents although they suggested there are barriers such as lower average incomes and lesser insurance coverage that may affect uptake of genetic testing by African Americans and Latinos compared to Whites. [23] Based on data from the telephone surveys, Singer et al suggested African Americans may hold a number of beliefs including religious beliefs that conflict with their observed preference for genetic testing and discourage them from pursuing it. Additionally, data indicated African Americans tend to be less knowledgeable about genetic testing and its uses and more concerned about privacy especially in terms of governmental access to information. [23] This research provided more information on the attitudes of minority populations toward genetic testing however it did not address their willingness to participate in genetic research particularly studies collecting DNA for the study of gene-environment interactions.

Most of the literature regarding African Americans attitudes on genetic testing involves opinions about predictive testing for cancer risk. A 2002 study by Peters et al investigating differences in attitudes about predictive genetic testing for cancer risk between African Americans and Caucasians involved 351 women who were called for jury duty in Philadelphia. One hundred and seventy or 48% were African- American and 181 or 52% were Caucasian. Results indicated that African American women were less aware of genetic testing than white respondents (49% vs. 72%). After data was adjusted for age, gender, and educational level, African Americans remained more likely than Caucasian respondents to think the government would use genetic tests to label groups as inferior and less likely to endorse the potential health benefits of testing. [21] Peters et al suggest the results of this study are consistent with well documented African American concerns about racial discrimination on the basis of genetic information which have their roots in the sickle cell screening program of the 1970's, the

eugenics movement of the 20th century and past abuses of African Americans in medical research including the Tuskegee Syphilis Study. [21] The results of this study are important because they suggest that racial differences in attitudes toward predictive genetic testing could result in disparities in uptake of tests and subsequent disparities in burden of disease. [21] Predictive genetic testing is projected to have a greater role in healthcare in the future therefore understanding the perception of African Americans toward genetic testing is imperative to ensure equal access and benefits.

Recognizing that genetic testing may be used to identify individuals at increased risk for disease to provide medical management and the existing racial and ethnic disparities in traditional methods of screening, early detection, and access to treatment, Zimmerman et al (2006) conducted a survey to assess racial differences in beliefs about genetic determinants of disease, genetic testing, and religion. [24] Data from 314 telephone interviews with respondents ascertained through inner city neighborhood health centers (157 African Americans and 157 Caucasians) was analyzed to determine if certain beliefs about genetics were associated with race. The majority of respondents believed that genetic testing to check for risk of getting a disease is a good idea and research on genetics will bring cures for many diseases. When data analysis was controlled for socio-demographic variables, African Americans were more likely than Caucasians to agree that genetic testing will lead to racial discrimination, research on genetics is tampering with nature and unethical, and that all pregnant women should have genetic tests. Results from this study indicate that racial differences in perceptions toward genetic testing and research exist and should be further explored by those in public health to ensure that these perceptions do not lead to further health disparities. [24]

1.1.6 Qualitative Research Methods in Public Health Research

As described in the above paragraphs, focus groups have been utilized in exploratory studies with minority populations on the topic of research and genetics. [15, 17, 22, 23, 27] Qualitative research has been defined in various ways however generally it describes the collection and analysis of data to better understand the social processes and beliefs underlying complex issues. [25,26] Through simultaneous data collection and analysis, qualitative researchers can begin to identify the perspectives of those being studied to provide new insights into motivations behind observed phenomena. Qualitative data may provide researchers with new topics for exploration or better modes of studying their current research question. [25] Qualitative research is especially useful in research with populations and topics for which little is known about the opinions because it may help illuminate issues that researchers have not been able to envision based on available research. [26] In qualitative research, investigators look to the data to provide context for interpreting previously established knowledge or constructing new theories about social processes. [26] Qualitative data may be collected through a variety of methods including open-ended interviewing, narrative analysis, focus groups, participant observation/ethnography and participatory action research. [26]

Focus groups are a type of interviewing that has its roots in market research. Focus groups involve inviting a small group of individuals to participate in a discussion on a topic chosen by researchers. The discussion is focused or facilitated by a moderator who is often a principal investigator or a research assistant to obtain information from the participants and the interactions between participants. The moderator initiates a discussion on the research topic through a series of questions and probes that are designed to gently direct the conversation. Participants are encouraged to share their opinion and the moderator often observes and assists

the discussion to ensure that everyone has the opportunity to contribute and the conversation stays within the boundaries of the research topic. Questions often follow in the order of an opening question or ice-breaker, introductory questions to focus the discussion and establish the participants understanding of the topic, transition questions to move the discussion toward the main questions, main or key questions that focus on the main areas of interest, and the ending question to wrap up the conversation by making certain that all essential information has been addressed. Questions are often open-ended so participants may share their opinions and experiences and compare and reflect on the opinions and experiences of others. [27] Focus groups may consist of individuals who share similar backgrounds or cultural/racial make-up (homogenous groups) or individuals from different backgrounds or cultural/racial make-up (heterogeneous groups). There are advantages and disadvantages to both types of groups. It has been suggested homogenous groups may be less likely to present a broad range of opinions because of similarities in background however they may provide the opportunity to focus on racial/cultural issues specific to the group being studied. While heterogeneous groups may report more diverse views, these views may be a result of the differences in background and experience. [27]

Data collected during a focus group is often in the form of tape-recorded discussions, field notes, and transcriptions. Data collection is considered complete when saturation is reached during the focus groups. Saturation occurs when a redundancy in ideas expressed during focus groups is observed and new information does not enhance the researchers' conceptualization of the phenomena under study. Data is often reviewed a number of times during the analysis process. Ideally, data analysis begins after the first focus group so information in the questions can be modified to address emerging issues. [25,26,27]

Data analysis often involves systematically taking notes and highlighting key issues while reading transcripts and listening to tapes. Data analysis also involves incorporating impressions generated from voice inflection and non-verbal cues expressed during the meetings. In addition to hand-written notes and highlighting, computer programs exist to organize the data collected during analysis of focus group transcripts. These computer programs do not provide interpretation of the data collected but allow researchers to clean-up the data and concentrate on coded material during their interpretation of the data. [26] Thematic analysis is one method employed in analysis of data collected during qualitative research. In thematic analysis, data is reviewed to identify, analyze, and report themes or patterns. A theme represents a response which is noted in a number of instances across the data and provides information relevant to the research question. Themes can be identified by coding the data with or without trying to fit it into pre-existing codes. Coding of data without trying to fit it into pre-existing codes is called inductive analysis because it is not driven by a researcher's theoretical interest in the topic. [28]

The results from a focus group are often written up in a manner which addresses the themes and uses examples from the focus groups to illustrate these themes. The results of a focus group may not be generalizable but they provide researchers with insight that is essential for future projects on topics for which little is known. Qualitative research is gaining recognition as a valuable tool in public health's efforts to understand complex issues. [26]

The present study employed focus groups for data collection and thematic analysis to assess the perceptions of African-Americans toward genetics research involving the donation of DNA because there is limited information in the literature on the topic. The Center for Minority Health felt it was important to perform exploratory research on the donation of DNA for genetic

studies because African American participation in these studies will be necessary if researchers want to be able to draw conclusions about racial and ethnic health disparities.

2.0 METHODS AND PROCEDURES

2.1.1 Healthy Black Family Project

The Healthy Black Family Project (HBFP) is a community-based intervention designed by the Center for Minority Health (CMH) to promote health and prevent disease through lifestyle behavior change. The program is focused on reducing risk factors for hypertension and Type II diabetes. The HBFP targets residents in a geographic area called the Health Empowerment Zone which includes: East End neighborhoods, specifically – East Hills, East Liberty, Homewood North, Homewood South, Homewood West, Larimer, Lincoln-Larimer, and Wilkinsburg. A majority of the residents of these neighborhoods are African American (average 79.1%) and a high percentage (average 25.7%) live below the federal poverty line. The Genetic Family Health History is one of the assessments used in the HBFP.

2.1.2 Family Health History Initiative

The Family Health History component of the HBFP was designed to engage the community in a discussion of family history as a risk factor in disease development. Since 2003, students from the Genetic Counseling Program in the Department of Human Genetics at the University of Pittsburgh's Graduate School of Public Health meet with members of the HBFP to draw their family history. During these one-on-one sessions, which last approximately 45

minutes to an hour, students record a detailed family medical history, or pedigree, by hand. Once the pedigree is completed, the student provides a general risk assessment focusing on common diseases such as diabetes or heart disease that the individual may be at increased risk of developing based upon their family health history. The student then provides the individual with information on relevant behavior modifications such as physical activity or stress management classes that are available through the HBFP. Additionally, the individual is encouraged to share the information with other family members and health care providers. The individual is given the hand drawn copy of the pedigree at the end of the meeting but may elect to have the student create a computer generated version of the pedigree using Progeny® software. The computer version is sent to the individuals along with applicable health education materials, a letter of appreciation, and a certificate of completion. Individuals who complete their family health history also have the opportunity to enroll in the Minority Research Recruitment Database.

