Laying the Foundation in Genetic Medicine: Understanding Why African Americans and Hispanic/Latinos are Underrepresented in Genetic Testing and in Genetic Research.

Karey M. Sutton

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Doris T. Zallen, Chair
James Bohland
Ann Laberge
Edward J. Smith
Lee L. Zwanziger

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LAYING THE FOUNDATION IN GENETIC MEDICINCE: UNDERSTANDING WHY AFRICAN AMERICANS AND HISPANIC/LATINOS ARE UNDERREPRESENTED IN GENETIC TESTING AND IN GENETIC RESEARCH

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ABSTRACT

Genetic medicine is a field progressing at a rapid rate. Even with all the new advancements, there are still minority groups who are less visible when it comes to the uptake of some forms of genetic medicine. African Americans and Hispanic/Latinos have been shown to experience certain conditions more than Caucasians. In the 2008 African American profile for North Carolina, African Americans had higher age-adjusted mortality rates for heart disease, cancer, stroke, diabetes, kidney disease, and chronic liver disease (North Carolina State Center for Health Statistics, 2010). Hispanics/Latinos in North Carolina had higher incidence levels of cancer, HIV and kidney disease as opposed to other races (North Carolina State Center for Health Statistics (b), 2010). Despite these poor health outcomes, African Americans and Hispanic/Latinos are less visible when it comes to participating in medical genetics research opportunities and also in genetic testing (Shavers, Lynch, & Burmeister, 2002). Lack of participation among African-American individuals can attributed to mistrust, due to past misuse in clinical research settings such as the Tuskegee Syphilis Study and a variety of other factors (i.e. access to care, socioeconomic level) (Smith, Thomas, Williams, & Ayers, 1999). Among Hispanic/Latinos, concerns exist about immigration and governmental bias, as well as language barriers and cultural differences between the researcher and participant (Gelman, 2010). These cultural histories have become particularly salient as the field of genomics becomes increasingly reliant on initiatives to increase minority participation in research efforts.

In order to explore beyond what previous quantitative studies have found, ethnographic research methods such as focus groups and semi-structured interviews were utilized to understand why members of these two heritage groups are underrepresented. The initial phase of my study was completing two separate focus groups, one with only African Americans and one with only Hispanic/Latinos. The information shared in the focus groups sessions revealed potential areas of exploration for the individual semi-structured interviews. Thus, I conducted 65 semi-structured interviews with African American individuals and 25 semi-structured interviews the other with only Hispanic/Latino individuals. The analysis of the interviews revealed that factors such as age, religion, education level, and finances play key roles in decisions about participating in genetic testing or genetic research. Understanding the views and concerns of African Americans and Hispanic/Latinos could not only help identify potential barriers to genomics research and testing, but could also provide effective means of overcoming them. As an outcome of my study I argued for the need for community input in setting the research agendas. Engaging the community in the design and implementation of genetics research can be a useful method of bridging the trust between minority communities and the research institution. Additionally, community-academic partnerships can be beneficial in addressing the barriers of genomics research and testing by providing useful collaborations in defining perspectives on race and genetics. Moreover, the information gained from community collaborations can be used to develop policy recommendations relating to genomics research (Jones & Wells, 2007). This study was not intended as advocacy for genetic testing, but to lay the foundation for understanding the health care decisions of African Americans and Hispanic/Latinos in this new era of genetic medicine.

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DEDICIATION

I would like to dedicate this dissertation to my late grandparents: James O. Hayes Sr., Mattie Hayes, Grady Sutton Sr., and Prevella Sutton. To my grandparents, it is your shoulders I stand on to reach my goals in life. I promise to make each one of you proud. I love you!

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CHAPTER I
Introduction

Breast cancer has ravaged and ransacked the lives of many of those close to me. Thirteen women on my mother's side have been diagnosed with breast cancer of the left breast. Being faced with this reality, the option of genetic testing has become all too familiar to me. My mother is fearful of her future. Seeing her own mother (my grandmother) and sister (my aunt) affected with this disease, she has also worried about what may happen to me. My mother sought out information concerning genetic testing for the BRCA1 or BRCA2 gene involved in breast cancer, but she has never gotten tested. An educated, financially stable, proactive medical consumer refused genetic testing. Why? Trying to answer that question forms the foundation of this work.

My mother's story is not unique. It is actually the experience that many African Americans share when faced with the decision of not only genetic testing, but also utilizing health care services. African Americans and Hispanic/Latinos are greatly affected by health disparities. According to the Centers for Disease Control and Prevention, Office of Minority Health and Health Disparities (OMHD), African Americans have the highest mortality rate of any racial and ethnic group for all cancers. The high mortality rate is attributed to late detection of disease due to various reasons. For example, in 2005, African American women were 10% less likely to be diagnosed with breast cancer, but they were 34% more likely to die from breast cancer as compared to Caucasian women. Also according to the OMHD, African American men were 30% more likely to die from heart disease as compared to Caucasians. The rate of infant mortality for African Americans is 2.5 times that the rate of infant mortality for whites; Hispanic/Latinos are 2.6 times more likely to have diabetes than whites; the incidence of prostate cancer of African American males is triple that the incidence of prostate cancer among Asian

males; African Americans and Hispanics are much more likely to have HIV/AIDS, diabetes, hepatitis, and tuberculosis than are white Americans (Centers for Disease Control and Prevention, 2006a). Hispanic/Latinos are the most likely to be uninsured of all racial groups, 33% compared to 14 % of Caucasians, and 20% of African Americans(Reyes, Van de Putte, Falcon, & Levy, 2004). Hispanic/Latinos and African Americans are less likely to receive preventive care and many receive care only when an illness has progressed to late stages. These two groups are less likely to have mammograms, pap tests, and blood cholesterol tests (Cornelius, Smith, & Simpson, 2002; Vargas, Chen, Rodriguez, Rizzo, & Ortega, 2010). Hispanic/Latinos, who are unregistered, often slip through the cracks and receive no health care. Many are not covered by the health care system. Clearly being uninsured is a barrier to getting primary and preventative care. Furthermore, 25% of the nations' 44 million citizens are uninsured Hispanic/Latinos (Aguirre-Molina & Molina, 2003). Aguirre-Molina, a professor of public health at Columbia University, attributes this statistic to employers not offering insurance coverage and to those who are not United States citizens being unable to receive coverage. By 2025 the Hispanic/Latino population of the United States is predicted to increase from 31 million to 59 million. More research is needed into why there is such a disparity concerning the uptake of preventative health services (Centers for Disease Control and Prevention, 2006a). It is important to gather information about race and ethnicity in health in order to understand these racial and ethnic differences in health disparities and to take measures to eliminate them (Burchard, et al., 2003)

One can recognize that there are racial and ethnic differences in health without assuming that there are biologically distinct racial or ethnic groups, since various social and environmental factors, such as income, education, housing, culture, diet, alcohol or drug use, geography, and

discrimination can explain most of the inequalities in health among these groups (Sankar P. , et al., 2004). The fact that African Americans and Hispanic/Latinos typically have less income and less access to health care than whites can account for much of the observed variation in health between these two groups. Racial discrimination, bias, and stigma also have a significant influence on the health of African Americans.

Not all racial and ethnic differences in health are due to social and environmental factors, however, since research has shown there are many genetic differences among racial and ethnic groups that affect health. These differences may only involve a small percentage of the total genetic makeup, but they can still have a major impact. One mutated gene can be the difference between disease or disability and health. For example, African Americans are more likely to carry the gene that causes sickle cell disease than Caucasians; Ashkenazi Jews are more likely to carry a gene for Tay Sachs disease, and Caucasians, in general, are more likely to carry a gene for cystic fibrosis (American College of Obstretics and Gynecology, 2002; Mazornet, 2006; Sickle Cell Disease Association of America, 2006)

In spite of the health disparities that currently exist, there was a time when African Americans were advocates for a mass genetic screening program for sickle cell anemia. Sickle cell disease is an inherited disorder which affects those most commonly of African ancestry. In addition to those of African ancestry, those people from regions of South and Central America, the Caribbean, the Mediterranean, and East India can also be affected by sickle cell disease.

Sickle cell is an inherited condition. Two genes for the sickle hemoglobin must be inherited from one's parents in order to have the disease. A person who receives a gene for sickle cell disease from one parent and a normal gene from the other has a condition called sickle cell trait. Sickle cell trait produces no symptoms or problems for most people. A couple in which

both partners are carriers (have sickle cell trait) has one chance in four that their child will be normal, one chance in four that the child will have sickle cell disease, and one chance in two that the child will have sickle cell trait. This probability exists for each pregnancy. Having the Sickle Cell trait helps prevent against malaria (Sickle Cell Disease Association of America, 2006).

Sickle cell disease occurs due to the presence of an altered shape of hemoglobin present in red blood cells. Hemoglobin picks up oxygen in the lungs and delivers it to the peripheral tissues to maintain the viability of cells. Red blood cells, all with the altered hemoglobin, form a sickled shape when in conditions of low oxygen, that is, after the red blood cells have exchanged oxygen with the tissues. The irregular shaped cells create blockages in the circulatory system that prevent the normal flow of blood to the tissues. Due to the blockages, an individual with sickle cell may experience many complications. They can experience severe bouts of pain, anemia as the body tries to remove abnormally shaped cells (hence sickle cell anemia), enlargement of the spleen, or damage to some of the body's other vital organs (Scott, 1970).

During the late 1960s to the early 1970s awareness about sickle cell anemia was coming to the forefront. In *The Troubled Dream of Genetic Medicine,* authors Keith Wailoo and Stephen Pemberton (2006), historians from Rutgers University stated that the sickle cell program emerged on the heels of the Tuskegee Syphilis Study and also the civil rights movement. It was the talk of churches, barbershops, and community centers. The sickle cell anemia (SCA) screening program of the early 1970s was one of the first federally mandated acts to implement mass mandatory genetic testing for African Americans. Though public health agencies, physicians, African American activists, and federal and state governments were well intentioned, the program's results did not meet expectations.

The political environment played an important role in the sickle cell gene-testing program. The late 1960's and early 1970's coincided with the peak of the civil rights movement, wider voter registration among blacks, and increased activism by the African American Church. Sickle cell disease, which was characterized as the "neglected disease", became intertwined in congressional politics. White Americans were embracing the disease and acknowledging the pain of its sufferers (African Americans) as an act symbolic of redemption for years of social discrimination. In the wake of legislative debates about health care insurance and cuts in biomedical research funding, President Richard Nixon was compelled to acknowledge the "neglected disease," by signing into law the National Sickle Cell Anemia Control Act in 1972 (Rutkow & Lipton, 1974). With this new legislation came funds for medical research, community clinics, and genetic counseling programs. However, with this national attention also came controversy.

The Sickle Cell Gene Testing Program had its fair share of problems. African Americans were misled about the results of carrier testing. Often those who were diagnosed with the sickle cell trait (the carriers) were told they were afflicted with sickle cell disease. Because it was characterized as the "black disease" since it only affected African Americans, researchers and clinicians were faced with a dilemma. Medical researchers and clinicians were struggling with how to avoid stigmatizing an entire population because of their predisposition to such a crippling disease. African Americans feared this sort of stigmatization and the potential negative outcomes from it. The Sickle cell testing made national news and it was discriminatory. Wailoo and Pemberton referred to the words of Linus Pauling, chemist and Nobel Laureate, who discovered the molecular basis of sickled hemoglobin, "There should be a tattoo on the forehead of every young person, a symbol showing possession of the sickle gene or whatever similar gene …that

he has [been] found to possess a single allele"(p.131). The suggestion of Dr. Pauling was inflammatory during a time when racial politics were at the forefront of the national agenda.

The overwhelming fear of a disease that researchers knew little about fueled rash reactions. Reacting to misinformation, governmental regulations were put in place to protect those with sickle cell disease and the trait, but in turn, those regulations were insensitive. For example, in the state of North Carolina before African Americans could get married they first had to be tested for the sickle cell gene (Rutkow and Lipton, 1974). The United States Air Force barred healthy African Americans with the sickle cell trait from becoming pilots because they were afraid of a possible sickle crisis that might occur during flight. Employers across the United States screened for the sickle cell gene as a means to exclude individuals from employment. Many were not educated about the difference between the sickle cell trait and the sickle cell disease. Also, many thought that sickle cell was a communicable disease. In the state of New York doctors quarantined individuals with sickle cell. Those who were diagnosed with the sickle cell trait thought that they were sick, when, in fact, they were not. Along with the lack of education and legislation, sickle cell testing facilities were not equipped with enough trained human resources and appropriate technologies. The initial test used for the sickle cell screening was called the sickledex. The sickledex was incapable of distinguishing between those who possessed the sickle cell trait and the sickle cell disease. There were few trained professionals who could analyze the test results and also ensure the confidentiality of the test results (Wailoo & Pemberton, 2006; Rutkow & Lipton, 1974).

The haste in implementing the laws caused legislators to ignore the possibility of stigmatizing an entire population. Many African Americans who had the sickle cell trait lost their jobs, insurance, and were even banned from school. Employers imposed unfair testing

polices upon their employees, an action which prompted uproar in the community (Rothenberg, Fuller, Rothstein, Duster, & Ellis, 1997). Unfortunately, since sickle cell anemia was labeled a "black disease" many were unaware that Sickle Cell affects people other than African Americans. In actuality it also affects Spanish-speaking people from South and Central America and Cuba. One in every 100 Hispanics has the sickle cell trait and one in 1000 Hispanics has the sickle cell disease (National Human Genome Research Institute, 2010; Wailoo & Pemberton, 2006). Sickle Cell disease incidence is increasing among Hispanics, but they are unaware of the risks. Physicians are consistent with paying attention to the risk factors of African Americans, but are less vigilant with the Hispanic population and Sickle Cell.

After the Sickle Cell Gene Testing Program, there have been more advanced genetic testing technologies were developed. Medical genetic research covers a number of different areas. It includes research that yields more information about individual genes, tests to identify mutations in genes, and treatments that can be individualized according to one's genetic make-up. The Human Genome Project, which lasted from 1990 until 2003, was an international research effort to not only identify genes present in human genetic material (the "genome"), but to sequence all present. The findings from the Human Genome Project have aided in the progression of genetic medicine. Currently there have been genetic tests developed for over 1700 diseases and 1400 of these are used in clinical settings (Centers for Disease Control and Prevention, 2009). Despite the advancement of genetic medicine, African American and Hispanic/Latinos have lower participation rates in genetic testing when compared to whites. Did the shortcomings from the Sickle Cell Gene Testing program of the 1970s influence the African American community's view of genetic testing today?

Purpose of the Study

The purpose of this study is to understand the views of African Americans and Hispanic/Latinos concerning genetic testing and genetic research. I examine how members of these two minority groups obtain their genetic information, and what they do with any genetic information received.

The research explored two main questions:

1. Why are African Americans and Hispanic/Latinos underrepresented in genetic testing?
2. What are the underlying reasons why African Americans and Hispanic/Latinos are underrepresented in research in the area of medical genetics?