2.1.3 The Minority Research Recruitment Database

The Minority Research Recruitment Database was created by the Center for Minority Health to increase minority recruitment into biomedical and public health research. The majority of the individuals enrolled in the Minority Research Recruitment Database (MRRD) have been recruited through the Family Health History initiative of the HBFP. After completion of their family history, individuals are given the opportunity to enroll in the MRRD. An individual who provides informed consent and elects to participate in the MRRD has his/her pedigree stored in Progeny®. The Progeny® database allows the CMH to search for individuals who meet participation criteria for upcoming research and clinical trials. Individuals who meet inclusion criteria are sent the details of the study including contact information and instructed to contact

researchers if they are interested in participating. To ensure confidentiality, the CMH does not release the names or contact information for participants of the MRRD to study investigators.

2.1.4 Assessing the Perceptions of African Americans toward Genetics and Genetic Research

The purpose of this exploratory research is to assess public opinion of a large population based study examining the relationship of genes and environment in health and disease. Specifically, the study aims to:

1. Assess African-American community members knowledge of genetics and genetic research
2. Assess African-American community members view on the role of genetics in disease risk
3. Assess African-American community members willingness to participate in genetics research
4. Understand the circumstances under which African-American community members would be willing to donate DNA for a large population research study of genes and environment.

This study was funded by a grant from the National Institutes of Health, National Center for Minority Health and Health Disparities: EXPORT (5 P60MD-000-207-03), and received approval from the University of Pittsburgh Institutional Review Board in November 2006. (See Appendix A)

The present study recruited participants from the Healthy Black Family Project (HBFP) because it is a community based project sponsored by the Center for Minority Health (CMH). Based on its role as a community based intervention created by the CMH to reduce racial and ethnic health disparities in Pittsburgh, the HBFP provides a unique opportunity to engage community members in discussion about current trends in biomedical and public health research that may impact health disparities. Community-academic partnerships have been identified as

critical elements in setting the agenda and reaching the goals of public health therefore the opportunity to conduct this study with participants of the HBFP acknowledged the importance of the community's opinions in the planning of future public health research. [32] The use of potential research participants during formative research may help create a large population based study that meets the community's needs and helps extend the HBFP's effort to decrease racial and ethnic health disparities by encouraging African American participation in research. If a large population based study collecting DNA from African Americans is going to be successful in Pittsburgh researchers must first understand how to design and implement a culturally sensitive and appropriate research protocol.

2.1.5 Procedure

Since most of the published literature on the beliefs of African Americans toward genetic testing and genetic research does not include a discussion of the donation of biologic material for the study of gene-environment interactions in disease development, focus groups were chosen as the methodology to explore participants' attitudes toward this type of research. Four focus groups interviews, attended by 43 people (10, 10, 9, and 14, respectively), were conducted between December 2006 and January 2007 at the HBFP Headquarters located at the Kingsley Association, a community center located in Pittsburgh's East Liberty neighborhood. Male and female participants age 18 and older were recruited from the Minority Research Recruitment Database and Healthy Black Family Project activities. Individuals enrolled in the database were contacted via telephone and read a recruitment script detailing the study (see Appendix B). If an individual was interested in participating in a focus group they were given an option of dates and times. At the end of the call, participants were told they would receive a confirmation letter (see

Appendix C) and a phone call the evening before their scheduled focus group date to confirm attendance. Flyers were placed in the Healthy Black Family Project office at the Kingsley where a majority of the activities take place. Individuals attending HBFP activities were free to take a flyer which briefly described the study and provided investigators contact information (see Appendix D). Additionally, an advertisement also appeared in the monthly HBFP newsletter so participants had the opportunity to contact investigators directly. Individuals who responded to the recruitment flyer or newsletter announcement were provided with a description of the study similar to the recruitment script. If an individual was interested in participating in a focus group after being informed of the details of the study, they were given an option of dates and times. Similarly to individuals recruited through the MRRD, individuals who contacted CMH about participating were told they would receive a confirmation letter and a phone call the evening before their scheduled focus group to confirm attendance. Participants were recruited solely through the HBFP because homogeneous groups were desired in order to focus on racial/cultural issues specific to the group being studied.

A Caucasian female graduate student researcher from the Center for Minority Health served as moderator of the focus groups. She was assisted by another Caucasian female graduate student researcher from the Center for Minority Health who served as note-taker and ensured the audio recorder functioned properly throughout the meeting. Additionally, Dr. James Butler, Dr. Robin Grubs, and Ms. Elizabeth Gettig, each attended a focus group to assist in moderating the discussion. Individuals were greeted upon arrival at the focus group and asked to fill out a brief survey which included questions on demographics and research opinions (Appendix E). These survey questions were described previously by another graduate student researcher from CMH in her thesis. [33] Additionally, participants were asked to write their first name or a pseudonym on

a name-card to place on the table in front of them. Participants were offered a beverage and a light snack because the meetings were held during meal times. Once everyone arrived, the moderator introduced herself and her colleague. Additionally, she reviewed the topic of discussion and the ground rules for the focus group. Participants were given the opportunity to ask questions prior to the start of the meeting.

The moderator conducted all focus group interviews using a written moderator's guide (Appendix F). Dr. Butler provided valuable assistance in creating the guide by supplying a sample moderator's guide. The guide was intended to provide an outline of key questions which addressed the aims of the study. Open-ended questions were created to generate discussion regarding the topics of interest. Probes followed the open-ended questions to better clarify participants experiences and beliefs. The focus group began with a question regarding the HBFP to break the ice. The three general topics of interest were addressed in the following order: knowledge of genetics, opinions on genetics research, and willingness to participate in a biobank (i.e. study of gene-environment interactions collecting biologic material). Questions assessing knowledge of genetics served as introductory questions to focus the discussion and establish the participants understanding of the topic, the questions on the topic of genetics research were transition questions to move the discussion toward the main questions about willingness to participate in a biobank. The focus groups ended with a summary by the moderator and the opportunity for participants to contribute closing remarks. The moderator clarified statements by answering participant questions. The major contribution of the moderator to the focus group discussion was the presentation of a biobank so participants had a working definition of the type of research being discussed. Focus groups were allotted two hours and most finished within this time frame. All meetings were audio-taped and transcribed for data

analysis. Participants received a \$25 gift card to a local grocery store for their participation in the study.

2.1.6 Data Analysis

All field notes and transcriptions were reviewed to identify, analyze, and report themes or patterns across participant responses. This type of analysis is called thematic analysis. A type of thematic analysis called inductive analysis was used because codes were not developed prior to the initiation of the focus group discussions but emerged during the interpretation of the participant responses. One investigator initially read and coded all transcripts by hand. Transcripts were then uploaded into QSR NVivo® Software and coded using the software program. QSR NVivo® was utilized to organize and search the data more efficiently during data analysis. Responses to the pre-discussion questionnaire were entered into and analyzed using Microsoft® Excel.

3.0 RESULTS

During the course of this study from December 2006 through January 2007 a total of 43 individuals attended four focus groups held at the Kingsley Association. All individuals agreed to have their comments recorded. One female participant did not wish to fill out the pre-discussion questionnaire therefore the following section regarding participant demographics and opinions on research only includes the responses of 42 individuals. The surveys were anonymous which did not permit comparison of responses during the discussions to data collected during the questionnaire.

3.1.1 Characteristics of Participants

3.1.1.1 Demographics of the Study Population

Demographic information collected included the participants' gender, age, race/ethnicity, income, and education level. These data were collected to better describe the individuals participating in our focus groups and not to provide analysis regarding possible significant differences in responses during focus group discussion. In addition to this information, individuals were asked to rate their knowledge of genetics.

Forty-two participants completed the surveys. The participants ranged in age from 20 to 81, with an average age of 52 and a median age of 54. Ninety percent of the participants were

female and 98% self-identified as Black or African American while 2% reported their race/ethnicity as mixed Black or African American and other. The majority of individuals (72.5%) had a household income of \$35,000 or less. Sixty-two percent report 1 to 3 years of college (some college or technical school). The majority of participants (82%) rated their knowledge of genetics as fair or good. See Table 1 for full list of participant demographics.

3.1.1.2 Participants Opinions on Research

The pre-discussion questionnaire also addressed individuals' opinions on different aspects of research. Given that an aim of the focus group was to characterize participants' opinions on genetics research it was important to establish their general attitudes toward research. Analysis was not performed to determine if there were significant differences in responses during focus group discussion between individuals who answered the questions on research favorably versus unfavorably.

Participants expressed a relatively positive view of medical research however they are more reserved in their opinion of medical research involving people. Eighty-two percent feel medical research is very important and sixty percent described their general attitude towards medical research involving people as somewhat favorable. Forty-one percent of the participants report participating in a medical research study in the past. Seventy-eight percent state scientists benefit a great deal from medical research but only 40% feel their community benefits a great deal from medical research. Overall, it appears that participants see value in research but report benefiting less personally and as a community compared to scientists. See Table 2 for Summary of Participants Opinions on Research.