Examining these questions can lead to 1) an increased understanding of minority medical consumers and the medical institution as they look to improve their relationship with each other; and 2) to an increased understanding of the apprehensiveness towards genetic testing that exists within these two minority groups. Furthermore, a heightened awareness of what influences medical decision-making can be translated into policy applications in healthcare for both the African American and Hispanic/Latino communities.

I have no position on genetic testing or research participation that I am trying to impose. However, without an understanding of the reasons that African Americans and Hispanic/Latinos tend to shun genetic testing and medical-genetics research, our knowledge regarding health-care disparities will be at a disadvantage. By revealing these reasons, better informed health care policies can be created that are sensitive to the needs and preferences of these two minority groups.

Organization of the Dissertation

In chapter # 2, I provide background by describing the major forms of genetic testing and their uses. I also discuss and provide definitions of prominent terms such as race and ethnic

categories used throughout the dissertation. In Chapter 3, I review the relevant literature regarding of African American and Hispanic/Latino experiences with genetic testing. Gaps in this literature are also noted. Additionally, I review the literature concerning potential areas that may shape minority views concerning genetic testing and research such as trust and other cultural determinants. Chapter 4 presents my methodological grounding. Why use a qualitative approach? What are the advantages of qualitative versus quantitative methods? This chapter also describes my research design, descriptions of the recruitment process, interviewing format and procedures. The Grounded Theory approach is introduced as part of the theoretical framework used to analyze the interviews. Chapter 5 discusses the themes that were gathered from the semi-structured interviews. I found that financial concerns, religion, mistrust, and lack of knowledge were the main factors influencing African Americans' participation in genetic testing and genetic research. The Hispanic/Latino population's main categories to emerge from the interviews were religion, financial concerns, mistrust, lack of knowledge and cultural competency. Lastly in Chapter 6, I recommend policy applications in the area of genetic testing and minority communities. I also provide strategies for policies for engaging minority communities in medical research.

CHAPTER II

Review of Relevant Terms

Many terms are used throughout the dissertation that need clarification and explanation. In this chapter, I will explain the various types of genetic tests that I referred to in my semi-structured interviews. Also being cognizant that I am using terms such as "African American" and "Hispanic/Latino," I define here how I am using these racial/ethnic categories to avoid confusion. Lastly, I will provide a brief discussion on the troubling nature of using racial proxies in research, a dilemma I confronted throughout my research.

What is Genetic Testing?

Genes are hereditary units that are made up of a chemical substance known as deoxyribonucleic acid (DNA). Genes are organized on structures called chromosomes. Each person has twenty-three pairs of chromosomes so there are forty-six chromosomes in total. The Human Genome project estimates that a human possesses somewhere in the range of 20,000-25,000 genes. Genetic testing involves examining an individual's DNA sample to determine the status of the chromosome number or the status of particular genes, and identify the presence of abnormalities. Genetic tests can be performed on hair, blood, skin, and amniotic fluid cells. Chromosome abnormalities can occur when there is an absence or addition of a chromosome (Centers for Disease Control and Prevention, 2009). Also abnormalities can be structural where a chromosome is missing a piece, or a part may be inverted, or parts of it may be duplicated. Conditions related to chromosomal abnormalities include Down Syndrome and Turner Syndrome. Down Syndrome is a numerical chromosomal abnormality where there are three copies of chromosome 21 instead of two. Turner syndrome occurs when a female is born with only one sex chromosome, an X (Yoon, et al., 1996).

There are many types of genetic tests conducted at different stages of the life cycle and for different purposes. Available types of genetic testing include: prenatal testing (including pre-implantation testing), newborn screening, carrier testing, pre-symptomatic testing, and susceptibility testing. According to the National Human Genome Research Institute of the National Institutes of Health (NIH), there are over 1700 genetic tests currently available and more are being developed (Centers for Disease Control and Prevention, 2009; Genetic Testing, 2010) .

Prenatal Testing

Prenatal genetic testing is testing of the early embryo or fetus prior to birth. An embryo is defined as the developmental stage up to 8 weeks after fertilization and a fetus is defined as the developmental stage lasting from 8 weeks until birth. Prenatal testing is often recommended to women who have conceived above the age of thirty-five. This arises from the fact that girls are born with all the eggs they will ever have. So if a woman is 35 years old then so are her eggs. Researchers believe that as the eggs age, there is more of a possibility that chromosome errors can occur in the genetic material over time leading to a higher risk of having a child with a chromosomal abnormality (Chromosomal abnormalities, 2010). For example, the likelihood of a woman under 30 to have a child with Down Syndrome is 1/1000, but risk increases to 1/400 to women who become pregnant at age 35 (Yoon, et al., 1996).

Testing may also be recommended to those with an increased risk of disorders in individual genes due to family history or following abnormal test results examining the mother's blood. A woman may choose from many genetic tests at different stages of her pregnancy.

Chorionic villus sampling (CVS) is a prenatal procedure that can be performed 10- 13 weeks of gestation. A pregnant woman may elect to have CVS to identify chromosomal abnormalities or inherited single-gene disorders in the embryo or fetus. Chorionic villi cells are

rapidly growing cells on the exterior of the chorionic membrane, the outermost membrane that surrounds the developing embryo or fetus. The test involves removing chorionic villi cells from the placenta either transcervically, in which a catheter is guided by ultrasound through the cervical canal, or transabdominally, in which a needle is guided by ultrasound through the abdomen to the chorion. The cells that are collected are examined in various ways and results are usually ready one to two weeks after the procedure depending on the test selected. There is some risk for a woman when undergoing CVS testing. The risk for miscarriage due to the test procedures is 0.5%−1.0% (Olney, Moore, Khoury, Erickson, Edmonds, & Botto, 1995). CVS can be covered by insurance. The cost of the procedure ranges from $1200 to $1800 and the results of the chromosome testing are 99% accurate (Read & Donnai, 2007).

Amniocentesis is a procedure performed during the 14th through 20th week of pregnancy. This testing procedure involves placing a needle through the mother's abdominal wall, through the chorion, and into the amniotic sac. Within the sac is amniotic fluid. This fluid, mostly fetal urine and washings from the lungs, surrounds the unborn fetus during pregnancy and serves many purposes, such as aiding in bone growth, protection from blunt impact, and maintaining a constant temperature for the fetus. After the procedure, cell culture takes about two weeks to provide enough cells for analysis. Amniocentesis can be covered by insurance especially for women over 35, but the test can range in cost from $1200 to $1800. There is a 0.25%−0.50% risk of miscarriage due to the test itself, around the same risk for CVS testing (Olney, Moore, Khoury, Erickson, Edmonds, & Botto, 1995; Read & Donnai, 2007)

There are newer methods of prenatal genetic testing that are still not widely used. One such method is pre-implantation genetic diagnosis (PGD) testing. This technique indentifies genetic defects in embryos created through in vitro fertilization before implantation. A single cell

is chosen from an eight-cell embryo to be tested for the genetic disorder of interest. If the single cell from the embryo is found free of the genetic defect, the remaining embryo is implanted into the woman's uterus. PGD is a highly specialized form of testing and can cost from $10,000 to $15,000 (Harper & Bui, 2002; Eisenberg & Wapner, 2002).

Ultrasound imaging is an established non-invasive method for fetal testing. It is usually done around 18 to 20 weeks to closely look at the fetal anatomy. More sophisticated scans can give thirty to forty images of the fetal structure and identify characteristics, which allow for sex detection. A fetal anomaly scan, which is actually different from other scans, can pick up structural anomalies, which can lead to further investigations by amniocentesis. Imaging can also detect signs of spina bifida, congenital heart conditions, and kidney malformations. There is little to no risk for ultrasound imaging. The cost of is $700–$1200 (American College of Obstetrics and Gynecology, 2007; Read & Donnai, 2007).

Prenatal testing raises ethical concerns–for example, the question of what a mother does with information she may view as unfavorable concerning her embryo or fetus? Undesirable results cause a mother or couple to explore options that she or they may have not considered. Concerns can lead to contemplation of abortion, giving a child up for adoption, or even the choice not to have children in the future.

Newborn Screening

Under state laws, when children are born in a hospital in the United States they are screened for certain genetic diseases. Screening is meant to catch diseases that can be treated to reduce harmful symptoms. The American College of Medical Genetics recommends that newborns be screened for 29 conditions. By 2006, two-thirds of newborns were screened for at least twenty conditions (Read & Donnai, 2007; American College of Obstetrics and Gynecology, 2007). Each state has different regulations regarding the diseases for which newborns are

screened. All states order that the newborn be screened for phenylketonuria (PKU), which if left untreated can cause severe mental retardation, and for congenital hypothyroidism, a disorder of the thyroid which decreases the production of thyroid hormones, and can lead to mental disability or abnormal body growth (National Newborn Screening and Genetics Resource Center). In addition, Virginia screens newborns for over 45 other conditions including fatty acid disorders carnitine uptake defect, trifunctional protein deficiency, and hemoglobin disorders such as sickle cell anemia and thalassemia (Virginia Department of Health, 2010).

The doctors collect the blood sample by pricking the heel of the infant in order to get a few drops of blood. Results of the tests can take anywhere from a few days to a few weeks. With the results from newborn screening, doctors treat the infants, if needed, which can save lives. For instance, if trifunctional protein deficiency were detected, doctors would provide a low protein diet and supplements (Read and Donnai, p.288, 2007). In the case of PKU, a strict diet is required that is low in phenylalanine. Phenylalanine is found in milk, eggs, and other common foods (North Carolina State Laboratory Public Health, 2010).

Newborn screening varies in cost from state to state. Virginia charges $53 for its screening services; whereas the state of North Carolina charges $19 and Georgia bills $40 for these services. The cost of the tests is set by the state budget and also reflects the number of test required. If a mother cannot pay the fees for the newborn screening, there are programs in place to help cover the expense (National Newborn Screening and Genetics Resource Center; Virginia Department of Health, 2010; North Carolina State Laboratory Public Health, 2010).

Carrier Testing

Everyone has two copies of each of their genes, one copy from each parent. A dominant disorder is a disorder in which you only need one mutant copy of the gene for the disease to appear. A recessive disorder is a disorder in which in order for the genetic disorder to manifest

itself, a person needs two copies of the flawed gene. A carrier of a genetic disorder is an individual who has one flawed gene and one normal gene. Having one normal gene in the pair is enough to prevent the disease from developing. However, if two people who are both carriers for the same genetic disorder have a baby, there is a 25 percent chance that at any pregnancy a child will be born with the recessive disorder. This probability applies each time a couple conceives (Sickle Cell Disease Association of America, 2006; Wailoo & Pemberton, 2006). Carrier testing may be done to inform couples that they carry a recessive gene that could cause certain inherited diseases such as cystic fibrosis, sickle cell disease, or Tay Sachs in their children if their partner is also a carrier. Carrier tests are done on blood samples, and can also easily be obtained from other tissues such as lightly scraping the mouth lining (Zallen, 1997).Genetic testing for carrier status is usually done if there is a family history of a particular disorder. Children are not normally tested for carrier status unless there is a direct medical benefit from knowing the test results. The cost of carrier testing is sometimes covered by insurance, but the out-of-pocket expenses can be from $300 to $1000. Different ethnic groups may be more likely to have different mutations and tests may not search out all mutations, just all currently known mutations. Carrier testing raises the issue of how does one share carrier status information with partners and others?

Presymptomatic Genetic Testing

Presymptomatic genetic testing is done for late-onset genetic disorders--disorders that occur later on in a person's life--before symptoms appear. The most prominent disorder of these types is Huntington disease, which affects the brain cells and can occur in the fourth and fifth decade of life. Huntington disease causes lack of muscle control, loss of memory, and confusion or disorientation. Caused by a single dominant mutant gene, one only needs one copy of the flawed gene to develop the health disorder in the future. There is no cure for this genetic

disorder and no known way of stopping the disease from becoming worse. Other such dominant gene disorders include neurofibromatosis, which affects the growth of nerve cells and causes multiple tumors that can be disfiguring and cancerous; and retinitis pigmentosa, which affects the cells of the retina leading to blindness (Zallen, 1997; Norrgard, 2008). The cost of presymptomatic genetic testing ranges from $500 to $5000. Presymptomatic testing for diseases such as Huntington's disease follows a protocol concerning the dissemination of results. Extensive pre-test counseling is used in this form of testing because the results can cause psychological distress, stigmatization, and possible discrimination (Norrgard, 2008).

Susceptibility Testing

Susceptibility gene tests provide information as to the elevated risk for disease that an individual patient may have if he or she possesses a mutant form of a particular gene. The diseases for which there are now susceptibility tests include breast/ovarian cancer, colon cancer, and Alzheimer's disease, among others. In the case of breast cancer, current testing is done to see if the individual has the mutation in either the BRCA1 or BRCA2 gene. If an individual has such a mutation there is approximately a 70% percent chance she will develop breast cancer and a 60−65% chance she will develop ovarian cancer in her lifetime depending on the mutation. Because there is not a preventive treatment available for breast or ovarian cancer women often take measures to screen for cancer. Increased personal surveillance methods are ways of detecting the cancer early if present (Armstrong, Weber, Ubel, Guerra, & Schwartz, 2002). Methods include mammograms and clinical breast exams for breast cancer. For ovarian cancer a woman may elect to have blood tests, transvaginal ultrasounds, and antigen testing. More drastic measures include undergoing surgery to remove the tissues that may be at risk. A woman may choose to remove breasts or ovaries before the actual development of the cancers. In the case of detection of the colon cancer gene, a person may elect to remove parts of the colon before the

cancer manifests itself. The cancer susceptibility genes associated with colon cancer are MSH6, PMS2, MLH1, and MSH2 (Vogelstein & Kinzler, 2004). According to Zallen (1997) for approximately one in two hundred men and women with the flawed gene MSH2, the chance of getting colon cancer is 80 percent.

Researchers have found four mutations of the gene associated with Alzheimer's disease. Three of those genes−located on chromosomes 21, 14, and 9−are linked to early-onset Alzheimer's, which occurs in the late 40s and early 50s. The fourth mutation is APOE-e4, associated with the development of late-onset Alzheimer's, the common form of the disease. However, having a copy of APOE-e4 does not mean one will develop Alzheimer's, but the risk is increased. Having two copies of APOE-e4 increases the risk even more. For Alzheimer's testing, fifty-five percent of those born with one copy (e4) have no signs of Alzheimer's at age eighty (Kane & Kane, 2009). Susceptibility testing can be very costly to the patient. It can cost up to $5000 in some areas.

When there is no form of treatment available, genetic testing reveals uncertain implications. For example susceptibility testing for cancers such as breast, colon, and ovarian identifies the risk of a person developing the specific cancer over time, but does not provide definitive answers of whether a person will develop these disorders. This debate leaves medical consumers faced with the dilemma as to what to do with the genetic information? Should there be early intervention such as mastectomies in the case of breast cancer or colectomies for colon cancer?