Table 1 Participant Demographics

Demographic Variable	Participant (N=42) Response (%)
Median Age	54
Age Range	20 to 81
Age	
18-35	10%
36-50	33%
51-65	33%
66+	23%
Gender	
Female	90%
Male	10%
Race	
African American	98%
African American and Other	2%
Income Level	
<\$10,000	20%
\$10,000-\$20,000	25%
\$20,001-\$35,000	27.5%
\$35,001- \$50,000	12.5%
\$50,001-\$75,000	10%
>\$75,000	5%
Education	
Grade 8 or less	0%
Grades 9 through 11	0%
Completed High School (or GED)	19%
1-3 Years College	62%
4+ Years of College	12%
Graduate School	7%
Knowledge of Genetics	
Poor	7.3%
Fair	46%
Good	36%
Very Good	9.8%
Excellent	0%

Highlighted text indicates category or categories representing majority of the participants

Table 2 Opinions on Research (N=42)

Question	(%)
How important do you feel that medical research is?	
Very important	82.5%
Somewhat important	17.5%
Not very important	0%
Not important at all	0%
Don't know	0%
Have you ever participated as a subject in any medical research?	
Yes	41%
No	58%
Have you ever been offered the chance to participate in a medical research study and decided not to participate?	
Yes	24%
No	73%
Don't know	2.4%
General attitude towards medical research involving people described as:	
Very favorable	35%
Somewhat favorable	60%
Somewhat unfavorable	0%
Very unfavorable	0%
Neither favorable nor unfavorable	2.5%
Don't know	2.5%
How much do you think scientists benefit from medical research?	
A great deal	78%
A moderate amount	17%
Only a little	0%
Not at all	0%
Depends	4.8%
How much do your community benefits from medical research?	
A great deal	40%
A moderate amount	40%
Only a little	12%
Not at all	0%
Depends	7%
How much do your family benefits from medical research?	
A great deal	40%
A moderate amount	40%
Only a little	12%
Not at all	0%
Depends	7%
How much do you benefit from medical research?	
A great deal	42.5%
A moderate amount	45%
Only a little	7.5%
Not at all	0%
Depends	5%

Highlighted text indicates category or categories representing majority of the participants

3.1.2 Thematic Analysis

3.1.2.1 Knowledge of Genetics and Genetics Research

Family was a common theme that emerged during discussion prompted by a series of questions (Appendix F) to assess participants' knowledge of genetics. Although most responses could be categorized as uninformed, participants did demonstrate awareness of the association between genetics and familial characteristics. Other main topics addressed during discussion could be divided into the following categories: communication of health information within families, motivation to increase knowledge, sources of genetics information, and extreme views of genetics research.

Family

Numerous participants referenced family members and relationships to family members with medical conditions they are concerned about developing when talking about their meaning of genetics. The following quotes characterize the common sentiment that family history is associated with their understanding of genetics:

You know when you think about genetics to me it's a family tree you're talking values and all of that and when I think of genetics I think of my mother and my grandmother, my sisters, and brothers.

A few participants referred to "good genes" and "bad genes" when talking about the genetic information they received from their family because of medical conditions they had such as hypertension or diabetes. Participants felt "your genes have a lot to do with some of the diseases and conditions you can have." Hypertension, diabetes, cancer, cardiovascular disease, lupus, and mental illness were the conditions most commonly referenced when participants talked about genetic conditions in their families.

Overall, participants are aware and report increasing awareness that genes have a role in disease development. One participant demonstrated the increasing awareness of genetic risk factors with the following comment:

its just like for myself high cholesterol is a genetic factor for me so I have to be doubly careful because of that but I never knew that I was never aware it could be genetic I thought it came from just what you eat but its not its from genetic as well.

Another participant communicated this opinion in the comment:

We've been hearing quite a lot about genes in that a lot of the ailments you weren't aware of are definitely caused by a particular gene you have and that you can do everything in the world rightyou got that gene its going to cause you to have certain things.

Despite an emphasis on the genetic contribution to disease risk most groups involved a discussion of environmental factors and lifestyle behaviors in the development of diseases. The moderator had a written question in the guide to prompt discussion of the roles of lifestyle behaviors and environmental exposures on risk of disease but participants in each group began discussing this topic without being guided by the moderator. Individuals were aware that eating habits and lack of exercise can contribute to an individuals' chance of developing a disease. They also stated that interactions between genes and the environment may affect a person's health. The following three comments from participants illustrate the belief that genes do not act alone to cause disease: "I think genetics play a part, environment plays a part it all gets in there," "sometimes you might have a genetic predisposition but your environmental and your situation factors could maybe predispose you to it more than genetics," and "you have a predisposition, I mean the people that know their family has diabetes and high blood pressure I mean that doesn't mean you are actually going to develop it we have a predisposition to it so if we go out there and eat crazy or not watch we're more likely to develop it."

Although participants did not articulate biologically accurate definitions of the terms genetics, genes, or inheritance their responses alluded to these concepts. Participants had an understanding that genes are passed through families which is reflected in comments such as: “I think of family, I think of relationship to relatives and what they had and what their genes produced in us,” “genes means one bloodstream passed on to the next bloodstream like one generation to the next that is what it means to me through the blood line,” and “a trait definitely a trait and its almost so predetermined if you say inheritance I mean almost passed down from one generation to another and its almost like there is nothing you can do.” Although participants were unable to articulate accurately the intricate aspects of genetics they were able to share examples that demonstrate the role of genetics in health care decisions. One participant stated “I think of prenatal genetics” and went on to share the experience of her first pregnancy which was terminated after a prenatal diagnosis of Down syndrome. Another participant relayed watching a news program about a woman who underwent predictive testing for a genetic predisposition to breast and ovarian cancer. He related the following story:

She decided to get the test done to see if the gene was in her that ran through the rest of the females in her family and it turns out she had two of the genes that cause the breast cancer so the young lady had both her breasts taken off.

Despite awareness of genetic concepts misconceptions were expressed about the more technical aspects of genetics. The following quotes illustrate a basic knowledge about the transmission of genetic material from parents to children through chromosomes however they also reveal a slight misunderstanding about forms of inheritance. The following comment demonstrates an accurate presentation of chromosomes as the units of inheritance because each

individual typically receives 23 chromosomes from their mother and 23 chromosomes from their father. Although the respondent correctly identifies chromosomes as the structures that carry the genetic information (DNA) which is responsible for determining how an individual grows and develops, the participant inaccurately describes recessive inheritance. “You get 23 chromosomes from your dad, you get 23 chromosomes from your mom so they both could have had that recessive gene and it showed up in you and it became dominant in you.” The participant is correct that two individuals who carry one non-working copy of a gene for a recessive condition may be unaware of their gene status because recessive conditions do not cause symptoms for carriers. Genes are inherited in pairs. One copy of a gene pair is donated by the mother and one copy of the gene pair is donated by the father. The participant is incorrect when she states that a gene can become dominant in an individual. It may appear that a gene becomes dominant in an individual if both parents have a recessive gene because in a recessive condition an individual must inherit two non-working copies of a gene, one from each parent, in order to have a condition. If both parents carry one non-working copy of a gene, there is a 1 in 4 or 25% chance with each pregnancy of having a child with the recessive condition. The following comment also demonstrates an incorrect perception that individuals can “make” a recessive gene associated with a recessive condition. “Certain people make a recessive gene and it might show up in their children so that is another reason people do genetic testing to see if I mate with this person what is the likelihood that my child is going to have this problem or don’t have this problem.” Typically, a non-working copy of a gene associated with a recessive condition is passed through generation after generation of a family. A family may only become aware of the presence of a non-working copy of a gene in their family when a member with the non-working copy of the

gene has a child with someone who also has a non-working copy of the gene and their child is affected with the condition.

Communication of Health Information within Families

Communication of health information within African American families was addressed repeatedly in the focus groups during discussion of genetics. This topic emerged at different points during the discussion but the common thread was that traditionally families do not share a lot of health information with each other. A common response was that “we’ve been taught to keep secrets something that is bad we keep that secret it’s pushed in a special place and held there.” Many participants noted this to be true with the older generations, their mothers, fathers, and grandparents but report feeling that this tradition may be changing. This sentiment is reflected in one participant’s statement:

I agree with her about the secretiveness cause I remember when my mother was younger you know be quiet you don’t say this and I always had the tendency to want to know why well you just don’t question older people but I think we’re getting better with not keeping all these silly secrets.

Lack of education, desire to protect others from worrying, fear of appearing weak were put forth as reasons why older generations may have kept secrets about their health.

People also shared the experience of not addressing health concerns until someone was diagnosed with a condition. One participant shared “we didn’t start doing our genetics until my mom got cancer and my aunt died of cancer and then I really started looking.” Another participant validated her experience by stating “there was a time when people were afraid to say the word cancer it was a curse.” Participants also relayed the experience that no one shares this information when you are young and healthy because you don’t think you will get sick. They felt that by addressing the health issues in their families honestly they could potentially start to

take steps to prevent future generations from developing the same conditions. One participant relayed that younger generations were the inspiration for sharing information and learning more about their families' health; "over the last ten years or more I like to know the issues exist in my family and our family simply because of grandchildren." Participants shared their ideas for family health reunions so extended family members can share information and everyone can become more aware of the conditions that may be traveling in their family.

Sources of Genetics Information

When asked to identify where they obtain their information on genetics participants commonly referenced the media including local and national news programs, newspapers, magazines, and the internet. Additionally, they mentioned specific fictional television programs such as CSI and House and other non-fictional television programs on channels like Discovery as sources of information. Participants also reported that their doctors speak to them about genetics. When probed about the information provided to them by their physicians participants responded that they ask about their family history of cancer, diabetes, and stroke during an exam. Participants suggested that although family history is addressed during an initial exam they don't receive follow-up with additional genetic information. One participant articulated this feeling by stating, "most of my doctors they will ask you about your family history but there is never closure...They take it and that's the end of it." The tone and delivery of his comment indicated that he would like his doctors to provide him with an interpretation of his family history and a description of how this information aids in his personal healthcare.