Race and Ethnicity Terminology

The terminology used to classify the United States public by race and ethnicity has changed over the years to be more consistent with current language and also as a result of the emerging changes in the population. In 1790 the census had three racial groups, Whites, Blacks, and Civilized Indians. During the 1800s and 1900s the census racial groups were Whites, Blacks, and Other Coloreds. The "other" was added to the colored group to include Mexicans, Japanese, and other immigration groups. The categories of concern for my research are "African American" and "Hispanic or Latino". In 2000, The Office of Management and Budget (OMB) defined the race Black or African American as "A person having origins in the black racial groups of Africa." Terms such as "Haitian" or "Negro" can be used in addition to "Black" or "African American." Additionally, OMB defined Hispanic or Latino as "A person of Cuban, Mexican, Puerto Rican, South or Central American and other Spanish culture or origin, regardless of race. The term "Spanish Origin" can be used in addition to Hispanic or Latino (Atrash & Hunter, 2006)

Under the revised definitions, a person could describe him or herself designating more than one racial category. As part of the 2010 Census, African Americans were defined as self identified black people born in the United States. Many government agencies are troubled on how to draft a definition of race that is as inclusive as possible. For the purposes of my research, I am using part of the definition from the 2010 Census Department. Under the African American designation, I will be using self-identified African Americans who have origins in any of the black racial groups of Africa.

The definition of Hispanic and Latino is also confusing. Hispanic and Latino Americans are Americans with origins in Hispanic countries of Latin America or in Spain. Some members of the community prefer to be referred to as Hispanic and others as Latino (Atrash & Hunter,

2006). There are differences between the terms Hispanic or Latino, and within each group, exists distinct subgroups. Latino is a term that applies to all ethnic groups with Spanish or Hispanic origin ancestors. This term is used primarily for cultural identification.

The term Hispanic was first used during the Richard Nixon administration. As evident with the term African American, Hispanic was a troubling term to define for the government as well. Initially, Hispanic people were referred as "Spanish-speaking Americans", "Spanish Americans", and "Spanish-surnamed Americans" (Grieco & Cassidy, 2001). As you can see, these terms are inaccurate and culturally insensitive. The terms Hispanic and Latino are distinct terms that are not identical. Hispanic is derived from the Latin word for Spain, which refers to cultures who speak Spanish (Spain and much of Latin America). If you were to think about the terms in this way, Brazilians are Latinos but not Hispanic because they speak Portuguese and not Spanish. Neither term refers to races. A person who is of Latino or Hispanic origin can be any race.

It is important to recognize that there are intra-ethnic differences within each minority population. Hispanic is a general term created by the U.S. Census Bureau to identify people of Spanish origin or descent, and includes Mexican or Mexican American; Puerto Rican; Cuban/ Cuban American; Central or South American. It is a heterogeneous group. Some people only speak Spanish and some are bilingual with both Spanish and English.

The definitions provided for race and ethnicity are fluid and ever changing. Hispanics coming from the Dominican Republic view themselves as different from Hispanics who come from Puerto Rico. Similarly, the term African American has different meanings. Some in the black community use "African American" to mean that the individual's parents are from Africa, reserving "Afro-American" for individuals of color who have been in the United States for

generations. Being aware of these subsets and their differing histories will remove the temptation of making generalized statements concerning an entire population group.

Race: Biological vs. Social Category

Throughout this research I have been faced with the internal dilemma of how I might be reifying the concepts of race and ethnicity in medicine and society. In the last five decades, researchers have made great strides in discrediting the notion of biologically distinct races and ethnicities, and clinicians have worked toward eliminating racial and ethnic discrimination and bias in health care. Civil rights activists and many politicians have also fought a brave battle to eliminate racial and ethnic discrimination in college admissions, hiring, money lending, insurance, and other aspects of social life. The trend has been to move toward a world in which people are not judged according to the color of their skin, the shape of their nose, or the pronunciation of their last name.

Prior to the 20th century, most scientists understood race and ethnicity as biological categories, like sex, which clearly distinguish groups of human beings (Root, 2001). Scientists used physical characteristics (such as skin tone, hair, and shape of the face) to classify people according to their race or ethnicity. The major racial groupings at that time—Caucasian, Negroid, Mongoloid, Australoid, and American Indian—were linked to the continent of ancestry. Scientists thought that members of different races not only had different visual appearances but also had different physiological and psychological phenotypes (such as strength and intelligence). Scientists hypothesized that genetic differences among people explained phenotypic differences among races, and many claimed that some races were superior to others. The eugenics laws and proposals developed from 1880-1920 in the United States and Europe, as well as Nazi Germany's quest for racial hygiene, were based on the idea of biologically distinct racial or ethnic groups (Gould, 1981).

In the late 20th century, research in human genetics discredited the idea that race and ethnicity are biological categories that clearly distinguish between different groups of people. Studies have shown that all human beings share more than 99.9% of their DNA and that there is greater genetic variation within racial or ethnic groupings than across racial or ethnic groupings (Winkler 2004; Bamshad 2005). However, these findings have not convinced most physicians or biomedical researchers that race and ethnicity have but a slight significance for biomedical research or clinical medicine only because there are well-documented racial and ethnic differences in health.

One of the goals of The Department of Health and Human Services' (DHHS) Healthy People 2010 initiative is to eliminate racial and ethnic differences in health (Centers for Disease Control and Prevention, 2006). Obviously, society cannot meet this goal if race and ethnicity are eliminated as categories for biomedical research, because scientists need to record racial and ethnic data to determine whether progress is being made toward eliminating disparities. Additionally, knowing a patient's race or ethnicity can help a clinician to diagnose and treat that patient because this information can tell the clinician about the patient's risk for some types of diseases (Burchard, et al., 2003). For example, a family physician performing a physical exam on a 70-year-old African American male should be concerned about the patient's increased risk of prostate cancer, and a fertility specialist helping an Ashkenazi Jewish couple have a child should be aware of their risk of having a child with Tay Sachs.

One can also recognize that there are genetic differences among racial and ethnic groups without assuming that race and ethnicity are biological categories, since variations in the frequency of specific genes in specific populations can be linked to ancestry and geography. Genetic and archeological evidence support the hypothesis that the modern human originated in

Africa about 100,000 years ago (Stewart & Stillman, 2004). As human populations migrated out of Africa, the proportions of different genetic variants present in those populations changed over time due to founder effects, natural selection, and random genetic drift. Over thousands of years, humans spread out over the world to the different continental areas (Europe, Asia, the Americas, and Pacific Islands), forming the five main ancestral groups that correspond to what we call races. Additionally, smaller populations (or ethnic groups) formed and began to diverge from the five main groups. In some populations, such as the Pygmies in Africa or Bushmen in Australia, genes for short stature became more prevalent. In populations where malaria kills many people, genes that confer resistance to malaria in hetereozygotes (but cause sickle cell disease in homozygotes) became more common. Throughout human history, interbreeding occurred among these different populations, so that very few human populations have been reproductively isolated from the rest of the world. Those who identify themselves as African-American, for example, may be able to trace their origins to Africa, Europe and North America, due to genetic admixing among populations (Foster & Sharp, 2004; Rogers & Jorde, 1995).

If this view of human evolution and genetic variation is correct, then race and ethnicity can also be understood as crude proxies for ancestry (Collins, 2004; Bamshad, 2005). Knowing a person's ancestry can be useful in understanding his or her biology because ancestry often correlates with specific patterns of genetic variation (Collins, 2004). A person who identifies him or herself as African-American is more likely to have the gene for sickle cell disease than, a person who identifies as Caucasian, because there is a greater chance that the African-American person can trace one's origins to a population on the African continent where the genetic variant is common. A clinician can use this information, therefore, in deciding whether to recommend that the spouse of someone who is a known carrier of sickle cell disease take a genetic test for

the gene prior to conceiving children with that person.

Race and ethnicity are not biological categories that clearly distinguish between different groups of human beings. Nevertheless, these classifications can be useful in biomedical research and clinical practice as rough proxies for social, environmental, or genetic factors that affect one's health. Since race and ethnicity are only proxies, clinicians and biomedical researchers should treat them as temporary markers on the way to a more complete understanding of the different factors that affect health (Winkler, 2004; Bamshad, 2005; Sankar & Cho, Genetics: toward a new vocabulary of human genetic variation., 2002). Once we have a better understanding of the underlying causes of so-called racial and ethnic differences in health, clinicians and biomedical researchers will not need to use these racial and ethnic categories, but until that day arrives, race and ethnicity do matter in biomedicine.

Is it possible for health care practitioners and researchers to use racial and ethnic concepts in therapy and research without treating them as biological categories? Indeed, one might argue that the reification objection arises because it assumes that people who have an understanding of modern biology and medicine would continue to treat race and ethnicity as biological categories. As noted earlier, race and ethnicity should be treated as rough proxies for social/environmental variables or ancestry. As long as health care practitioners and researchers use the concepts in this way, they will not succumb to the temptation to think of race and ethnicity as biological categories. For this to happen, it is important for investigators and clinicians to have a sound understanding of race, ethnicity, and population genetics. They should have some general knowledge about how income, access to care, housing, diet, culture, discrimination, and other social/environmental variables can impact health, and they should have some basic information about the role of genetics in human disease. To ensure that health care practitioners and

researchers have this information, it is important to provide students, trainees, and established professionals with some education in these topics through college courses, graduate seminars, and continuing education workshops and conferences for professionals. Health care practitioners and researchers should also educate the public about the relationship between race and ethnicity and health to help counteract the tendency in society to think of race as a biological category.

CHAPTER III

Review of the Literature

The literature reveals many insights pertaining to the topic of African American and Hispanic/Latino regarding their participation in genetic testing and genetic research. As you will see, there is a substantial amount of literature pertaining to African Americans and genetics testing, but as of yet very little concerning Hispanic/Latinos. Despite the number of studies on African Americans, there are some critical gaps. Before looking at the specific studies about genetic testing and research and minority groups, it will be useful to look at the literature on social constructivism.

The Social Construction of Technology

The social construction of technology (SCOT) is a founding theory in the field of Science and Technology Studies. The prominent scholars of SCOT are Wiebe Bijker and Trevor Pinch. Social constructivism of technology lays the argument that technology does not shape the users (individuals), but in fact the users (individuals) shape the technology. Furthermore, a technology cannot be fully understood, until the social context within which the technology exists is also understood. Using SCOT as a research methodology allows for scholars to explore why a particular technology is accepted or rejected because they can examine the social context in which the technology exists. Additionally, this sort of approach allows one to see how a technology or technological artifact is defined by different groups of people. These groups of people are often referred to as relevant social groups. Relevant social groups can users or producers of the technology. Characterized by shared interests and interpretations of a

technology, often there are instances where those belonging to subgroups (i.e. different classes, races, or genders) of the relevant social groups are excluded from the discussion.

Under the umbrella of SCOT is the concept of interpretative flexibility which means technology has different meanings and interpretations by various relevant social groups (Bijker, Hughes, & Pinch, 1987). Wiebe Bijker and Trevor Pinch, related this concept to the design of the bicycle. The different users of the bicycle such as the sports cyclist opted for design changes to the existing bicycle that would allow for more speed. When examining the social context of in which the bicycle existed, women emerged to share their views on the bicycle design in relation to changes in fashion and their role in society.

The social construction of technology can be useful when try to think about why African Americans and Hispanic/Latinos are underrepresented in genetic testing and in genetic research. As the SCOT method would suggest, both African Americans and Hispanic/Latinos have developed different meanings for a genetic test when compared to Caucasians. Seeing that many Caucasians see genetic testing as being acceptable, what are the underlying reasons for why African Americans and Hispanic/Latinos do not regard genetic testing in this same manner? To continue to find answers to this question, we can review the studies completed on the views and perceptions minorities have of varies forms of genetic testing. Many studies have looked at the belief systems of African Americans and genetic testing. Few of these studies research the perceptions of Hispanic/Latinos.

The Views of Minorities on Participating in Genetic Testing

The common theme these research studies continue to illustrate is that interest and concern about genetic testing exists within the African American and Hispanic/Latino communities, however there are some known barriers such as lack of knowledge, mistrust, and

financial concerns concerning genetics that keep them from utilizing genetic testing. African American women have differing views of risk and developing breast cancer as opposed to Caucasian women. Additionally, African American women are less likely to believe that their risk is elevated due to having a relative with cancer compare to Caucasian women. However, in some instances knowledge about the familial connection and cancer can lead to greater interest in genetic testing for breast cancer. As found in the study by Learman and colleagues, from the University of California San Francisco, when African American women were educated on the relationship between breast cancer genetics and family, they became more interested in genetic testing. But yet the knowledge levels of breast cancer genetics has been shown to be very limited in African American women. African American women have a lower level of knowledge about breast cancer genetics in comparison with Caucasian women (Learman, Seay, Balshem, & Audrain, 1995). Chanita Hughes-Halbert, psychiatry professor at the University of Pennsylvania and research team administered a survey over the telephone to access the interest levels of both Caucasian and African American women about breast cancer susceptibility testing. The study results revealed that African American women on a breast cancer genetics knowledge assessment questionnaire scored 4.55 out of 11 compared to 6.33 out of 11 in Caucasian women (Hughes, et al., 1997). Drawing from what was learned from her previous study, Hughes-Halbert and colleagues surveyed 97 African American women and 310 Caucasian women from the Washington, DC, about their knowledge of and attitudes about genetic testing for cancer. These women all had a first-degree relative with breast or ovarian cancer. The investigators found that African American women had limited knowledge concerning genetics and what it meant to be genetically tested compared to the knowledge set of Caucasian women part of the study. Also the perceptions of benefits of genetic testing were greater in African American women then

Caucasian women. African American women felt they would benefit from the testing because they would know the need for more cancer screening and additional measures to prevent cancer. The investigators found that although African American women had less knowledge about genetic testing they still had high hopes for what it could do for them.

Anita Kinney, research scientist at Huntsman Cancer Institute, and colleagues, also found that African American women have limited knowledge about breast cancer genetics. The investigators used a survey tool to assess the genetic counseling and testing needs in African American women with a known BRCA 1 mutation. The women involved in their study were first-degree relatives of women with breast cancer or ovarian cancer. The researchers found that there was a high level of interest regarding genetic testing among the African American women surveyed, but that they had a limited knowledge about breast cancer genetics. Having a first-degree relative with breast or ovarian cancer directly affected their genetic testing intentions because it altered their view of perceived risk (Kinney, et al., 2006). What are the dimensions of limited knowledge of breast cancer genetics?

A possible area of concern as to why African Americans have limited knowledge about genetic testing is because they may be unaware that genetic testing exists. Hughes-Halbert (2005), found 31% of African American women reported never hearing about genetic testing, compared to 14% of Caucasian women. Another study found 10% of African American women compared to 30% Caucasian and 27% Ashkenazi Jews who had 1st degree relatives with breast cancer, were unaware of breast cancer susceptibility testing. Satia and colleagues, from UNC Chapel Hill, found while assessing the interest levels of African Americans regarding genetic testing for colon cancer, 87% of the 658 respondents would take a genetic test. However, only 42% of the respondents had read or heard something about genetic testing (Satia, McRitchie,

Kupper, & Hughes-Halbert, 2006). In 2001, Nancy Press et al., from the Oregon Health Sciences University, studied the attitudes about and interest in genetic testing. Using a quantitative survey tool, they examined the views of 246 women, of which one fifth were African American. Of the African American participants, 43% had heard of the breast cancer gene and 70% expressed a hypothetical interest in possibly taking a genetic test for breast cancer as compared to 56% of the Caucasian women (Press, Yasui, Reynolds, Durfy, & Burke, 2001). In another study, Hispanic women who were part of the Ramirez study, had positive views of genetic testing for breast cancer susceptibility, but their awareness levels were very low. These women had family members with breast cancer and resided in the San Antonio, TX area (Ramierz, Aparicio-Ting, de Majors, & Miller, 2006). A possible reason for this high level of interest could be because of the lack of knowledge about genetic testing. However, because these studies utilized survey methods, little insight was given to reasons for such high levels of interest.

Perceived Benefit. From the published studies there appears to be a difference in expectations among African Americans as opposed to Caucasians. African American women said that knowledge about genetic testing would increase their chances of survival and also the opportunity to pursue preventive health measures. This type of expectation of the benefits of genetic testing was greater among African American women. The improvement of health outcomes, increased health surveillance and awareness can be seen as a possible benefit of genetic testing for a disorder for which there is no cure. In the Kinney et. al, study 90% of African Americans women reported that genetic testing would be helpful in motivating them to become more health conscious. Moreover, the high expectation level may correlate to the high level of interest in genetic testing among African American women (Kinney, et al., 2006). The interest in genetic testing among African Americans was fairly high when compared to

Caucasian women in a study conduct by Sharon Duffy, a medical ethicist at the University of Washington and research team. The majority of the 38 African women who were in the study had never heard of a breast cancer gene before. Nonetheless, 87% of the African American participants indicated they would be interested in genetic testing because of the possible benefits, but would be less likely to participate if they had to pay for it (Durfy, Bowen, McTiernan, Sporleder, & Burke, 1999).

A quantitative study concerning predictive genetic testing for Alzheimer's by Yvonne Hipps and colleagues at Morehouse School of Medicine, researched the differences between African Americans and Whites with not only their attitudes/general interest but also why would they choose to seek genetic testing for Alzheimer's disease. This was one of the few genetic testing studies that looked at a disease other than breast cancer.

Hipps and colleagues began their study using statistics from a preliminary general population telephone study, 79% of respondents expressed hypothetical interest in a hypothetical test for Alzheimer's disease. A positive result for Alzheimer's would effectively change behavioral patterns and finances because there is a risk of financial and emotional burden. Additionally, other surveys referenced by Hipps mentioned that first-degree relatives of African American Alzheimer's patients showed interest in a hypothetical genetic test. Hipps situates her research upon the fact that little work has been done on cultural differences of genetic testing for Alzheimer's disease.

The Hipps research group developed a survey using focus groups and in-depth interviews. The survey tool was then given to volunteers located in various parts of the United States. Four hundred and fifty-two white and black respondents completed the survey. One notable part of the study was the effort to achieve a diverse sample of African Americans. The

research team used African American recruiters, collaborated with the African American church and community, and used African American medical professionals to gain participants. The respondents were given hypothetical scenarios concerning intentions for testing, reasons for testing, beliefs about testing, and consequences for testing. The responses were based on a five-point scale ranging from strongly disagrees to strongly agree. Using a scale such as this provides an opening for further exploration of the reasoning behind these responses, which is useful information. Hipps et al. found that the African Americans surveyed were less aware of facts about genetic testing for Alzheimer's and less interested in the hypothetical situations.

A concern about the study was the identification of the African American group. Hipps et al. mentions their interest in studying cultural differences, however I am not sure how the term culture is being used. Is their use of it synonymous with racial identities? They go on to state that they would like to use the results of the study to develop culturally sensitive genetic education and testing, but once again their meaning of culture is unclear?

The perceptions of the benefits of genetic testing are high among African Americans but yet there are still concerns about risks and family impact. Hughes et. al (2003), found that concern about familial impact was greater among African American women than Caucasian women. Women, who often hold the role of caregiver in the home, hold more concern about the effects of an unfavorable testing result on the emotional state of their family.

Researchers Donovan and Tucker (2000), psychologists from the University of Alabama at Birmingham, studied the knowledge and attitudes about genetic testing for inherited risks for breast and ovarian cancer in women without a personal or family history of breast or ovarian cancer. The overall goal of the study was to compare a diverse sample of African American and Caucasian women with regard to their knowledge and interest in genetic testing for breast cancer

susceptibility. They used mixed methods such as structured interviews and questionnaires to examine the views of 220 participants, 50% Caucasian and 50% African Americans, who were awaiting medical services at the University of Alabama Medical Center's women's clinic. They found African American women were less knowledgeable about breast cancer risks than Caucasian women, being unfamiliar with how family history affects the risk rate, for example. They also found that African American women were more concerned than Caucasian women about what to do with the test results and the emotional impact the results could have on family members. Additionally, 72% of the African American participants were concerned about confidentiality of the test results.

Issac Lipkus and research team, from Duke University, explored the relationships between the concern about breast cancer because of family history and interest in genetic testing in African American women. They began with a 15 minute interview and followed up with an additional interview two weeks later. Their goal was to obtain were trying to obtain the views of 266 African American women, of which 130 had a family history of breast cancer and 136 who did not have a family history of breast cancer. They found that those women with a family history of breast cancer were more interested in breast cancer genetic testing when compared to women without a family history of disease (Lipkus, Iden, Terrenoire, & Feaganes, 1999).

The previous studies illustrated high interest levels in genetic testing for breast cancer among African Americans, but there is evidence that African American women may not be interested. Tambor et al. from Duke University Cancer Center, supplied written surveys to female members of a HMO in 1997, to assess the awareness of genetic testing for breast cancer and evaluate knowledge. The study consisted of 473 women of whom 83% were Caucasian and

14% were African American. The African American women showed a significantly lower rate of interest in testing than their Caucasian counterparts (Tambor, Rimer, & Strigo, 1997).

As evident in the Durfy, Donovan and Tucker, Lipkus, and Hughes-Halbert(2003) studies there is a disconnect between interest level and actual participation level in genetic testing. The studies indicate that African American women are interested in genetic testing, but there are barriers to testing that must be explored.

Barriers to genetic testing. One possible barrier to testing is financial concerns about genetic testing. The Kinney et al. study, found that if the African American women participants had to pay for the genetic test, their interest level declined (Kinney, et al., 2006). However, there are other barriers in addition to financial concerns. A prominent study on the topic of barriers of genetic testing was done by Eleanor Singer. In April 2000, Eleanor Singer, a professor at the University of Michigan and her colleagues conducted a survey-based study to explore the beliefs of African Americans, non-Hispanic whites, and Hispanic/Latinos with regard to participating in prenatal testing and adult genetic testing. To achieve a representative sample, the Singer research team used a computer-aided telephone dialing system for recruitment, inviting members over the age of eighteen to participate in the study. The interview questions were based on a previous study completed by Singer in 1990. As a part of the study, Singer et al.,studied African Americans and Caucasians beliefs about the health care services including genetic testing. Initially, the survey results revealed that African Americans have barriers with regard to health-care services in general such as, lack of financial coverage; lack of information regarding what is a genetic test, and a lack of trust by African Americans of the medical community.

Using what was learned from the 1990 study, the researchers were aware of some of the potential thematic areas. Following the completion of the survey analysis follow up was done

with open-ended questions, to explore some additional areas left incomplete by the surveys. This is one of the few examples the use of an interview format along with a survey form has been used in studies about views concerning genetic testing. The researchers found that barriers such as lack of financial coverage and lack of information still existed with regard to genetic tests, but African Americans and Hispanic/Latinos were interested in knowing more about prenatal testing in fact even more than the Caucasians in this study (Singer, Antonucci, & Van Hoewyk, 2004). This interest in prenatal testing was attributed to feelings of concern and wanting to protect their children from potential diseases. A key limitation of this study was the African American population was chosen from households with telephones. Those who were without home telephone service were excluded from the study. There was no opportunity to truly achieve a representative sample.

The Singer studies highlighted some of the perceived barriers to genetic testing there are also definite concerns about abuses of the genetic testing results. Thompson and colleagues, from the Mount Sinai School of Medicine, explored the attitudes about genetic testing for cancer risk among African American, Latina, and Caucasian women. Both the Latina and African American women were strongly concerned about testing abuses compared to Caucasian women. These two groups were also concerned with medical mistrust. However, due to the structured interview design, the dimensions of mistrust were not explained. There are varying levels of mistrust. Also there is the question of mistrust of what or whom?

There are cultural barriers to genetic testing. Zimmerman and research team from the University of Pittsburgh School of Medicine surveyed 314 older adult patients from inner city health centers in the Pittsburgh area about beliefs the genetics of diseases and belief systems. They found that African Americans and Caucasians have different beliefs about genetic testing

and that African Americans were more likely to feel genetic testing results could lead to racial discrimination (Zimmerman, Tabbarah, Nowalk, Raymund, Jewewll, & Wilson, 2006). The fear of racial discrimination from genetic testing is more evident in African Americans than Caucasians (Peters, Rose, & Armstrong, 2004).

Other studies seem to indicate that there are no racial differences with regard to participation in genetic testing for breast cancer susceptibility. Thompson and colleagues (2003) used 76 participants to understand the predictors of participation of African Americans in genetic counseling and genetic testing for breast cancer. All of the 76 women had a family history of breast or ovarian cancer; 52.6 % of the women had already participated in counseling and testing and 47.4% of the women had never received any genetic counseling or testing. The participants reported via a written survey tool that there were few barriers to genetic testing and they knew a lot about breast cancer (Thompson, Valdimarsdottir, Jandorf, & Redd, 2003).

The literature pertaining to the lack of participation in genetic testing among Hispanic/Latinos is even more limited than for African Americans, which makes this area of research even more appealing to study because of the evident void in the literature. What can be drawn from the genetic testing studies?

- African American women are interested in genetic testing if there is a perceived benefit such as a positive impact on family.
- African American and Hispanic/Latino women have limited knowledge about breast cancer genetics.
- African American and Hispanic/Latino women who have a family history of breast cancer are generally more interested in genetic testing for breast cancer.

- African American women and Hispanic/Latino women shared concern about financial coverage, mistrust and the negative impact unfavorable results could have their family.

We can learn from the conclusions drawn from these studies but yet there are questions still to be answered. Most of the studies concerning genetic testing and minorities are discussed the views and perceptions of breast cancer susceptibility testing. Would these conclusions change for other forms of testing, such as carrier testing for sickle cell, or pre-symptomatic testing for Huntington's disease? Furthermore, a vast majority of the articles mentioned were quantitative studies comprised of mostly telephone surveys. Survey statistics do provide some descriptive data, but understanding the depth of the survey responses is missing in these studies. Lastly, it would be beneficial to see if these types of barriers to genetic testing also exist for participation genetic research.

Minority Participation in Medical Research

It is widely known that African Americans are hesitant to participate in medical research studies. There is great difficulty in recruiting minority participants because of historical abuses, religious beliefs, lack of benefits for testing, and schedule of conflicts. In effort to gauge minority willingness to participate in research, Shavers, Lynch, and Burmeister, epidemiologist for the University of Iowa, recruited 231 African American undergraduates from historically black colleges and universities to evaluate a questionnaire about factors for participating in research studies (Shavers, Lynch, & Burmeister, 2002). The participants identified mistrust as the main barrier to participating in medical research. A limitation of this study was administering the questionnaire in the classroom setting. The student participants may have felt unfairly swayed due to fear of a lower grade. Despite this limitation, the results illustrate that mistrust of

research transcends all education levels. Mistrust is a phenomenon only affecting the uneducated.

What is the overall definition of trust? I agree with Vanessa Gamble, professor at George Washington University, that "trust is not static, it is an ongoing dynamic." (Gamble, 2006) There are lower levels of trust towards the medical community for African Americans and Hispanic or Latinos. Of course one cannot dismiss the notion that there are varying levels of trust. There can be mistrust of a physician or researcher, or maybe mistrust of blood donation or organ donation because of one's belief system. African Americans' mistrust of the health care community is not a novel idea or research subject. Researchers have shown that the lack of trust is a significant barrier between African Americans and their participation in clinical research (Smith, Thomas, Williams, & Ayers, 1999; Byrd & Clayton, 2000) . Mistrust is associated with the lack of enrollment in clinical trials and apprehensiveness when utilizing physicians. Fears about being treated like guinea pigs or being potentially misused in research studies are sentiments shared by many African Americans. The fears of white doctors date back to the days of slavery, which is noted as the beginning of human experimentation on African Americans. Such is the example of James Marion Sims, the "Father of Gynecology", who conducted vaginal fistula surgeries on black female slaves without the use of medicine or treatment of the wounds. Dr. Sims often boasted on the strength of the black woman, which made her the ideal patient for research.

The impact of the Tuskegee Syphilis study on other health care programs is far reaching. Crawley (2001) and other researchers have claimed that the reason for this mistrust is directly related to the Tuskegee Syphilis Study, which was conducted by the U.S. Public Health Service from 1932 to 1972. The study included 399 black men from Macon County, one of the poorest

areas of Alabama. The men were sharecroppers and for the most part illiterate. Taking advantage of their lower mental abilities, doctors never communicated with the men of what disease they were suffering. The men were told they possessed "bad blood." The men were eager to see a doctor weekly. Many of those who had never visited a doctor, were impressed with the prospect of free care. Additionally, a black nurse Ms. Eunice Rivers picked them up in a nice vehicle to transport them to their doctor's visits. As mentioned earlier, the men were extremely poor, so riding in a car was seen as an added bonus to participating in the study.

The researchers, who were both white and black, were studying the effects of syphilis in Blacks as opposed to Whites. One of the many atrocities of the Tuskegee syphilis study was the extreme measure taken by the researchers to deny treatment to the men. In 1945, penicillin was discovered as a cure for syphilis. The men were denied the medication. When 250 of the men registered for the draft for World War II, the Public Health Service exempted them from the draft to prevent them from getting treatment. The researcher did not give the men the option of leaving the study. In fact, the surgeon general of the United States, provided the men with certificates of appreciation to signify 25 years of participation. Even until the end of the study in the 1972, the Public Health Service enlisted the help of local health departments to track those men who no longer resided in Macon County, and to keep those men from receiving treatment. By the end of the experiments in 1972, 28 men died from syphilis, 100 died due to complications from the disease, 40 wives of the men were infected, and 19 children were born with congenital syphilis (Jones J. H., 1993). The Tuskegee Syphilis Study is noted as one the most horrendous cases of research ever completed in the name of science.

The effects of the Tuskegee study are far reaching. According to Vanessa Gamble, medical historian and physician now at George Washington University, "the Tuskegee Study

continues to cast its long shadow on the contemporary relationship between African Americans and the biomedical community" (Gamble, 1997) She noted that many African Americans fear a repeat of the atrocities of Tuskegee and therefore distance themselves from medical institutions. As a result of this distancing, the overall quality of the health in the African American community has suffered.