Motivation to Increase Knowledge

Several participants expressed a desire to learn more about genetics. As the moderator guided the conversation to assess participants' understanding of genetics participants requested

she share her knowledge on the topics with them. One participant responded by asking “can you explain genetics?” while another participant said “no one has sat down and told me exactly what it (genetics) means. I want to know what determines whether you have it (a condition) or not, is it your mother or father or is it anybody in your lineage like your cousins or uncles?” Another participant wanted clarification about where genetic information comes from, “so is it coming from DNA or chromosomes or is all of that both the same?” The moderator explained that chromosomes are the structures that carry genetic information and provide the instructions for how the body grows and develops. These instructions are written in the code of DNA. Typically, an individual has 46 chromosomes in every cell of his/her body. These chromosomes can be arranged into 23 pairs because one copy is inherited from the mother and one copy is inherited from the father. The moderator explained that because they receive half their genetic information from their mother and half their genetic information from their father they share genetic information with individuals who are related by blood to their parents such as their grandparents, aunts, uncles, and cousins.

Participants overwhelmingly expressed the belief that a person has to be their own healthcare advocate by researching information on their own in order to interact with their physician and take control of their health. This opinion extended to the topic of genetics with participants believing the focus group was actually a stepping stone in increasing their knowledge of genetics. One participant responded:

I think it is nice to put some things on the table as far as genetics is concerned and prior to today I had only heard DNA testing paternity testing and testing for research against different diseases and things.

The same participant later stated that “I am here so I can get some information and I can learn more about genetics but the more I am finding out lately this is a real deep topic.” Participants felt getting information about genetics into the African American community would be a benefit.

Extreme View of Genetics Research

In order to establish their knowledge of genetic research participants were asked “What comes to mind when you hear the term genetic research?” Participants primarily referred to stem cell research and cloning. When probed about their knowledge of stem cells and stem cell research participants were unable to accurately describe where stem cells originate but they knew it was a controversial topic and could speak about some of the potential uses for stem cells; “I’ve heard about the stem cell controversy” and “like stem cell research being able to grow what they are saying to repair the damage to your heart through stem cell research.” They cited recent news stories on TV and in print media as the sources of their information on stem cell research. Participants had a negative view of cloning. Many misconceptions were expressed on the topics of stem cell research and cloning. Most of the comments about cloning were tied to expressions of distrust which will be discussed in a following section however overall they conveyed apprehension and fear of cloning. The following comments illustrate the opinions expressed toward cloning:

I think if it’s not misused I think if it helps us to have a better quality of life to give us a longer healthier life I think its good. If you go off to freaky stuff cloning and all that stuff that might be different” and “before you know it they are going to be trying to clone themselves to try and make a perfect being.

Participants were very distressed about the potential of cloned meat being sold at the supermarket. There were a number of examples across the discussions of participants referring to buying cloned meat without being told it was cloned. Despite this fear some participants

remained hopeful that individuals would abstain from cloning; “Cloning could be an issue and I guess that’s not a good thing if somebody gets your DNA matter and starts cloning I guess that wouldn’t be a good thing but who really has plans for that.”

Table 3 Responses to Questions Assessing Knowledge of Genetics and Genetics Research Grouped by Content Area

<p>Family Relationships Health Conditions Interaction between lifestyle/environmental and genetic factors Limited understanding</p>
<p>Communication of Health Information within Families Secrecy Unworried well</p>
<p>Sources of Information News media Television Internet Physicians</p>
<p>Motivation to Increase Knowledge Inquisitive Personal advocate</p>
<p>Extreme View of Genetics Research Stem cell research Cloning</p>

3.1.2.2 Opinions on Genetics Research

Participants held mixed opinions on research. Although they felt there are benefits to research, their positive feelings were balanced by expressions of concern. Overall, responses expressed during the discussion about genetics research could be sorted into one or more of four categories: distrust, optimism, social issues, and ethical concerns.

Distrust

Issues of distrust were not restricted to research but were also expressed in general discussion about the medical system. For some participants the term genetic research elicited the response of “guinea pig”. When this topic was explored it was revealed that a guinea pig is a symbol of experimentation, “because you are testing things on people or animals and they have an idea what is going to happen so it is a trial its something they are trying out on pigs, mice whatever and they are guinea pigs because it is experimental that is what it means to me” and “guinea pig comes to mind and the fact that they want to use humans in their research is scary to me because back to the penicillin I am always afraid of that and the fact that they didn’t tell a lot of stuff they don’t tell you in the research and that’s a scary thought.”

This last quote is also illustrative of a lot of responses expressing concern that researchers are not honest. A number of participants exhibited distrust of the research community by communicating fears that participants are not fully informed when they agree to participate in research. The following quotes also illustrate the belief that research is taking place that people are unaware of: “we’ll never know because as far as the research is concerned they tell you what they want you to know,”

I think there is a lot that is going on that is totally out of our control we don’t even know how long the genetics testing and things have been going on and what is taking place and how it has affected us how it affects how we act today or whether or not we are being tested on and don’t even know it because when I think back I remember how the African American race was always the ones they did the tests on before they did the animals,

and

historically they have not been upfront with that I mean they will tell you oh no this will not hurt you I mean and this is not this DNA testing I am talking about testing across the board and the next thing you know five years later you are wondering why you come up with this disease or that disease.

Many participants provided historical references as support for their feelings of distrust toward the research community. The following comments are representative of the historical references reported by participants:

You know the syphilis experiment the other forms of African American exploitation when it comes down to certain things like that and you may not get such a warm reception from that segment because there is always going to be a certain distrust because of dirt done in the past and the thing I am upset about goes back to when they gave these black men syphilis that bothers me to this day and we didn't learn that for years. That bothers me to this day and I am very, very skeptical about medicine.

These sentiments were raised across the four focus groups and demonstrate the common perception that history may repeat itself and therefore individuals must proceed with caution in research.

Optimism

Although a high level of distrust was communicated, participants also relayed feelings of optimism toward the potential benefits of genetic research. They spoke about research being a double edged sword. It has both advantages and disadvantages. While some individuals focused on the disadvantages others chose to recognize the potential for research to improve health. Some of the advantages that were expressed included preventive measures, treatments, and cures. Participants also described the difficulty in diagnosing some conditions such as lupus and felt if there was a genetic test based on genetic research this could help with the diagnostic process. Some individuals stated they wanted to know what conditions their family was at risk to develop because they didn't know much about their family history so they would be interested in tests that could provide that information. The following remarks illustrate the optimistic view of research held by several participants: "research in order to discover which genes are related to

things like diabetes and heart disease and cancer I think are very important” and “I think it’s advantageous as far as preventative measures as far as finding cures for different things diseases and such that there has not been a cure to.”

Social Issues

A number of social issues emerged during the discussion of research. The issues focused on access to benefits obtained through research and skepticism regarding the prescription of medication. While participants acknowledged research may lead to better treatments for many health conditions they did not feel they would benefit as a community. Many participants expressed the feeling that “a cure or break-through will go to the privileged people first who can afford the medicines or the very good health insurance first before it will go to the underprivileged people who can’t afford it.” Many participants viewed the African American community as the individuals who would benefit last from research. One participant expressed this belief through the comment:

when any new drug or anything comes out on the market it always trickled down starts up there with the people that got money and then trickles down to the rest of us....even though research might start with the poorer parts of society because they do give benefits and people will say I can’t afford it but if I get into this research study its going to be free for me and that’s the only way I am going to be able to benefit from it so the research will be done on the lower few but once it gets perfected then the higher ones will benefit from what we have done and that’s how our society has always been built on the backs of others and then these people up here benefit from what everybody else has done.

Another participant more explicitly stated this perception in the following comment:

my thinking is most of the drug companies aren’t out here making or using the data to develop drugs specifically for the black community they are making it for the population that will buy it....they have to get their money out of it in the first 20 years

before it gets down to where it becomes generic enough for the black community.

An unexpected topic of conversation that recurred in the focus groups was a discussion of prescription medications. Many participants had a negative view of medication and the number of prescriptions they receive from their physicians. Some participants stated they did not fill or take the prescriptions their doctors gave them for conditions such as high cholesterol. One participant stated:

I am supposed to have high cholesterol so I think they do this to all of us as we get older. I got the Zocor I brought it home so I said let me change I think I was eating too many cookies. I go back to the doctors he said what is your secret I never told you but I never took the Zocor.

Participants felt there was a tendency by doctors to “just prescribe prescription after prescription after prescription after drug after drug.” Many participants felt that “doctors will tell you any old thing” and “just give (you) medication” and the onus is on the individual to “question the doctors and to educate yourself and take what you need and discard all the garbage that you don’t need and extra medicines just because your doctor needs to pay his mortgage and car loans.” There was the perception that physicians profit from writing prescriptions. Some participants commented on the medical industry being a business and felt negatively about researchers profiting financially off of their participation in research.

Ethical Concerns

Ethical concerns including selective breeding and over-stepping the boundary of religious beliefs emerged during the discussions. Participants acknowledged that intentions may be altruistic in the beginning but expressed concern that increasing genetic knowledge may lead in

harmful directions. The following comment summarizes the feelings expressed by individuals who were concerned about the use of genetic information:

I think genetic testing yeah for some things like she said to find out if you got heart disease but then again its like how far is this going to go? Once they do it do people get to pick what their baby is going to look like?

Another participant communicated the concern about the unforeseen consequences of genetic research and genetic testing shared by a number of individuals with the following comment:

I know they want to alter in a positive way but...there are a host of ethical issues in terms of altering something you would think is so innate as genetic make-up something that is almost god given should we even step over that line even if we could it just could open a door to a number of other studies that may not be positive.

One participant suggested that the objective of curing disease could be inconsistent with individuals' religious beliefs.

You said that you would hope that one of the something like eliminating or curing all diseases. I think from a standpoint of somebody with strong religious beliefs that is not god's will and from the religious standpoint you are probably going to get opposition cause I guarantee there is a lot of pastors and ministers of the churches that will not support a program of that particular nature simply because their understanding of the bible their knowledge of the bible ain't so.

Some individuals articulated finding a balance between religion and new developments. They recognized the need to reconcile religious beliefs with new technology but felt that better treatments or cures should not be discarded solely on tradition.

Table 4 Opinions on Genetics Research Grouped by Content Area

<p>Distrust</p> <ul style="list-style-type: none"> Experimental Lack of honesty Past Abuses
<p>Optimism</p> <ul style="list-style-type: none"> Improve health Prevention Diagnostic
<p>Social Issues</p> <ul style="list-style-type: none"> Access to new technology Over prescription of medication
<p>Ethical Concerns</p> <ul style="list-style-type: none"> Selective breeding Religion Pandora's box

3.1.2.3 Willingness to Participate in Biobank

After a description of a specific type of genetic research that would collect DNA to study the genetic and environmental contributors to disease (called a biobank in the moderator's guide), participants were asked to express their opinions on this type of research. Although participants initiated their comments by asking follow-up questions, responses could be classified into four categories including optimism, distrust, and factors influencing participation.

Optimism

Participants expressed favorable views of a biobank as a means of learning how to identify individuals at an increased risk for developing certain health conditions. Additionally, they articulated positive views of the potential to determine why one family member developed a condition and another family member did not based on information about the interaction between genetic and environmental factors obtained through a biobank. They saw preventive strategies such as avoiding an environmental trigger as an advantage of the research conducted using a

biobank. Respondents suggested that community participation may help provide valuable information about the causes of premature morbidity and mortality from diseases that affect many of their families so that they can improve the health of future generations.

Distrust

Despite recognition of advantages participants were hesitant to positively endorse participation in a biobank. Many of their concerns stemmed from distrust about donating their DNA. They were afraid researchers would not be straightforward and could use their genetic information to perform studies they didn't know about. One participant characterized this feeling by stating "it seems like they have your blood and they can go in there anytime they want who is to say they don't mix it with some molecules and do whatever and make a whole other person that is what I think." Participants feared that researchers would not have the best intentions which is reflected by the comment:

what comes to mind again is an invasion and when you talk about a bank where you can withdraw DNA and you can do this research on it, it sort of takes me back to a time when people separated other people because of their genetics and that kind of disturbs me a bit.

A number of participants were concerned about confidentiality and access to genetic information. Despite a discussion about de-identifying the information participants felt that someone would know they had participated and have access to their genetic information; "the first thing I would ask okay with this information is my name attached to it and I know it is going to be even though they will say its going to be completely private and confidential." Participants conveyed fears that individuals could access the DNA stored in a biobank and use it to implicate people in crimes. One participant expressed this concern by stating "I am discouraged I wouldn't advise my son to (do) DNA testing I don't trust the government take my son's DNA

and put it on a murder weapon” while another participant thought if he donated DNA someone else might “go into this database or bank and get some of this DNA and kill up a few folks slash that DNA all over the crime scene here and I am in New York walking through Central Park ain’t got nothing to do with it but all of a sudden the man hunt is out for me.” Distrust of the government was a recurring topic of discussion and when participants were asked about what type of organization they would be willing to donate DNA to they were more receptive to a local agency with a reputation they could investigate personally. It was apparent from the discussions that a biobank sponsored by the government would not be received well.

When participants were specifically asked about the creation of a biobank for African Americans to study diseases that disproportionately affect African Americans, statements reflected themes of distrust and inclusion. Participants were wary about the intentions of researchers if a biobank was solely for African Americans. They questioned “for what why are we separated I need to know more about the study why is it just African Americans?” Participants wanted to know why race would be considered and felt that separation by race may actually lead people not to participate in a biobank. Recognizing that a biobank specifically for African Americans may limit participation one respondent suggested:

Maybe the study should not only signal out black race but race period any kind of race doing the study doing the same type of research instead of just blacks per se because you can obviously see there are some people do have mixed emotions about the studies and research.

Many participants expressed the feeling that a biobank should be for all races because the conditions being studied effect people from all races. This sentiment was reflected in the following comment:

I think it should be everybody because we have different skin color but we all bleed the same inside...lupus is a black disease but you

also have white people and other races that have lupus so for me I wouldn't just stick it one race I want everybody to be helped for whatever.

Additionally the issue of the definition of African American was raised. People suggested that although they may be African American their ancestors may have been from many different racial or ethnic backgrounds. This feeling is characterized by the following comments: “that is what African American is a mixture of everybody”, “we have a little bit of everything in us”, and “at this point in time and even back in our ancestors time there was not pure African American so we don't have a pure African American heritage at this point there is all races mixed within our blood.” Although there was concern about a biobank specifically for African Americans some individuals thought African Americans should be open to a biobank because it could provide valuable information to help improve the health of their community. This feeling was demonstrated in the following comment “I think as African Americans we need to have a database too just so we can be included and perhaps whatever good is going to come out of it is going to do us some good also.”

Factors Influencing Participation

Given the issues of distrust and concerns about confidentiality and privacy, participants were asked if they would participate in a biobank and if there were factors that would encourage their participation. They were very interested in learning more about who would be conducting the study, what they would be studying, what they would be expected to do, and how long the study would take place before they would participate in a biobank. The most common reason participants cited for participation in a study collecting genetic material is to provide future generations of their family with information. They reported being more likely to participate in a study that was investigating the genetic and environmental causes of a condition present in their

family. Participants overwhelmingly reported wanting to know the results of studies performed on their DNA. Participants expressed a sense of entitlement that if they donated their DNA then they should receive their results because it is their genetic information. One participant summarized this view by stating “it is different when you say DNA because basically your DNA that is you that is you, that’s your kids, your mom, your grandma and your future and they can find out more about you than you know.” Another participant stated “If I would participate in the study I would like to know the information about me so if I participated in a study like that yes I want to know I mean tell me what is going on with my DNA what did you all find out.” Participants also stated that “the more specific they would be the more comfortable you would feel on signing off on it because the more information you have the more comfortable you are with participating.”

One of the recurring issues was the issue of risks to the participant. Participants report that being informed of the risks of their participation in a biobank would be very important in their decision to participate. Many individuals reported aversion to participation in research that was invasive. The most common definition of invasive involved taking medications. Participants also reported concern about who would be conducting the research. They felt it was very important to be able to research an investigator on their own to determine if they had a reliable reputation. Participants identified access to healthcare and medications and financial compensation as incentives that may encourage their participation in a biobank.

Table 5 Responses to Willingness to Participate in a Biobank Grouped by Content Area

Optimism Prevention
Distrust Lack of honesty Confidentiality Access Government Separation by Race
Factors Influencing Participation Honesty Information for family Invasiveness Institution

4.0 DISCUSSION

Many common issues and perceptions emerged during the focus group discussions. Although, the results of focus groups cannot be generalized to a broader population the results begin to characterize the perceptions of African Americans toward the collection of DNA for genetics research. Findings suggest participants are acutely aware of potential negative consequences of donating genetic material however, cautious optimism was expressed when discussing benefits of research. Additionally, the results suggest that researchers must actively work to build trust with potential research participants to increase willingness to participate. Participants provided researchers with suggestions to increase participation. The findings also suggest a strong association of the term genetics with family history, a limited understanding of the biological aspects of genetics, and a sensationalized view of genetics research. These last three issues may be addressed through a genetics education outreach program.

Participants in this study clearly demonstrated hesitancy to donate DNA for use in genetics research. Participants were not completely adverse to the idea of donating their genetic material but they were very suspicious about how their genetic material would be used and who would have access to the material. This suspicion was heightened when they were asked about participating in a study collecting DNA solely from African American participants. Many of the concerns expressed by participants appeared to stem from deeply rooted feelings of distrust toward the medical and research communities. Numerous studies, some of which were detailed

in the background of this paper, have been conducted to examine the relationship between race and trust in healthcare and research. Many of the reasons for the distrust observed among African American individuals put forth by these studies including the legacy of the Tuskegee Syphilis study, concern about intentional deception of research participants, and concern about confidentiality and privacy, arose during our focus groups. However, the primary reason identified by participants in the focus groups appeared to be the belief that African American individuals have been exploited and deceived by researchers in the medical field for many years.