There are other instances of medical abuses that are less prominent than Tuskegee. Brandon et al. (2005) of The Johns Hopkins School of Public Health studied the correlation between knowledge of the Tuskegee study and medical system mistrust. Using a telephone survey of 277 African American participants and 101 Caucasian participants, they found that there was not a difference among races as far as knowledge of Tuskegee. Each racial group knew the basic facts of the study, such as who was studied, what was being studied, and where the study was located. Also, the Tuskegee Study did not play a persuasive role in the trust or lack of trust of the medical system within the African American community. Thus, they found that mistrust of the medical community spans far beyond the reach of the Tuskegee Study and that Tuskegee is just one factor among many that exist (Brandon, Issac, & Laveist, 2005).

There also exists the idea of physician mistrust among African Americans and Hispanic/Latinos. In a community tracking study of 60,446 people, both Hispanic/Latinos and African Americans voiced that their physicians were inaccessible. The survey consisted of two parts, one measuring physician style and the other measuring trust. These two minority groups were less satisfied with medical care compared to whites. Also it was expressed that white physicians fail to provide quality care to those belonging to minority communities. (Gamble, 2006).

I have focused much of the information about lack of participation in medical research on African Americans. However, this is something to be known about Hispanic/Latino apprehensiveness of medical research. One study, by Ransford, Carrillo, and Rivera (2010), researched the health seeking behaviors of Latino immigrants. The study was broken into two phases. Phase one was interviews with 12 community leaders from Mexico, El Salvador, and Guatemala. They were interviewed about health seeking behaviors of Latino immigrants. The Next phase was conducting 96 interviews with Latino immigrants residing in the Los Angeles area. These interviews were conducted in Spanish. By conducting the interviews and recruitment in Spanish, the researchers were able to establish some rapport with prospective participants. However, suspicion was raised when the IRB forms were presented prior to study participation. The participants were worried that the information may be shared with unwanted parties such as the immigration police. This distrust exists partly because of a noted fear of deportation; researchers purposely omitted any questions about citizenship from the interviews. Therefore, there was no record on who was undocumented. The investigators found that belief and structural barriers exist for Latino immigrants. The belief barriers were fear of deportation, cost of treatment, and fear of communication. These barriers result in Latino immigrants seeking medical care only when they were extremely ill. Structural barriers revealed in the interviews were, language, lack of health insurance, and poor access to care. Because of the existence of these structural barriers, many Latino immigrants depend on cultural alternatives such as traditional medicine and healing as opposed to utilizing western medicine (Ransford, Carrillo, & Rivera, 2010). Traditional medicine is a part of the Hispanic/Latino culture that is yet to be fully understood by the medical community.

Culture can be seen as beliefs, values and attitudes that a group may share. Culture is derived from family and other shared communities. Under the umbrella of culture is language. Language barriers are cited as a barrier for Hispanic/Latinos for participating in medical research. It has also been found that language barriers result in decreased access, diminished understanding, and lower quality of care (Aguirre-Molina & Molina, 2003; Gelman, 2010). In the medical research community, the ideas about cultural influences in health care decisions are often ignored (Smith, Bussey-Jones, Horowitz, Whitehurst-Cook, & Chen, 2006). Being aware of societal problems and social contexts can help explain why an individual may or may not accept medical treatment. This sort of approach of using the social context as a means of understanding a technology is analogous to the SCOT approach mentioned earlier.

There is so much to gain from minority participation in research. Increasing minority participation in research studies can aid in the generalizablity of the data from medical studies to apply to diverse populations. In 1993 former President Bill Clinton signed the NIH Revitalization Act in effort to promote the inclusion of more women and minorities in clinical trials. The act requested the following: 1. Women and minorities are to be included in all studies. 2. Women and minorities are to be included in all phase III clinical trials. 3. Cost cannot be a reason for exclusion from a study. 4. More initiatives to increase recruitment of women and minorities in clinical trials (National Institutes of Health, 1993). Currently, initiatives to recruit minorities for research are more critical because of the emergence of population based biobanks and new research efforts on the relationship between health disparities, race/ethnicity, and individual genetic makeup. The barriers to medical research are similar and almost identical to those of genetic testing. The studies presented produce gaps that I intended to explore in my research. First, a majority of the literature pertaining to research

participation of minorities, lacks reference to the specific type of research in question. For example, would minorities be more willing to participate in research leading to genetic medicine treatments? Mistrust was a prevalent theme for both genetic testing and medical research. I would like to explore the elements of mistrust. Is there a particular type of mistrust that African Americans and Hispanic/Latinos are experiencing? Additionally, I am interested in researching the varying definitions of lack of information, culture influences, and financial concerns. Moreover, unlike a majority of the studies used, I intend to recruit from places other than health clinics, and existing cancer registries.

Many of the studies utilized quantitative methods such as surveys and questionnaires as a means to assess minority attitudes towards genetic testing and genetic research. Therefore I employed the use qualitative methods such as semi-structured interviews to hear the experiences African Americans and Hispanic/Latinos may have had with genetic technologies. Use of qualitative methodology allowed for an in-depth look at the themes mentioned in the literature and provide a more nuanced view of African American and Hispanic/Latino perceptions of genetic testing and genetic research.

CHAPTER IV

Methods

Why Qualitative Research Methods?

A review of the literature in chapter 3, illustrates that previous studies have relied on survey methods to probe the interest of African Americans and Hispanic/Latinos with regard to participating in genetic testing and genetic research. Little has been done to go further in exploring the reasons behind their views in these studies. Surveys are useful to some research topics. Surveys provide descriptive statistics concerning areas that cannot be observed. For example, surveys can gather data about opinions regarding the effectiveness of genetic research in minority communities. However, the survey method alone in some types of studies is not adequate because it lacks the rich in-depth descriptions you can gain from qualitative interviews (Babbie, 1973). To determine the reasons for the underlying views held by two different ethnic groups and their subgroups, in this dissertation project I utilized ethnographic methodology. The first phase employed focus groups and second phase employed semi-structured interviews.

Qualitative research study designs often are positioned to reveal how people develop ideas of meaning (Creswell, 1998; Patton M. , 1990). Qualitative methods are also cognizant of the viewpoints of participants and how they view their experiences. Sensitivity is especially important in studies dealing with minority populations who have already shown a marked hesitation when participating in various forms of medical research. Additionally, semi-structured interviews allow for the analysis of themes and concepts with further exploration on any given topic.

Interviewing provides a personal interaction that is so often lost when using surveys. In-depth interviewing is not meant to evaluate pre-determined hypotheses, but to understand the lived experiences of other people. Interviewing provides access to people's understanding and

behaviors. Using semi-structured interviews as my specific qualitative method provided a descriptive voice as to why African Americans and Hispanics/Latinos are apprehensive towards genetic services, whereas a survey would just provide statistics with no explanation and nothing behind the numbers.

Role of the Researcher

My role as the researcher is complex and requires a constant self-reflection process. My personal experiences make me deeply connected to the roots of this project. Therefore I had to be aware of providing the most honest and accurate account of the lived experiences of the subjects in this study.

In approaching this research project I acknowledged what my personal experiences can bring to this study. My sensitivity towards the views of minority groups was enhanced because I am an African American woman. I find being African American is a positive detail because I can relate to those with racial similarities. However, I must be conscious that I am an outsider also. Being a black female who is obtaining a doctoral degree may negatively affect the interview responses because I do not "belong." I may be viewed as someone in power or authority rather than the laid-back southern woman I see myself as.

Our personal experiences can often contribute to who we are as researchers and help us better examine the lives of our participants. Due to my personal experiences with genetic testing and cancer, I have a heightened awareness of issues faced by those of other minority groups. I wanted the interview responses to give voice to those of the African American and Hispanic/Latino communities in the health policy arena.

Focus Groups

Focus groups are interviews in which a researcher can assemble a group to generate data from discussion. The benefits of focus groups are that they are flexible and can examine a wide

variety of topics. They are relatively simple, quick, and an easy way to learn from a group of people of a variety of backgrounds in one setting. Unlike in an interview setting, the interaction is not between the researcher and the participants, but the interaction of the participants is with each other. Focus groups are often used when exploring views and attitudes concerning certain topics such as films, television programs, or the introduction of new products (Kitzinger, 1995). Focus groups can be used at different points of a research project. However, they are often used in the preliminary stages of the project (Stewart, Shamdasani, & Rook, 2007). Prior to the focus groups used in my research, I had drafted interview questions. I tested those questions in two pilot interviews and after analysis, I determined that the questions were too limited. A focus group is not a free brainstorming session. There is an agenda. As the name implies there is a "focus". Results from focus groups can add insight to areas of future exploration or provide confirmation on previous hypotheses (Stewart, Shamdasani, & Rook, 2007). Thus, I employed focus groups as the basis for the development of the interview questions that I would use in subsequent one-on-one interviews. There were two separate focus group sessions held on the campus of Virginia Tech in March, 2007. One was comprised of only African Americans and the other only of Hispanic/Latinos.

Careful planning of recruitment is an essential tool of focus group recruitment. Often the composition of the group can correlate with the quality and the direction of the conversation. Recruitment for the African American group was completed by posting flyers in grocery stores, on the campus of Virginia Tech, and also at the Blacksburg community center (see Appendix A-focus group flyer). I also sent a letter over email list serves to the African American students at Virginia Tech, the Virginia Tech Black Caucus, and the Black Graduate student association (see Appendix B-focus group recruitment letter). After posting the information concerning the study,

I waited two weeks for responses. The potential participants were invited to contact me via email, phone, or mail regarding their interest in the study. When contacted, I explained the study details, answered any questions, and also provided two copies of the informed consent form (see Appendix C) and consent to audio-tape form (see Appendix D). I instructed those who were still interested to bring one-signed copy of the informed consent and the consent to audio tape form to the focus group session. I was able to recruit thirteen African Americans. The members of the focus groups were residents of the community surrounding Blacksburg, Virginia.

In March 2007, these thirteen participants were invited to the Graduate Life Center at Virginia Tech for the African American focus group. Upon arrival, I collected all consent documents and asked all participants to complete a demographic information form (see Appendix E). The make-up of the group was eight women and five men. The ages ranged from 20 years old to 45 years old. There was a wide spread of educational background ranging from a high school education to medical and doctoral students. Having different backgrounds represented allowed for the focus group dialogue to offer varied experiences. As the focus group facilitator, I introduced probes to initiate and guide the conversation with the group members (Appendix F- focus group guide). The participants then guided the direction in which the conversation proceeded. I ensured we stayed on topic and that the participants continued to speak in a kind and respectful tone. The focus group was audio-taped, but I also had a research assistant writing key discussion points on a white board. The session lasted for an hour and a half. For compensation of time and effort, a fifteen-dollar gift card to a local store was given to all participants in both focus groups. In addition to a gift card, a pizza dinner was provided.

In the African American focus group session participants spoke freely on topics dealing with genetic testing, health insurance coverage, health policy, and the inclusion of minorities in

research. The focus group members appeared comfortable with sharing personal experiences with health care, fears and trust issues related to medical practitioners, and internal struggles with religion and genetics. After analysis of the transcript, three major themes revealed in the African American focus group:

- The role of religion in health care decision-making.
- The degree of medical mistrust that exists within the African American community.
- The lack of awareness of many African Americans of their family medical history.

The thematic areas of medical mistrust and of African Americans being unaware of the family history have been indicated in the literature. However, the role of religion in health care decision-making is a relatively new area that the literature does not explore.

Recruitment for the Hispanic/Latino focus group was relatively similar to the African American focus group recruitment. I posted flyers in major grocery store chains, on the campus of Virginia Tech, and also at a Hispanic/Latino market in Blacksburg. The flyer (see Appendix G) invited participation from those who identified themselves as belong to a Hispanic or Latino heritage group and who would be comfortable discussing ideas about health policy and health care in a group setting. This flyer and also a letter was also forwarded to email list serves for Hispanic/Latino students, the Hispanic faculty caucus, and Latino sororities and fraternities all at Virginia Tech(see Appendix H). I followed the same consent process mentioned earlier that was used with the African American focus group session. I was able to recruit ten Hispanic/Latino individuals. The members of the focus groups were residents of the community surrounding Blacksburg, Virginia.

In September 2007, I invited ten participants to the Graduate Life Center at Virginia Tech for the Hispanic/Latino focus group. The same procedures used with the African American group were followed concerning the collection of the demographic information. The ages of the participants ranged from 18-40 years old. The stratification of the Hispanic/Latino group was less widely spread than that of the African American group. The group was comprised of 8 women and 2 men. It consisted of mainly students at Virginia Tech and Radford University. There was one Virginia Tech Faculty member and one Blacksburg community member present.

As focus group facilitator, I again introduced probes to the group to commence fruitful dialogue among the group members. This focus group session was also audio-taped. A research assistant was present to write down key points that were disclosed during conversation. The session lasted for about an hour. The group participants conversed about issues concerning the Hispanic/Latino community such as: access to health care, language barriers with doctors, and possible policy recommendations to aid in alleviating health inequities affecting the Hispanic/Latino community. An analysis of the transcript from the session revealed a few major themes:

- The lack of cultural sensitivity among doctors and researchers
- The lack of trust of the government due to immigration issues
- The role of religion in health care decisions making

Using the themes from both groups, I was able to develop interview questions that covered the pertinent issues that emerged from the focus group sessions. The information gained from the focus groups was the foundation for the development of a new interview guide.

Development of the Interview Protocol

The next phase of the research process involved developing an interview protocol and the interview questions to guide semi-structured interviews. The protocol also included a short demographic information form (see Appendix I) for the participant to fill out. The use of semi-structured interviews allows for flexibility, such that the interview tool is used as a guide, but it can be modified as the interview progresses. This method also permits the researcher to probe and explore certain topics of interest as the participant describes her or his experiences. Additionally, semi-structured interviews permit the researcher and participant not only to control but also to explore areas of the lived experience that may be left out by using other methods such as surveys or structured interviews (Rossman & Rallis, 2003). Interviewing allows for rich details and deeper insights to be gathered about African Americans' and Hispanic/Latinos' views on genetic testing and in genetic research. Examples of a few of the interview questions asked are:

- What is the health problem that you believe you and your family may be at higher risk of developing?
- Do you think that a tendency toward this health problem is inherited in your family, that it may be related to your genes?
- Have you ever received information about genetic testing?
- In what way have your religious beliefs or belief in a higher power ever influenced your health care decisions?

With the interview protocol completed and the questions drafted (see Appendix J- Interview Guide) recruitment of research participants could commence.

The Recruitment Journey

Target Population. In chapter 2, I provided explanations on the the racial and ethnic categories used in my research . I am interested in self-identified African Americans--those who have origins in Africa-- and Hispanic/Latinos—those who have origins in Latin American countries or Spain. A goal of my study was to reach members of the identified heritage groups across a broad spectrum of socioeconomic statuses and demographics. In order to achieve a sufficiently diverse sample of participants from many different backgrounds, I expanded the recruitment beyond Virginia and the Virginia Tech communities to include other areas of Virginia and also North Carolina, Maryland, and Washington, DC.