Responses were particularly skeptical when the idea of a study solely for African Americans was addressed. Participants expressed concern about people being separated by race if research is investigating conditions such as lupus or diabetes which affect people from all racial and ethnic backgrounds. Additionally, participants inquired how individuals who are biracial or may be a combination of many racial/ethnic backgrounds but identified themselves as African American would be categorized in this type of study. Findings suggest researchers would have to explicitly explain a research design that was only collecting DNA from African Americans. Results also suggest individuals may be more likely to participate when the study was collecting DNA from individuals from different racial and ethnic backgrounds.

Findings suggest researchers interested in collecting DNA from African American individuals to use in genetics research would need to engage in an open, honest, and ongoing discussion about the purpose of their project, the protection against research abuses, the risks to participants, the benefits to participants, the protection of privacy, and access to individual research results. An open dialogue that allowed participants to question and engage researchers in discussion prior to making a decision about participation may assuage fears of being abused and misinformed. Additionally, researchers may encourage participation by providing

assurances for protection against deception and exploitation. By supplying participants with guarantees and avenues for investigating that these guarantees are being carried out, researchers may foster a trusting relationship. Participants repeatedly endorsed the need for individuals to be proactive and educate themselves so they could make more informed healthcare decisions. It appeared that if researchers gave participants the tools to feel like they could make a knowledgeable decision about participating in a study they would be more likely to participate. Developing educational materials on current research issues and recruitment materials in appropriate language may be strategies to encourage participation.

Despite concerns about donating DNA for genetics studies, participants indicated that research is important. This sentiment was reflected in their responses to the pre-discussion questionnaire with approximately 83% of participants responding that medical research is very important and during the focus group discussion. They were encouraged when discussing the possibility of more effective preventive or treatment strategies being developed through genetics research especially for conditions that affected their families. Findings suggest that researchers may want to specifically highlight the potential uses and benefits for genetics research when approaching African Americans about donating genetic material. Addressing how the collection of DNA would be used to benefit the study of genetic and environmental contributors to disease may help ease concerns about selective breeding and cloning. These issues were seen as negative consequences of genetic research and it was apparent that participants felt researchers may engage in these activities so by preemptively discussing these activities and the true intentions of research it may alleviate concern.

A potential barrier to African American participation in genetics research may be the notion that they will not benefit from discoveries made from their genetic material. Although

42% of participants believed they benefit a great deal from research this is lower than the perceived benefit to the scientists conducting research. Seventy-eight % of participants responded that scientists benefit a great deal from medical research while only 40% of participants believed their community benefits a great deal from research. This discrepancy suggests that researchers may want to determine strategies for approaching the community about participation in research that incorporate demonstrating a direct impact on the health of the community. Research is often about developing generalizable knowledge and researchers may want to focus on this aspect of research and communicate how generalizable knowledge can contribute to improved health for the overall community. The sentiment that their community does not benefit as much as other populations was also reflected in comments made during discussion about unequal access to medication and medical care. Participants were aware that if they donated their DNA they may be unable to benefit from new technologies because they do not have enough money or adequate health insurance to cover such services. Researchers may provide the incentive of access to medication or other treatments developed through research using their DNA to encourage participation.

Although respondents believed participants in research studies should be compensated for their participation, they were wary of money as an incentive. Their concern was tied to the belief that researchers would not offer money if there was not a risk associated with participation. The ethical concerns regarding provision of incentives for research participation including monetary compensation has been reviewed in many articles. [35,36,37] Although monetary incentives are often used to facilitate recruitment and motivate participation among individuals who might not otherwise participate in the research it has been suggested that payment may be objected to because it can be an undue inducement or influence. [35] Money may interfere with a person's

ability to discern the risks and benefits associated with participation in a study, may lead an individual to misrepresent themselves to gain entry into the study, risk their informed consent and well being, and risk the integrity of the study. [35] Singer and Bossarte suggest there are ethical principles for protecting the rights of research participants including those put forth by the Helsinki Declaration and the Belmont Report which are not necessarily violated by offering monetary incentives for research participation. [36] They also suggested that an individual will participate in research if they think the benefit which may include monetary compensation is greater than the cost. Singer and Bossarte recognize that each individual has a different perception of the risks and benefits associated with a particular study. The differences in perceived benefits and costs may impact the extent to which the incentive factors into their decision to participate. Singer and Bossarte suggest that research examining participant responses to hypothetical vignettes demonstrates that subjects do not exchange higher pay for greater risks. [36] This conclusion may be used to justify the use of monetary compensation because it supports the notion that a participant will not disregard the potential harm associated with participation in a study solely for money. Singer and Bossarte also recommend that researchers should provide justification for the use of money as an incentive. Some factors that should be considered in the justification include data quality, respondent burden, study designs requiring continued participation or the participation of special subgroups, improved coverage of specialized respondents, and rare groups or minority populations [36] Based on the comments during the focus groups, it appears that potential participants would appreciate justification for the incentive that is being offered. If researchers are offering financial compensation to participants donating genetic material they should clearly state why that is the incentive so

participants can accurately assess their perception of the risks and benefits associated with participation.

Education to enhance potential participants' knowledge of genetics and genetics research is desired in the African American community. Participants clearly expressed an interest in learning more about the biological aspects of genetics and how conditions are transmitted through families. It was apparent they are encountering these topics more frequently and they want to have the resources to make sense of the information they are absorbing. Education programs focusing on genetics may help dispel some of the extreme views of genetics research that were expressed during the groups. Participants cited various media outlets as a main source of information on genetics and this may contribute to their fears about issues such as cloning and selective breeding. It is important not to discredit their fears about cloning and selective breeding because these are common issues that accompany genetic testing and genetics research however education by genetics professionals may introduce individuals to the more scientifically sound objectives of genetic study.

In addition, education programs focused on genetics may help African American families share health information. Many participants communicated a tradition of secrecy around health issues and the need to start sharing more information with each other. Participants felt speaking about conditions that run in their family in an honest manner will help prevent future generations from having the same conditions. Although programs such as the U.S. Surgeon General's Family History Initiative have been created to help individuals recognize the importance of family history, individuals in public health genetics could create education programs that actually explain the concepts of genetics and why it is important to have a picture of your family's health. It is apparent people are becoming more aware of the conditions that run in their family but they

want to know how to interpret their family history and understand why they should be concerned, for example, about their mother's diabetes. Education programs focused on genetics may also aid in recruitment for studies collecting DNA for the investigation of the genetic and environmental contributors to disease because it would increase awareness of the importance of this type of research.

Interestingly, skepticism regarding prescription medication emerged during discussion. Participants felt doctors have a tendency to prescribe medication unnecessarily. Participants communicated not filling prescriptions because they thought they could effectively modify their behavior or did not think they required medication. The issue of medication adherence has been investigated in a variety of settings and for medication associated with a variety of health conditions. Medication adherence constitutes a range of behaviors both intentional and unintentional that can lead to either under-use or over-use of medications. These behaviors include not filling prescriptions, skipping doses, splitting pills, and stopping a medication sooner than the physician intended. [38] Medication adherence is a phenomenon affected by patient-related, therapy-related, condition-related, and socioeconomic factors. [39] Examples of patient-related factors are patient knowledge, attitudes, beliefs, perceptions of severity of disease and expectations from treatment while examples of therapy-related factors include frequency of dosing and complexity of medication regime. [39] Shenolikar et al conducted a study examining medication adherence among different races of Medicaid insured patients with Type-II Diabetes newly starting oral anti-diabetic medication. They found that medication adherence was significantly higher for whites as compared to African Americans. Medication adherence was 12% lower for African Americans than whites when adjusted for other covariates. [39] A racial difference in medication adherence was also observed by Bosworth et al in their study of males

with hypertension in the Veteran's study to Improve the Control of Hypertension. They found that African Americans had higher odds of being non-adherent with their medication. Bosworth et al suggested that findings indicate health care providers should assess patients' medication beliefs before prescribing antihypertensive medications because participants in this study had minimal financial barriers to medical care which has been suggested as a barrier to medication adherence in previous studies.

Another study by Wroth et al found that 21.6% of respondents in their survey of individuals in the rural south who have seen physician in the past year reported that they had delayed or did not fill a prescription during a one year period. Delaying or not filling prescriptions was more common among respondents who were under age 65, African American, reported income less than \$25,000, and reported fair or poor health. Additionally, medication non-adherence was more common among patients who reported transportation issues, a lack of confidence in their doctor's ability to help them, a lack of satisfaction with the concern shown to them by their physicians, and a lack of satisfaction with how welcome and comfortable they are made to feel by office staff. [38] Wroth et al suggested that medication adherence may be improved by resolving patient dissatisfaction and lack of confidence in their physicians as well as addressing transportation barriers. [38] The findings of these studies present interesting topics for investigation among our study population. Based on our discussions it is apparent participants engage in medication non-adherence and some of the reasons researchers have identified for such behavior including distrust of physicians were articulate by our respondents. An example of distrust of physicians included participants' perception that financial gain is one reason physicians prescribe medication. The topic of medication adherence would be an interesting area to explore given observed racial and ethnic health disparities in mortality and

morbidity related to common diseases such as hypertension. Unequal access to medication and/or medical treatment plays a role in health disparities but researchers may want to explore the perceptions of African Americans toward prescriptions to determine if these perceptions play a role in health disparities. Research has suggested that there is a racial difference in medication adherence however further research should be conducted to accurately identify the factors that contribute to the observed difference.