I did not conduct this study in search of statistical significance, but was instead seeking to obtain broad coverage so that the participant sample tapped into different categories of experience and revealed whether generational, gender, socioeconomic, religious, educational, and geographical (rural/urban) differences exist. Choosing participants for a qualitative study requires strategy and careful thought, guided by the research questions, the specifics of the research design, and the resources available (Merriam, 1998). Seidman (2006) stated two factors that should help in deciding the number of research participants: saturation and sufficiency. Saturation occurs when no new information is being revealed from participants. I decided that forty interviews with African Americans and forty interviews with Hispanic/Latinos would provide sufficient coverage and saturation.

I developed interview categories to ensure I achieved a sample across a broad spectrum of people. The main categories were age, gender, level of education, and degree of health insurance coverage (see Table 1). In general, I was looking for both male and female participants belonging to different age groups, with varying levels of education. I also wanted to know if

they had health insurance, and if so, whether it was a government issued plan such as Medicare or Medicaid. Insurance coverage and the source of insurance is a good indication of income level and employment. I developed these cateogories so that I was aware of the characterstics of those participating in my study. People fit into multiple categories.

In each category there was a projected number of people to interview who possess those particular characteristics. I gathered this information from the demographic information form that was distributed with the informed consent documents. I used interview categories to see that every listed category had representation. I was seeking to interview twenty African Americans with a high school education and below and twenty who had some college course work. Additionally I was looking to interview an equal number of people for each age group. Because women are generally seen as the medical decision makers of a household, I did not indicate a proposed number for gender.

Table 1. Interview Categories for African American Participants

Forty Projected African American Interviews			
Level of Education	**Age**	**Health Insurance**	**Gender**
• HS and Below • Some college coursework	• 18-29 • 30-41 • 42-53 • 54 and above	• Yes (govt. plan) • No health insurance	• Male • Female

The Hispanic/Latino interview categories were identical to the African American interview categories, but an additional category regarding primary language added (see Table 2 below). There is an equal number of projected interviews in each cell. Similar to the African American group, I did not have a projected number of participants based on gender, but equal numbers for age.

Table 2. Interview Categories for Hispanic/Latino Particpants

Forty Projected Hispanic/Latino Interviews				
Level of Education	**Age**	**Health Insurance**	**Gender**	**Primary Language**
• HS and Below • Some college coursework	18-29 30-41 42-53 54 and above	Yes (govt. plan) No	Male female	English Spanish

Recruitment. With the interview categories developed and the overall goal of eighty interviews projected, the recruitment process began. Recruitment of African Americans and Hispanic/Latinos was an extremely tedious process. There were lessons learned. I began recruitment using traditional approaches of fliers and letters. In the beginning, I posted fliers describing the study in medical facilities, storefronts, hair salons, and other places of business; I also distributed information through church and social groups' newsletters. I did not confine my fliers to just the Blacksburg area but across Virginia, as well as in North Carolina, Maryland,

Virginia, and the District of Columbia. The fliers (see Appendix K) and letters (see Appendix L) solicited African Americans and Hispanic/Latinos who had a family history of disease such as breast/ovarian cancer, Alzheimer's disease, colon cancer, or hypertension. The fliers invited potential particpants to make contact with me via email, phone, or U.S. mail. This traditional method was not sucessful. After posting the fliers, I waited a few weeks without any response from those wanting to participate. As a novice researcher, I was alarmed as to why I received not one response. This failure of my recruitment spurred me to create methods that would be more effective in reaching those from minority communities and forced me to consider why such recruitment was difficult.

One lesson learned after my intial recruitment failures was the role and importance of institutional gatekeepers. When interviewers try to contact potential participants whom they do not know, they often face gatekeepers who control access to those people. Irving Seidman, Professor of qualitative research at the University of Massachusetts, Amherest, states, " Gatekeepers can range from the absolutely legitimate (to be respected) to the self-declared (to be avoided)." Institutional gatekeepers can facilitate a research process by informing the researcher of potential subjects and setting the tone for the research project (Bogdan & Bilden, 1998).

The African American church dating back to the civil rights movement is more than a just a place of worship; it is also a place of politcal importance and social reform. Many African American churches provide services such as health care forums, employment assistance, and educational forums in the community the church is a part of (Blank, Mahmood, Fox, & Guterbock, 2002). Therefore my radar for recruitment was to visit the churches African Americans attended. Before posting or sending out recruitment materials, I met with pastors of

the churches to talk about my study and to obtain their views, if any, on genetic testing and genetic research. I also asked for permisssion to invite participants for my study from their church congregation.

After receiving permission, I was then able to post fliers in church bulletins and also wrote articles to be placed in the church newspapers (see Appendix M). The pastors of the church serve as institutional gatekeepers for their congregations. Unlike my first attempt to recruit, I invited people in the congregation to meet with me and talk about the research study. In doing so, I was able to provide a face they could associate with the research recruiting materials. They needed to be assured as to what they were committing to. This face-to-face interaction allowed me to slowly gain trust with the African American partipants .

However, I did not want all of my African American particpants to come from the churches, so I branched out with face-to-face recruitment in hair salons and barbershops that service black patrons. I visited over twenty-five hair salons and ten barber shops. Some days I would sit waiting to share my information with anyone who would listen. Overall, the gatekeeper approach was particularly effective. The owner of the salon/barbershop would often begin a conversation about my research. It was not uncommon for the stylist/barber to ask their patron, "Hey, what do you know about genetic testing?" That intial question led into thought-provoking conversation, which then led to people inquiring about participating in my study.

I used similar tactics to recruit in the Hispanic/Latino community. Acknowledging that potential Hispanic/Latino participants may not be fluent in English, I had flyers translated into Spanish (see Appendix N). The informed consent form (see Appendix O) and the consent to audio-tape form(see Appendix P) was also translated into Spanish. Additionally, the demographic information form (see Appendix Q) was also translated into Spanish. I did not go

into hair salons, but I did contact churches with services in Spanish and also the Catholic Diocese of Roanoke, VA and of Greensboro, NC. One institutional gatekeeper for the Hispanic/Latnio community was the priest or minister. Once again, to make sure I didn't have a sample population of only churchgoers I also went to super markets and restaurants that serve Latin American food. At the super markets I handed out flyers concerning my research study. While at the restaurants, I befriended employees who were Hispanic/Latino, and they passed recruitment materials to patrons they felt would be interested in the study. The reasoning behind going to such exteremes to recruit was that I did not want an entire research population of upper middle class, educated particpants. I took the risk of possibly looking foolish in order to reach a wider group of people.

My recruitment strategies proved to be successful, as I was able to complete 90 interviews with self-identified African Americans and Hispanic/Latinos that covered the range of interview categories I had set out.

Consent Process[1]. After learning about the research study, participants were invited to make contact with me to obtain more information about the study. If after the intial contact, they were still interested in the study, a consent form letter (see Appendix R), two copies of the informed consent form(see Appendix S) and consent to audio-tape (see Appendix D) was mailed or emailed. As mentioned previously, these materials were also translated into Spanish (see Appendixes O and P). After they received the documents, I contacted each particpant to explain the consent documents and set a time and place for the interview. Prior to the beginning of the actual interview, I answered any questions concerning the consent documents and the research study.

[1] This study was approved by the Virginia Tech Institutional Review Board. Approval # 08-655

Participant Information. This study included 65 African American men and women ranging between the age of 23-79. They lived in various areas of North Carolina, Virginia, Georgia, Maryland, and the District of Columbia. I asked each participant to fill out a demographic form (Appendix F) with information such as age, gender, health insurance, occupation, and other information. Even with the recruitment failures I experienced in the beginning, I was able to recruit more than forty African American participants for interviews. However, I did not experience the same success for the Hispanic/Latino population. Language barriers and locations played a significant role in the number of Hispanic/Latino people I was able to recruit for the study. Twenty-five Hispanic/Latino men and women ranging between the ages of 25-50 participated in the study. They resided in North Carolina, Virginia, and the District of Columbia. This was less than the projected forty interviews, but nevertheless something was gained from the experiences gathered. In chapter 5, I go into further detail concerning what was learned.

Interview Procedures

According to Seidman (1998), a 60-90 minute time length is sufficient for an interview. It is enough time for the participant to reflect and share experiences without the process becoming exhaustive and boring for either the researcher or the participant. In my study, the interviews I conducted were audio taped—which can present both negative and positive features. The usage of audio-taping also allowed me to review and reflect on my performance in the role of interviewer. Audio-taping provided a tool for accountability, I could review the questions asked and ensure that I obtained the most pertinent information possible from the participant. Audio-taping provides the researcher with an accurate account of the interview and allows preservation of the participants' words, which are sometimes lost or forgotten while using other research methods or relying on memory. On the other hand, participants may feel too

scared or not genuine with their responses because of the presence of a tape recorder. This is a main drawback. As a part of the consent process participants were given the option of having the interview audio-taped. If at any point they became uncomfortable during the interview, they could request that the recorder be turned off and I would only take notes. Out of the ninety interviews conducted, there were not any requests to have the audio-recorder turned off.

When interviewing, it is important that the interviewer connect with the participant rather than being concerned with conducting a "perfect" interview. Establishing a level of comfort is needed to put the participant at ease. You can do this by opening the interview with "small talk" (Seidman, 2006). As a result, I began each inteview inquiring where each participant lived and how long they resided in that area.

After the icebreaker, I discussed with the participant the details of the project. I explained the informed consent document they had seen and signed, highlighting that they could refuse to answer any question and that the tape recorder could be stopped at any time. After I obtained both verbal consent and written consent, I moved on with the interview questions. I did most interviews in person, however when distance was a factor, the interview was done over the telephone. For the interviews with Hispanic/Latinos who were not comfortable with English, a research assistant fluent in Spanish was part of the interview. The assistant would explain terms in Spanish as needed. The average length of the interviews was about 50 minutes, which appeared to be sufficient time for conducting the interview as well as building a rapport with the participant. In additon to audiotaping, I took field notes to capture observations that could not be heard on the audio tape such as uncomfortable body language, facial expressions, and nervous mannerisms.

At the conclusion of each interview the participant was given a $10 gift card. Ten dollars seemed to be an appropriate amount for the time used to participate in the inteview. When paying participants, there must be a strategy when devising the amount of compensation so that it is not seen as being coercive (Creswell, 1998). I assured the participants that if they did chose to discontinue the interview at any point, they still would receive the gift card.

Interview Analysis Using Grounded Theory and Coding

Data analysis is a constant process that starts from the literature review and proceeds through data collection, and leads to actual analysis of the interviews. As John W. Creswell (2006), Professor of Educational Psychology from the University of Nebraska Lincoln, suggested, I tried to transcribe the interviews and field notes within one to two days after the interviews. This method allowed me not to become overwhelmed with the data and also to recall the interview while it was still fresh in my memory. I transcribed the interviews to include all pauses, breaks, and emotional expressions. The interviews with the Hispanic/Latino participants were sometimes transcribed by my research assistant who was fluent in Spanish. We worked together on the transcriptions to make sure no data was lost.

Once the interviews were complete I immersed myself in the data, free from interruptions as suggested by Creswell (1998). I looked over all my field notes and examined all notations in the margins that may have highlighted an important occurrence during the interview. For example, I noted body language, facial expressions, and changes in voice tone. Although tentative hypotheses are presented in the literature I reviewed (for example, that certain factors such as age, religious beliefs, degree of education, or possession of health insurance may affect the subjects' views), the premise of the coding approach, grounded theory, which was developed by sociologists Barney Glausser and Anslem Strauss, is to begin without any theoretical constraints or pre-formed interpretations. Coding for this project was carried out in several steps.

The first step in the coding process was open coding, a method that allows the views and relevant experiences of the interviewees to emerge. I read the transcripts to identify the different coding categories that were present and the perspectives or properties within those coding categories that the text reflected. It was crucial to represent the views of those interviewed accurately and authentically as possible by a careful reading and re-reading of the texts. Once I established the coding categories, I re-examined the texts, this time looking for interconnections and causal relationships among the coding categories. For example, for the code of family benefit I decided to see if there was a correlation with financial concerns. This is analogous to the axial coding in the Glaser and Strauss terminology. Grounded theory ignores factors such as time and place and is focused on the generation of concepts that explain peoples' actions (Allan, 2003). In this way, I was be able to link the categories, where appropriate, and develop a richer and more nuanced picture of minority-group views.

Dr. Doris Zallen checked the coding process. She coded five interviews and obtained similar categories. Rossman and Rallis (2003) refer to the utilization of colleagues during this process as "intellectual watch dogging." We analyzed the coding scheme for clarity and to ensure the true essence of the lived experience was not lost. This method held me accountable as the researcher for as clear and unbiased analysis as possible. In the next chapter, I will discuss the themes produced from the coding process.

CHAPTER V
Interview Analysis

Chapter 4 provided the steps taken to obtain individual stories concerning African American and Hispanic/Latino experiences with genetic testing and genetic research. This chapter will provide an in-depth look at the responses obtained from the participants in my research study. The responses are separated by race/ethnicity and by major themes revealed from the semi-structured interviews. The purpose of this chapter is to present an analysis of the interview data through an exploration of the lived experiences, perceptions, and views of 65 African Americans and 25 Hispanic/Latinos. This chapter is organized as follows: (a) description of demographics, (b) findings and major themes for African Americans, (c) findings and themes for Hispanic/Latinos, and (d) summary of the overall findings. The qualitative method of in-depth semi-structured interviews used for this study allowed me to probe the lived experiences of African Americans and Hispanic/Latinos concerning genetic testing and genetic research. In Chapter 1, I presented two research questions I attempted to answer. They are: 1) Why are African Americans and Hispanic/Latinos underrepresented in genetic testing? and 2) what are the underlying reasons why African Americans and Hispanic/Latinos are underrepresented in research in the area of medical genetics? With these questions in mind, the interview process provided me with the opportunity to document participant views concerning these issues.

African American Study

Description of the demographics. The 65 African American participants varied by age, gender, marital status, and education level. This information was self-reported on a demographic form provided during the consent process (Appendix D). The gender breakdown of the study participants was 28% (18) of the participants were men and 72% (47) were women. The ages of

both the men and the women ranged from 19 to 70 years old. The participant pool consisted of 69% (45) individuals who were above the age of 29 years old. In Figure 1, you can see the differences in marital status and education levels. Of the 65 African American participants, 31% (20) reported they were single, 54% (35) reported they were married, and 15% (10) widowed.