Limitations

A limitation of this research may be that only one investigator read and analyzed transcripts. No other investigators confirmed codes or checked for consistency in coding therefore the coding may be subjective as it is one individual's interpretation. Another limitation may be that 26 of the 43 participants were members of the Minority Research Recruitment Database. These individuals have already participated in research and are interested in further participation. It may be assumed that this would lead to a bias in positive feelings toward research or suggest more knowledge about research topics. Numerous negative issues emerged suggesting that these issues should be studied further with respondents whose opinion toward research is unknown to determine if they are representative of the community at large. Conversely, the participation of individuals who are interested in research may be considered a strength of the study because they are the target audience for potential research studies and it is important to hear what would factor into their decision to participate. Another limitation of the study may be that it was conducted with individuals with the HBFP. These individuals are actively engaged in activities that address the importance of family history and behavior modification in disease risk so they may be more informed and more motivated to learn more about topics related to these issues. Despite being a limitation for generalizing the data, the

participation of members from the HBFP may be considered a strength for internal use because it characterizes the opinions of the individuals we would be partnering with on research endeavors. Another limitation of the research is that pre-discussion questionnaires were anonymous which did not permit comparative analysis of responses to questionnaires to comments during discussion. Additionally, participants did not sufficiently identify themselves so it was not possible to analyze the responses of individuals who are enrolled in the Minority Research Recruitment database compared to those not in the database.

5.0 CONCLUSION

The individuals who participated in these focus groups provided valuable information to researchers investigating a topic for which limited information is available in the literature. This research contributes to the growing studies investigating the opinions of African Americans' toward genetics and genetics research by confirming the existence of previously identified issues including: concerns about discrimination, governmental access to genetic information, and consequences of genetic testing. Additionally, it confirms the view that the potential to develop preventive strategies is a primary benefit of genetics research. Participants' honest discourse provides researchers with direction in their effort to better characterize the willingness of African Americans to donate DNA for genetics research. Based on the issues that emerged during discussion, researchers may develop a questionnaire that specifically examines the requirements necessary for an individual to donate DNA for genetic study to help understand on a larger scale the motivations and barriers for participation in a study of genes and environment.

This project was initiated because it has been proposed that the Healthy Black Family Project create a study collecting DNA from African American participants for genetics research. The Healthy Black Family Project has established a unique relationship with the African American community in the East End of Pittsburgh through activities that benefit participants. Community members truly appreciate and enjoy the activities offered by the HBFP and feel fortunate that this project has come into their lives. It is apparent through their comments during

the focus groups that they trust the HBFP and value its presence in their community. It is important to maintain this level of trust if the project is going to achieve its stated goal of reducing the incidence and prevalence of diabetes and hypertension in the African American community. One avenue for maintaining trust is engaging members in discussion about potential research involving their community. This is why researchers felt it was critical to gauge public opinion about the donation for DNA in genetics research before presenting it as a study affiliated with the HBFP.

Researchers need to be aware that individuals are not freely going to contribute their DNA to a research study without feeling their best interests are protected. Participants intimated several barriers to their participation in a biobank which can be sorted into the following categories: suspicion, inability to benefit from new technologies, invasiveness, and government involvement. The topic of DNA donation is very sensitive and raised many red flags for focus group participants so in an effort to protect the trust that has been established between the African American community and the HBFP we need to ensure that any research is broached in a culturally appropriate and sensitive manner. By addressing the subject areas that were highlighted as barriers to participation, researchers may more successfully engage the HBFP community in research collecting DNA.

The suspicion expressed by participants underscored feelings of distrust. Participants were very concerned about how and by whom their genetic material would be used. Their wariness appeared to be tied to feelings that researchers have misled research participants in the past by not informing them of the risks associated with research or the true intention of the research. A strategy for addressing the barrier of suspicion would be to engage potential research participants in open and ongoing dialogue about a study. Thoroughly reviewing the

credentials of the researchers, the requirements for participation, the risks associated with participation, and the goal of the study may create a level of transparency that reduces the feeling researchers will deceive participants. Developing and communicating safeguards and assurances that are aimed at protecting research participants' rights and privacy may also alleviate feelings of potential exploitation by researchers. Providing participants with materials that address the objectives of research in appropriate language may render the content more digestible and help reduce feelings of separation between researchers and potential participants. Ongoing dialogue including newsletters updating participants on the progress of the biobank and studies associated with the biobank may communicate respect for participants and reassure them that legitimate research is taking place and their contribution is not being abused. Additionally, education on the topics of genetics and genetics research may address the barrier of suspicion because participants that understand the terminology and the goals of research may feel better equipped to ask questions and know if researchers are answering honestly. An emphasis on the positive aspects of genetic study during education outreach may help balance the skeptical views of research.

The feeling that African Americans will not benefit from new technologies is associated with social issues including unequal access to medical care and differential treatment by the medical community. A strategy for addressing the issue of inability to benefit from new technologies may be to design a research protocol that aims to provide participants with preventive strategies that are developed with the contribution of their DNA. Access to medication developed through research is often offered as an incentive to participants however the negative feelings associated with prescription medication articulated by our participants suggests this should not be the primary incentive offered by researchers. Participants indicated

they would be more likely to participate if their family members would benefit from their participation so creating a means for family members to gain useful information would most likely encourage participation. Recognizing that research developments may take a very long time to materialize and that research is often aimed at contributing to generalizable knowledge instead of providing benefit to an individual more immediate incentives such as access to medical services may be another strategy for encouraging participation.

Invasiveness was repeatedly mentioned as a limiting factor in participants' willingness to participate in research. Most participants described invasive research as taking medications as part of a research protocol. Participants reported aversion to medication because side effects are unknown and there may be risks to their future health. Participants were wary of taking medication in general and this was particularly apparent during the discussion about research. Some participants even communicated that they would be willing to give DNA over taking medication. It would be important to define invasive more clearly in order to determine if the use of needles to withdraw blood would be considered invasive. A strategy for addressing the barrier of invasiveness would be to arrive at a clear definition of invasive and then address participants concerns through education and the consent process. It would be important to communicate to participants that they would not be expected to take any "experimental" medications as part of their participation in a biobank.

The barrier to participation in a biobank presented by governmental involvement was very obvious. It may have been the moderator's description of the biobank and use of the term government that solicited these responses however the responses emphasized that participation in a biobank would be limited if there was a clear connection to the government. Participants communicated an intense distrust of the government and were worried that government

participation may lead to lack of privacy, unjust profiteering, and abuse of research participants. One strategy for addressing such a concern would be to clearly state the institution that would be conducting the research. If there is any government involvement including provision of monetary support, participants should be educated about the role of the government as a funding source and the protections against governmental abuse of research participants.

Table 6 Barriers to Participation and Strategies to Address Barriers

Barrier	Strategy
Suspicion	Ongoing Dialogue Provision of assurances and safeguards
Inability to Benefit from Research	Incentives Discussion of objective of research to generate generalizable knowledge
Invasiveness	Exploration of community definition of invasive through targeted research
Government Involvement	Sponsorship by Non-governmental Organization

If and when a protocol is established, I recommend considering the issues addressed in these focus groups and consulting potential participants to make sure the study design and recruitment strategies would welcome participation. It would be unfortunate for HBFP participants to view a study collecting DNA as a violation of trust and sully the positive impact the project has had in the community when the intentions of such a study are to increase our knowledge of the genetic and environmental contributors to disease to ultimately create better strategies to achieve the goals of the HBFP.

APPENDIX A: IRB APPROVAL LETTER



University of Pittsburgh
Institutional Review Board

Exempt and Expedited Reviews

University of Pittsburgh FWA: 00006790
University of Pittsburgh Medical Center: FWA 00006735
Children's Hospital of Pittsburgh: FWA 00000600

3500 Fifth Avenue
Suite 100
Pittsburgh, PA 15213
Phone: 412.383.1480
Fax: 412.383.1508

TO: Stephen Thomas, Ph.D.

FROM: Sue R. Beers, Ph.D., Vice Chair 

DATE: November 16, 2006

PROTOCOL: Assessing the Perceptions of African Americans to Scientific Research

IRB Number: 0610019

The above-referenced protocol has been reviewed by the University of Pittsburgh Institutional Review Board. Based on the information provided in the IRB protocol, this project meets all the necessary criteria for an exemption, and is hereby designated as "exempt" under section 45 CFR 46.101(b)(2).

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

- If any modifications are made to this project, please submit an 'exempt modification' form to the IRB.
- Please advise the IRB when your project has been completed so that it may be officially terminated in the IRB database.
- This research study may be audited by the University of Pittsburgh Research Conduct and Compliance Office.