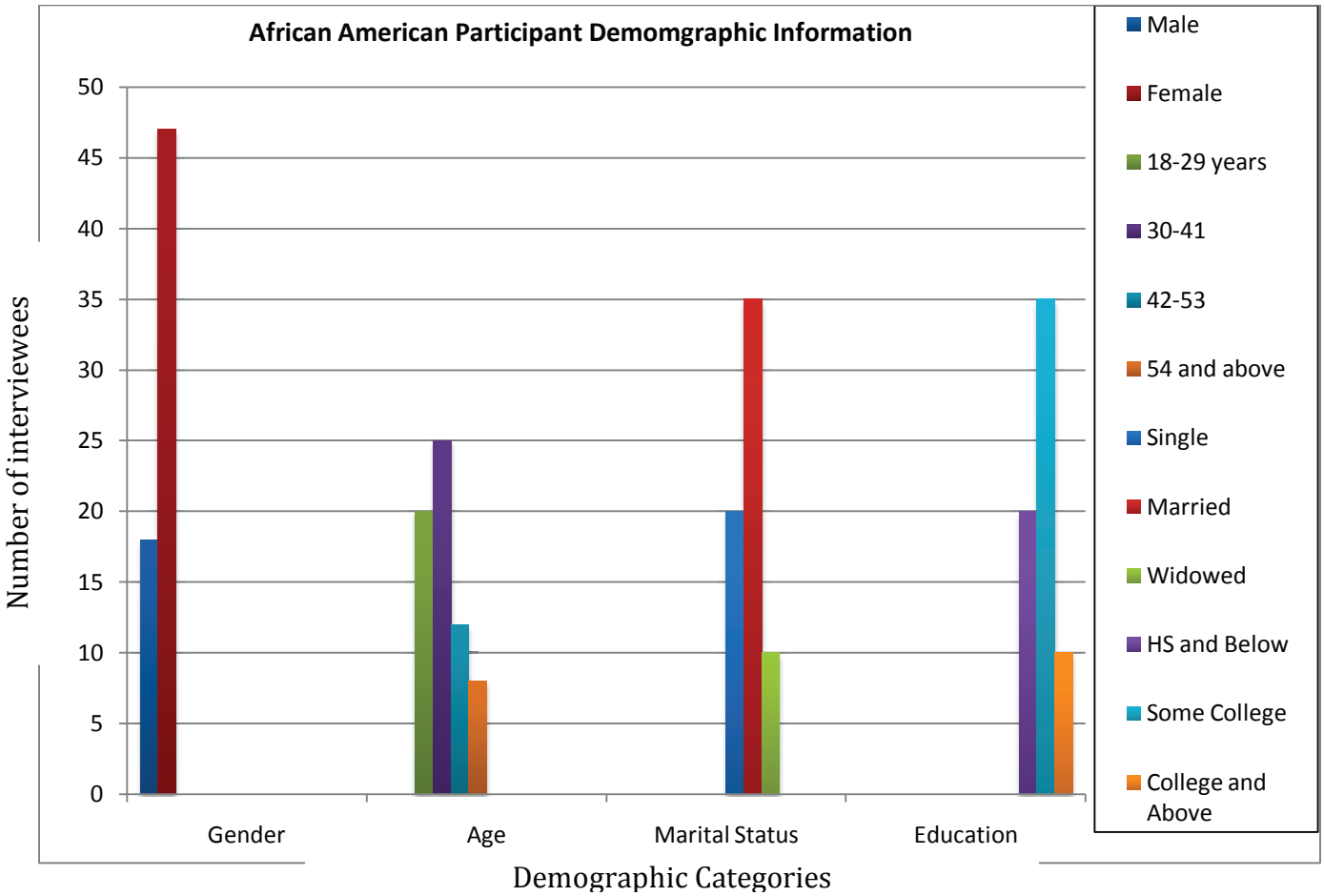

Figure 1. African American Participant Information

All of those in the African American category self- reported their race as being Black/African American. However, one participant who selected Black for race also selected Hispanic/Latino ethnicity. Education level among the participants included, 31% (20) with a high school education or below, 54% (35) who had completed some college coursework, 15% (10) with a college degree and above.

Findings and themes

As discussed in Chapter 3, previous studies have used quantitative methods to shed light on the possible barriers, but few have explored beyond the report statistics. Through open-ended questions, my study allowed for conversations and participant stories to be shared concerning experiences with genetic technologies and genetic research. From my analysis of the interviews, four themes emerged from the African American community regarding their reluctance to participate in genetic testing and research. Those themes were:

- financial concerns versus overall benefits
- mistrust
- religious concerns
- lack of knowledge

Financial Concerns. The first emerging theme for potential reasons why African Americans are less visible in genetic testing uptake was financial concerns. These financial concerns take several forms:

(a) insurance coverage--a concern about the adequacy of insurance coverage that would possibly minimize genetic testing costs

(b) justifying the cost--even if it could be afforded, genetic testing was not seen as something important enough on which to spend money

(c) perceived benefit- the notion, that even though cost is an important factor, if genetic testing could offer a real benefit the family, cost would no longer be an issue.

Insurance coverage. About half of the participants often described the possible inadequacy of their insurance coverage. They were unsure about whether not genetic testing was

covered under their plan. This concern was expressed for all forms of genetic testing including prenatal testing.

> AFR-010[2]: I just don't know if I am covered or not. Insurance these days is so limited I am not sure genetic testing is part of my plan. I mean just by going to the urgent care center I get charged 100 dollars for them to look at my sore throat. So I am almost positive that by someone looking at my genes it is more expensive. Hmmm I probably can't afford it.

> AFR-025: I have Medicare so I am sure testing is not covered. It can barely cover the cost of my medication. I cannot afford genetic testing without some kind of help.

> AFR-013: Insurance is so tricky these days. I don't even think genetic testing is part of my benefits. I would definitely have to pay out of pocket and I cannot afford extra out-of-pocket expenses. I guess we need health insurance reform right?

AFR-010's concerns were consistent with the views of many of the participants. Not dependent on marital status or gender, many participants were not sure of their insurance coverage and therefore would refuse genetic testing if offered. Those without insurance voiced the same concerns. This was most often displayed in the younger age category of 18-29 years old. Of the 20 participants below the age of 30, 12 of them shared they did not possess adequate health insurance.

[2] In order to comply with Institutional Review Board regulations on omitting identifying information of research subjects, I will be referring to each interview by a code number. For example, AFR-001 refers to African American interview #1. For Hispanic/Latino interviews a similar code was used. HISP-001 refers to Hispanic/Latino interview #1.

AFR-029: I am 23 years old so I can no longer be covered on my mother's insurance. It is hard to get coverage on my own, because individual plans are about 100 dollars per month for good coverage. I need to find a job with benefits. I want to have better health coverage.

AFR-035: I don't have insurance. I mean I do not work enough hours to even qualify for insurance. So how much does one of these tests cost? I am sure I cannot afford it, but if it is needed maybe I could sell something. I don't know. It is frustrating to think about, that I cannot do some of the things that would be good for my health because I do not have health insurance… I wish I had some kind of coverage. Because I don't even go to the doctor if I am sick. I hate to admit it but I use leftover meds, or over the counter junk. Having insurance would definitely open some doors. I could get all kinds of stuff done.

Lacking health insurance coverage is a growing concern for many African Americans. The statistics show that 21.4 % of African Americans are uninsured as opposed to 14.1% of Whites (Centers for Disease Control and Prevention, 2006). One interesting part of this quote was that this young man (AFR-035) was willing to sell something to have genetic testing if he thought it could help him. Additionally he had a feeling of guilt because he does not have health insurance and cannot acquire care if needed. This participant was 20 years of age and a college student. My field notes described how eager this young man was in discussing ways that genetic testing could be subsidized for those who could not afford it.

Many of the participants were worried about the cost of the test with or without insurance coverage. Additionally, they criticized genetic testing, saying that by making it so expensive researcher and clinicians were making it hard for minorities to be tested.

AFR-022: Why are these tests so expensive? I can't afford it but genetic testing from when I was having my little girl is a major expense. I am not sure how people afford it!

AFR-028: I guess genetic testing is only for rich people who can afford it. It is not covered in my insurance and I just can't pay out of pocket for genetic testing. You would think they would lower the costs so that poor people can have a chance. I guess our genes don't matter.

AFR-038: Before coming to this interview I did not know much about genetic testing costs so I looked it up. I did not know it was that expensive. I see why African Americans don't get genetic tests. We can't afford it. That is a shame. I would have to take out a personal loan to get one.

AFR-062: What am I supposed to get from a test on my genes? I mean they are so expensive I'm sure I am supposed to get some sort of follow-up or referral as to what to do with the new information. I am not sure I can afford to find out.

AFR-045: If I was wealthy of course I would love to have a genetic test for everything. But since I am not, and things are tight, I think I will have to wait until I can afford it. I

mean it isn't fair that not all people can have access to new stuff like this. It is just another way of keeping the poor black people out.

Justifying the costs. Another aspect of financial concerns was justifying spending money on genetic testing. This was widely felt by those who said they could afford a test but could not justify the frivolous spending on a test that may not reveal information that they deemed as pertinent.

AFR-035: I have my drawbacks for wanting to take a genetic test. I know I have a big family history of hypertension. So I mean I can just eat right and exercise and save money without them telling me something I already know. Do I need an expensive test to tell me to do the things I already know? I could spend the money elsewhere.

AFR-045: I know about genetic testing. I can't see myself spending $1000 on genetic testing. That $1000 is something I could use for bills or vacation. $1000 for a test about genes?

When asked in a follow up question if the genetic test gave information that could benefit her family or children, would she regard having a genetic test as frivolous spending?

AFR-045 continued: No, taking a test so that I can get information about my kids or family is priceless. I would spend any amount and wouldn't think twice about it.

Perceived Benefit. Every interviewee mentioned in some form that they would participate in research or testing if it could benefit their family. Cost was irrelevant to all ages, education backgrounds, and genders if there was a perceived benefit.

I[3]: Seeing that arthritis is the condition you are most concerned with, would you participate in research leading to a genetic test for arthritis?

AFR-019: I am not sure. I am kind of uneasy about this.

I: If the information learned from a test or research could benefit your family would you reconsider?

AFR-019: Yes, I have three daughters and two granddaughters, and I think they need to know that to expect if it is in their genes. I mean can something like that be a part of your genes? I am willing to participate so that doctors can find ways of doing whatever they need to do to prevent, prolong, or lessen the effects.

What was striking about this interview with AFR-019 was that in previous questions about genetic testing and research, she said she would not want to be a part of any study. However, when I asked if the test results or research results could benefit her family she was more willing to participate.

Mistrust. The second emerging theme from the interviews was mistrust. This took several forms: mistrust of clinical research, mistrust of white doctors, and mistrust of the government.

***Mistrust of clinical research*.** This was mentioned at least 30 different times among the 65 interviews. Most participants explained this mistrust as a fear that they would be used as guinea pigs for experimentation. There were many comments on this point.

AFR-023: I do not trust clinical research. I would not participate. I am not sure what these people would do to me. The side effects may be harmful if they give you a drug or something. I am sure that things these days are better but I would be uncomfortable because black people are always prey.

[3] In transcripts, "I" is used to refer to the interviewer-Karey M. Sutton.

AFR-060: I always see those ads on TV, but I don't ever respond. You know those ads that ask for people to volunteer to be in a research study. They look appealing; I mean they offer you money for these things. However, I just don't trust these studies. It seems that the black person is the one who always gets something, like a disease or taken advantage of. I am just too scared.

It should be noted that both of these participants shared in their interviews that they used the Internet and, as a result, they have a lot of information concerning their health—all of which made them more skeptical of research trials. The internet which is often seen as an educational tool reaching out to everyone (minorities included), had the opposite effect in this instance. AFR-016 shared her fears about participating in clinical trials, but she ended her response with some helpful advice to researchers.

AFR-016: I am old and I have never been a part of one of these studies. I am scared as to what may happen. They might take advantage of me because I am old. But I want to try some stuff. I could at least help them find some treatments for diabetes. I just wish they could educate us more. Black people need all the facts in the beginning. I want to know what may happen because of me being in the study.

Clinical research mistrust was described by the following common saying shared by many:

- "They will treat us like guinea pigs."

I did ask who exactly "they" was. I was told that "they" (in this context), referred to "white researchers." Ironically, when I delved further into this distinction, I was told that black researchers could be trusted a little more because of their shared lived experiences. I found this

viewpoint did not correlate with all the trying times I experienced as an African American researcher recruiting African American participants for the study. Other responses were:

- "They will take advantage of us.[4]"
- "They might give us something [e.g., illness]."
- "I just don't trust them."
- "I am scared because I need [to understand] motives [of white researchers]."
- "I am not sure the researchers have my best interest in mind."
- "I need to know who is researching me."
- "I would participate if I had all the information."

Mistrust of white doctors. Participants frequently shared their mistrust of white doctors. Many of the participants in the 30-70 age group explained that they would trust a black doctor more than a white doctor because black doctors would understand their illnesses better. Other comments included:

> AFR-011: It was not mentioned in those terms, but my parents used black doctors, but you would hear a comment on you can't trust so and so, and that is what I heard, but I knew why I heard it later. Cause those men would have been the same age as my daddy. So it was just inborn that you didn't trust those people…the reason why we don't trust is because our parents didn't and they passed that on to us. They knew why they didn't trust them."
>
> AFR-002: I want to think that the black doctor would know more about people more like him/her, he might know about some of my conditions. I have been to a white dermatologist. I just feel more comfortable talking to a black doctor. Our family doctor

[4] For key short quotes, no participant ID will be used.

when we moved to Greensboro was black. I just feel more comfortable talking to a black doctor, I feel like they can relate a little better.

- "Black doctors know my body better"
- "I have had a White doctor before and I just did not think he understood me."
- " I just feel like I am more comfortable with a Black doctor"
- "Some things affect Black people that don't affect white people, so how would a white doctor know about black diseases."

Another factor looming in the discussion of clinical medical research was the Tuskegee Syphilis Study. The ideas about the Tuskegee Syphilis Study's effect on medical research participation were different among the age groups. The older groups, which consisted of those 30 years and old and above, seemed more affected and attached to the details of the Tuskegee Study. Here are the views of a 60 year-old male participant:

ARF-047: That Tuskegee Study was something horrible. I mean those men did not know what was going on. The worst part of it is that the Government had its hand in the study. How can I trust the government, when I know they did that to those men? Not only those men but also what about their wives and children? And that small amount of money the government gave them to say sorry. I am ashamed of that pitiful amount.

AFR-002 (65 year old female): I don't trust anyone. I mean I want to know why they are prying and poking on me. Those men (Tuskegee research subjects) did not know what was happening. That is why black people don't want to be bothered today. I also think that is the reason why we aren't organ donors; I have talked to some people that they are not going to be an organ donor because they won't be protected. But I have to explain that I have a sister in law who had two kidney transplants and others too. It is just what we have heard in

the past that we may not have any grounds to support it now, except to say we don't trust them.

I also found that for some of the younger respondents there was not as much resistance to clinical trial participation. When asking them about their views on the Tuskegee Syphilis study I received responses such as:

- " I am not aware of what the study is about"
- "Is that the study that the movie *Mrs. Evers' Boys* is about?"
- "I am sorry, I am not sure what the Tuskegee study is"
- "I only know about Tuskegee University, I was not aware of a study."
- "Not sure, sorry. I think my father said something about it, but I am not positive about details."

Many of those who did not know about the Tuskegee study were more interested in participating in research.

> AFR-038: I would be willing to participate because I think there is a lot to learn out here. I mean I would educate myself on what the study was about but I am eager to see if there are treatments for diseases. I would also be willing to see what they can produce for future generations. I am not really scared at all. I mean times have changed and things are a little bit better.

This exchange with AFR-038 shows a view held by many of the participants who had no recollection of the details of the Tuskegee Study. The distinction between the views of those younger versus older than 30 was significant. As seen in Table 3, only 25% of the younger group knew about the Tuskegee Syphilis Study, compared to 67% of those above the age of 30.