Approval Date: November 16, 2006

SRB:kh

APPENDIX B: RECRUITMENT SCRIPT

Hello, my name is Leah Slattery and I work with the Healthy Black Family Project. I am calling to invite you to participate in a research study that I am conducting at the Kingsley. This study is interested in learning more about the opinions of African Americans toward genetic research. I would like to hear your opinions on genetic research involving human participants so I can communicate these beliefs to individuals interested in recruiting community members for research projects. If you are willing to participate we will ask that you attend a focus group that will be conducted at the Kingsley. A focus group is a group of people brought together to share their opinions on a specific topic. During this focus group, you will be asked to share your thoughts and opinions on questions posed to the group by a discussion leader. There will also be a brief survey at the start of the meeting. This focus group will take place at the Kingsley and should last approximately 2 hours. This study is open to members of the Healthy Black Family Project therefore there is a chance you may know someone else attending the meeting. Although there are no foreseeable risks associated with this project, you may experience discomfort sharing your opinion in front of other participants. Additionally, we will not be recording identifying information however there may be a breach in confidentiality because the sessions will be audio-recorded. We will do everything to ensure these tapes are kept confidential in a locked location and destroyed upon completion of the study but we would like to advise you of this risk. Your participation in this study is voluntary and you may withdraw at any time. Each participant will be given a \$25 gift card to Giant Eagle as a token of our appreciation. Refreshments will also be provided during the meeting. Would you be interested in participating in a focus group? If you have any questions regarding this project please call me, Leah Slattery, at 412-383-9822.

APPENDIX C: CONFIRMATION LETTER

Dear Ms. X,

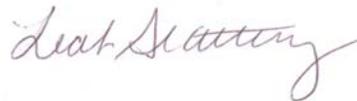
The Center for Minority Health at the University of Pittsburgh would like to thank you for agreeing to participate in the focus group on Genetic Testing, Screening, and Research. We value your opinion and we are very excited you will be joining us for our small group discussion about topics related to research, genetic testing, and genetic screening. This letter serves as a confirmation for your scheduled focus group. Please contact Katie Hoffman or Leah Slattery if you will not be able to attend your meeting or have any questions.

Date: Wednesday January 17th
Time: 6 pm
Location: The Kingsley Association
6435 Frankstown Avenue
Pittsburgh, PA 15206
Contacts: Katie Hoffman and Leah Slattery
412-383-9822

Sincerely,



Katie Hoffman, BS
Graduate Student
Center for Minority Health
412-383-9822



Leah Slattery, BS
Graduate Student
Center for Minority Health
412-383-9822

APPENDIX D: RECRUITMENT FLYER

**A HEALTHY BLACK FAMILY PROJECT
RESEARCH STUDY**



**Participate in a Focus Group on
Genetics Research**

We value your opinion.

*Brought to you by:
Center for Minority Health at the Graduate School of Public
Health
University of Pittsburgh*

Share your opinions on topics related to genetics research
in small focus groups at the Kingsley.

Participate in the focus group and receive a \$25 gift
card to Giant Eagle and refreshments.

**Call Katie or Leah at 412-383-9822 for more
information or to schedule a focus group.**

**Must be 18 & over and willing to commit approximately 2
hours of your time.**

Principal Investigator: Stephen B. Thomas, PhD

APPENDIX E: PRE-DISCUSSION QUESTIONNAIRE

We thank you for participating in this focus group. This survey 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. The survey should take approximately 10 minutes. We would like to thank you in advance for your willingness to participate in this study.

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

Section 2: Opinions on Research

7) 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

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

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

9) 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

10) 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

11) 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

12) 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

13) 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

14) 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

15) 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

15a) If you answered yes, what are your expectations? **(Please circle all that apply)**

I expect to receive information about *all* of the latest research studies.

I expect to receive information about studies that I am eligible for.

I expect to be rewarded for participating in research (paid, free health care, etc.)

I expect to get the best health care available.

Other: _____

15b) If you answered no, what are your primary reasons? **(Please circle all that apply)**

I am not interested in participating in research.

I am not interested in anything tied to my family/my genetics.

I do not want to be part of a database.

I do not want to disclose my contact information.

Other: _____

APPENDIX F: MODERATOR'S GUIDE

I. **Introduction** (10 minutes)

Good afternoon/evening and welcome to our session. Thank you for taking the time to join our discussion on genetic research. My name is Leah Slattery and I am with the Healthy Black Family Project from the Center for Minority Health at the University of Pittsburgh. Assisting me is Katie Hoffman

You have been invited because you are a member of the Healthy Black Family Project and your opinions on genetic research are important to us. Our research team is trying to understand how African Americans perceive genetic research. We are also interesting in learning if community members would be willing to participate in genetic research. We would like to hear your opinions in order to ensure that researchers approaching you about participating in their studies know how to be respectful of your beliefs and work within the context of your community. Clearly, we need your input to make future genetic research in Pittsburgh successful. We will ask you a number of questions and we need your honest thoughts and ideas. Please feel free to share your point of view even if it is different from what others have said. There are no right or wrong answers, only different points of view.

Now, let me share some ground rules. We want to make sure that everyone feels comfortable expressing his or her own opinion so we ask that you are respectful of everyone by listening to one another and waiting until the person speaking has finished before you begin. We also ask that you try not to have a side conversation with your neighbor during the discussion because everything said is important. What you are saying to your neighbor may be something that everyone could comment on and would provide us with useful information. We have placed cards on the table in front of you to help us remember your names during the focus group.

As you've probably noticed, we have a microphone on the table. We will be tape recording as well as video taping our discussion so that we don't miss any of your comments. To assure you of your confidentiality, we will only be using first names today and not use any names in our final reports.

The group discussion will last about 2 hours, so feel free to enjoy your refreshments as we begin. We will have a 10-minute break and restrooms are located near the gym on the first floor. You should have already completed the brief survey.

Icebreaker: Please share your favorite Healthy Black Family Project Activity. If not yet involved, please share the activity or activities you are most excited/interested in participating in as a participant in the Healthy Black Family Project.

II. Knowledge of Genetics

A. We want to get an idea about what you know about genetics.

Question 1: What comes to mind when you hear the word genetics?

Probe: Where have you heard this word mentioned? What have you heard X say about genetics?

Question 2: What comes to mind when you hear the word genes?

Probe: How are genes related to your overall health?

Probe: What role does your lifestyle or environment have on your health?

Probe: How does genetic information interact with lifestyle or environment in the development of disease?

Question 3: What comes to mind where you hear the word inheritance?

Probe: How does the health of other family members impact your health?

Probe: Who informs your opinions about what conditions you are at risk of developing?

B. Tell us about where you get your information about genetics....

Probe: Has a dr. talked to you about your family health history being a risk factor for developing a certain disease?

Probe: Who do you trust to share accurate health information with you?

Probe: How do you like to learn new information about your health or factors affecting your health?

II. Opinions on genetic research

A. After our discussion on what genetics means to you, we would like to discuss your opinions on genetic research.

Question 4: What comes to mind when you hear the term genetic research?

Probe: What health conditions do you think are being studied in genetics research?

Probe: What are some advantages and disadvantages to this type of research?

Probe: How do you feel about this type of research?

Question 5: Under what circumstances would you be interested in participating in genetics research?

If interested probe: what makes you interested in participating?

If uninterested probe: what are you not interested in participating?

Probe: Would the organization or individual who is conducting the research play a role in your decision to participate in the research?

Example: research institute, university, insurance company, medical center

Probe: Would you be more likely to participate if you or your family member has the condition being studied?

III. Willingness to Participate in Biobank

Now we want to talk about your thoughts on a specific type of genetic study in which researchers have access to DNA samples similar to how we have access to money from the bank. Individuals like you and I would make a deposit of genetic material to an organization similar to a bank. Our genetic material would stay in the bank until researchers withdrew the sample like we withdraw money. The genetic samples could then be used in research. In addition to collecting our genetic material, these organizations may collect our family health information, diet and exercise habits and medical records in order to study how genetics and lifestyle factors contribute to common diseases.

Questions 6: Please tell us what you think about this type of study?

Probe: Do you have any concerns about this type of study?

Probe: What are some of the advantages and/or disadvantages of this type of study?

Question 7: Would you consider participating in a study that collected and stored a sample of your genetic material?

Probe: What comes to mind when we say genetic material?

Probe: Would the type of material collected matter to you? (i.e. blood or cheek swab)

Question 8: What information would you require to consider participating?

Probe: Would you want to know how your genetic material was going to be used?

Probe: Would you like to know who is studying your genetic material and for what purpose?

Probe: How would you feel if your genetic material was studied outside of Pittsburgh or in Europe?

Probe: Would you want a time limit to how long your material could be used in research?

Probe: Should a researcher ask permission each time they withdraw your sample or are you comfortable with giving consent for it to be used for any purpose at the time of your donation?

Question 9: Please tell us what would motivate you to participate in this type of study

Probe: Would you expect results such as drug discoveries or predisposition information to be shared with you?

Question 10: If you could create the ideal circumstances for your participation in a biobank, what would they be?

Question 11: How do you think your community would react to a biobank specifically created for African Americans?

Probe: What do you see as the advantages or disadvantages to a biobank specifically for genetic samples from African Americans?

Probe: Do you think that people would be more likely to participate if they thought their community would benefit?

That concludes our discussion. Thank you for participating. We greatly appreciate the time and energy you have given to this discussion. It was a pleasure listening to your thoughts and opinions.

The last thing we ask is that you please sign for your incentive. Are there any questions? Thanks again. Have a nice evening.

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