Table 3. *Participants' knowledge of Tuskegee Syphilis Study*

Age (years)	No. of participants (*n*)	Knowledge about Tuskegee Syphilis Study	
		No.	%
Younger than 35 (OR '18 – 29')	20	5	25
Older than 30 (OR '30 and above')	45	30	67

Aside from mistrust about clinical research because of the Tuskegee Syphilis Study, many of the respondents were misinformed on the details of the study. Of the 65 African Americans interviewed, 23 of them believed that the men were deliberately infected with syphilis as part of the study.

> AFR-058: I think that it was horrible that they infected those men like that. They did not have to do that to them. I think it is so sad, because those men are the same age as my father. Just to think they did not know what was going on and those white researchers took advantage of them.

I went back and re-interviewed some of these participants to see if their view of clinical research participation would change if they had the actual facts. The conversation that I had with AFR-058 follows:

> I: During our conversation last week you shared some of your feeling about the Tuskegee Syphilis Study; you said that you were appalled that the doctors infected those men with syphilis and so you kind of fear participating in clinical trials.
>
> AFR-058: Yes that was horrible what happened

I: Well I did not mention that the doctors did not infect the men with syphilis. The men that were part of the study had syphilis before being a part of the study. The study was to see the effects of syphilis on the black male. Also there were both black and white doctors involved in this study. One of the major flaws was that treatment, which was penicillin, was available at one point of the study and the doctors withheld it. So now that you know some facts does that change your view at all about Tuskegee's influence on clinical trial participation?

AFR-058: No I am still not trusting clinical researchers. Thank you for telling me what really happened. But I am still scared because they withheld treatment.

Mistrust of the government. Another aspect of African American unease with genetic testing and research is their mistrust of the government. The African American interviewees noted that their mistrust of the government stemmed from a history of slavery and racism. The key phrases that encapsulate this kind of concern were:

- "Slavery was horrible and I cannot trust the government because of that."
- "I will not participate in research, because the government is trying to kill all Black people. Didn't you know AIDS was implanted into the Black community? It is a form of racial genocide."
- "Things are still not equal, Racism is real! Why would I participate in research to help white doctors who, probably behind my back, do not like me for the color of my skin?"
- "I don't trust the government. Plain and simple. There is no more to be said on that point."

There was an overall sentiment of anger when talking about the government. The majority of the participants felt that the United States government did not have their best interest at heart. This view was most widely held by those above 29 years of age; gender did not play a factor in this mistrust. One response that brings together all of the responses was from AFR-015:

> I just don't know how to think about things anymore. The more and more I reflect back on the history of African Americans, I see us a being a strong people. I mean we were enslaved for economic profit, separated from our families, given new names, taken from our homeland. Wow!! As a people we have endured a lot. I guess I am a little uneasy when talking about the United States government. Black people have all of these health problems and no one will help us. All they do is put our young people in jail. So you asked me if I trust them, absolutely not. I am not sure what they will try to do to us next.

Religious Concerns. Kibler and Brisco (2006) using a questionnaire with 231 African American undergraduates found that religious beliefs amongst African Americans might be important factors that influence their attitude towards research. Some of the participants noted that "God determines wellness and research does not" and "Illness and death is God's will and are not necessarily affected by research." (Kibler & Brisco, 2006). For many in the study, religious beliefs also influence health care decisions. As mentioned in Chapter 3, only a few of the articles concerning participation in clinical research and genetic testing involved a religious component. Many of the participants I met with voiced the view that genetic testing was like "playing God." When pressed, the phrase was not easily defined by any of the participants who used it. Unlike the categories of mistrust and financial concerns, religious concerns were a view shared by all participants regardless of age. Both the younger and older populations had some issues with genetic testing due to the belief in a higher power.

AFR-008: I have some issues with genetic testing. I mean it is like playing God. If God wanted me to know what diseases I am supposed to have in the future he would let me know. I would rather leave it up to God, he has healing power anyway.

AFR-016: Yes I believe in God and I pray about everything before I do it. Even when it comes to going to the doctor or accepting treatment I wait to pray. Sometimes I think God wants us to use medical doctors but other times I think we rely too much on medicine and not enough on faith.

AFR-005: I believe that God will heal my body totally so sometimes I don't listen to what the doctors say. I feel God knows everything and if I turn it over to him everything will be okay. I don't want to take all of the medicine those doctors have me taking. When I had my stroke, they said I would never regain feeling again on my left side. Little did those doctors know that I have all my feeling again and I play the piano every Sunday at church. You can't listen to those doctors.

AFR-018: Even if I got a genetic test it would not mean anything. God is the ultimate healer so a test couldn't scare me at all because I know who has the final say.

Lack of Knowledge. Lack of knowledge about genetic testing and research was divided into two subsets: the lack of information about genetic testing for disorders, and the lack of information about the existence of research studies. Some of the participants were uneasy about talking about genetics and using the scientific language that goes with it. I felt the apprehension when they would use the terms "gene," "genomics," "carrier," or "genetic information." There

was a lack of understanding as to what that the terms actually meant and how they related to their personal health. This lack of knowledge was not dependent on level of education or age. All respondents had trouble using and understanding some of the genetics jargon. In one interview I asked

I: What is the health problem that you believe you or your family may be at a higher risk of developing?

C: My family has had a lot of high blood pressure and diabetes. Maybe a few heart attacks along the way.

I: Could you explain your understanding of family history?

C: Well umm… my understanding is that it is something that everyone in the family has. It is kind of passed along. But I don't know.

I: Do you think that if a tendency toward diabetes is inherited in your family it may be related to your genes?

C: Our genes? That means we all have it. I don't know, I think it has more to do with our environment and what we eat. We are all heavy people.

This participant was reluctant to regard diabetes as being inherited as a part of her genes. In my field notes, I marked that this participant's tone changed as if she was offended that I generalized that diabetes in her family was genetic. She was more willing to say that the diabetes that many of her family members experienced was because of bad eating habits.

Also a few participants were confused about the procedure for a genetic test. One participant asked if the test was going to hurt. Another participant wondered if this was a surgical procedure. And one also assumed she would have to be put to sleep, and therefore would not undergo genetic testing because of that.

Lack of information about research studies. Some participants voiced the view that they would participate in medical research if the information were made available. This finding correlates with the finding from the Wendler study (2006). David Wendler, research scientist in the department of Clinical Bioethics at the National Institutes of Health, and his research team found that more African Americans would participate in clinical trials if they were asked (Wendler, et al., 2006). About 25 of the 65 African American participants in my study voiced the same sentiment. If only asked or given the information they would participate. However, those who were in the 18-29 years of age group more steadily held this view.

> AFR-017(19-year-old male): It seems that no one ever asks me to participate in a research study. I guess they are assuming that I would not participate. I do not think that is fair. I am not going to volunteer myself. But it seems that if they really need people they would just ask.

> AFR-051(25 year old female): I wish they [researchers] would stop assuming that I don't want to participate because I am black. Research studies for like medicine and stuff are helpful. I don't see why they don't ever ask me when I go to the doctor.

> AFR-041: I don't think that I have ever been asked or seen recruitment just for us [African Americans]. I mean if there were flyers or announcements in places I frequent maybe I would think about it more. I just don't have the information.

Hispanic/Latino Interviews

Demographic information for Hispanic/Latinos. There were 25 Hispanic/Latino participants who varied by age, gender, marital status, education level, and whether they were a

native English speaker or spoke English as a second language. This information was self-reported on a demographic form provided during the consent process (Appendix D). The gender breakdown of the study participants was 72% (18) were women and 28% (7) were men. The ages ranged from 20 to 60 years old with over half (64%) of the participant pool above the age of 29. Figure 2 displays the gender, age, marital status, and education stratification. Of the 25 Hispanic/Latino participants 40% (10) reported they were married, 48% (12) report they were single, and 12% (3) were widowed. Of the 25 Hispanic/Latino participants 40% (10) reported they were married, 48% (12) report they were single, and 12% (3) were widowed.

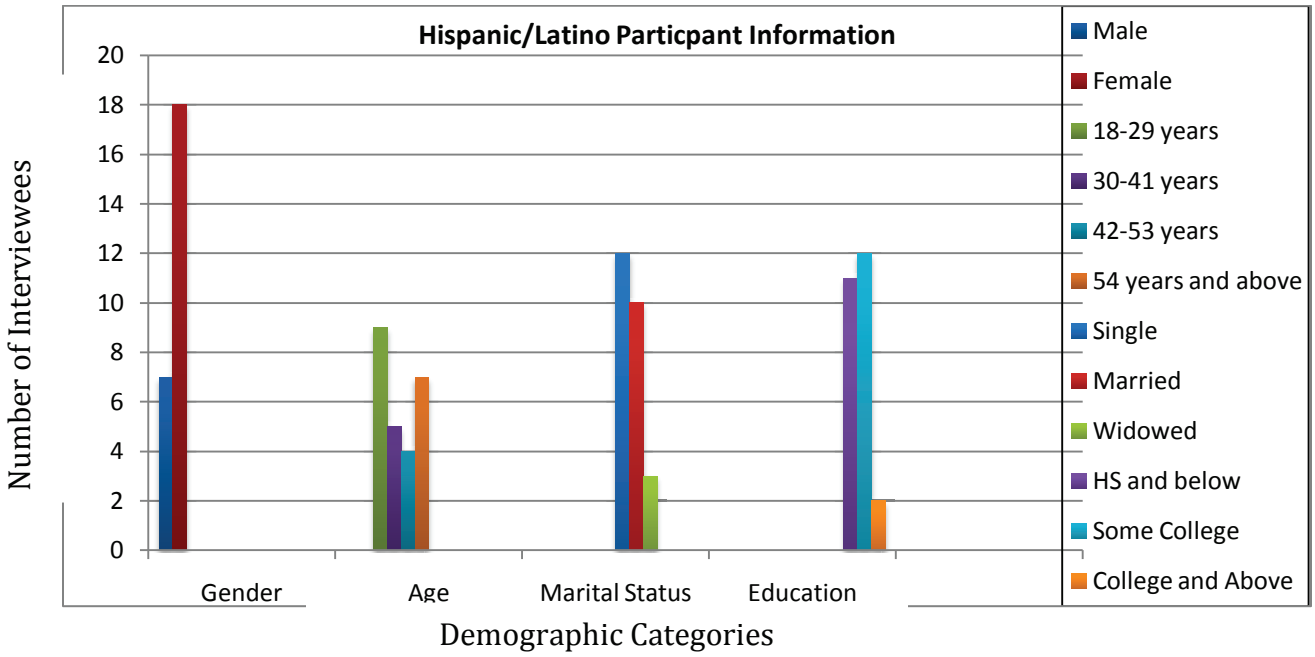

Figure 2. Hispanic/Latino Participant Information

All of the Hispanic/Latino participants self- reported their ethnicity as being the country where they or their parents were born. One participant selected in addition, black as race and Hispanic/Latino as ethnicity. Education level among the participants included, 44% (11) indicated with a high school education or below, 48% (12) who had completed some college coursework, 8% (2) with a college degree and above.

The interviews with the Hispanic/Latino participants were difficult for many reasons. There were challenges with the language barrier. For those participants who were less confident of their command of the English language, I had a translator present. Having an additional person as part of the interview changed the dynamics. In some instances I felt the participant was intimidated by the presence of two people. As a result of this intimidation, some of the responses were short and terse. This could also be due to the language barrier. As mentioned in the demographics section, only twenty-five interviews were conducted with Hispanic/Latino participants. I had hoped for a larger number, but recruitment in this community became overwhelmingly trying because access to this community is very guarded.

Findings and Themes

After initial analysis of the Hispanic/Latino interviews, the same four major themes, identical to those found in the African American interviews emerged: financial concerns, mistrust, religious concerns and lack of knowledge. However, an additional category: of cultural competency emerged.

Financial Concerns. The Hispanic/Latino interview participants were not as worried as to the process of the test, but more about the costs and if their insurance would handle the costs. As with the African American community these concerns were broken up into the same sub-categories of insurance coverage, justification of the costs and perceived benefits.

Insurance coverage. This sub-category was most addressed by the participants. Because of the inadequate insurance coverage among the interview participants they were concerned whether a test would be covered by their insurance. Also almost half of the Hispanic/Latino participants were not insured.

HISP-023: I do not have insurance so I am sure I could not have any form of genetic testing. It is actually scary not to have insurance because what if I get sick? What if my husband is sick? You just feel kind of helpless.

HISP-014: I know my insurance does not cover genetic testing. They take out $70.00 a month out of my check for insurance and I only get the bare minimum. I know genetic testing is not part of it. And without any insurance help I could not get genetic testing.

HISP-008: It is sad. I was sick a few years ago and almost lost everything because I did not have enough money to cover my medical bills. I mean I almost lost my house and car. It is hard to cover the costs for medical stuff when you don't have good insurance. I know I can't get prenatal testing for any kids because I just can't afford it.

Justifying of the costs. Another aspect of financial concerns was justification of spending the money on genetic testing. I found this view to be shared by those Hispanic/Latinos who were above the age of 29 years old.

HISP-025: Things are rough at home. I am barely making ends meet and I just do not see myself spending extra money on genetic testing when I could use the extra money on the house.

HISP-019: I heard from my doctor that genetic testing was expensive. I am not sure I can afford it. My husband will want to know why we are spending lots of money on a medical test.

Percieved benefit. As with the African American group, I asked if cost would be a factor, if the test could benefit a loved one? All of the 25 participants, without hesitation, would have a genetic test. Here are some of the key responses:

HISP-007: If I can do something to help my kids I would. I know I don't have insurance and would have to pay for everything out of pocket, but I don't care. I would do it so they would have a solid future. Genetic testing can't cost that much, right? If I had to get a second job I would.

HISP-019: This is an easy question to answer. Cost does not matter when I am getting something from it to help my family. My family has a lot of cancer and I would want to do something that could give information to our younger generations.

HISP-015: There is not a price for the love I have for my family. I would pay anything for a test if it would benefit my family. I mean I guess I would have to think about it some. I mean how I am going to pay for it, but I would want to do it for my family.

The responses concerning finances were similar to the African American interview responses. However, there were more concerns among the Hispanic/Latinos concerning insurance coverage. As noted earlier, a majority of the participants lacked health insurance coverage.

Mistrust of the government. The next emerging theme with the Hispanic/Latino interviews was the theme of mistrust. The analysis of the African American interviews also revealed a theme of mistrust. Unlike the African Americans, Hispanic/Latino participants indicated a mistrust of governmental policies related to immigration rather than policies due to

slavery, racism, and the Tuskegee Syphilis Study. Hispanic/Latinos have no Tuskegee Syphilis Study as part of their history, but recently the details of the Guatemalan Research Study were revealed (Landau, 2010). Between the years of 1946 and 1948, Dr. John C. Culter, a U.S. public health service doctor, conducted experiments on hundreds of Guatemalan people. Many of those experimented upon were male prisoners and wards of the mental institution. Dr. Cutler was studying whether penicillin, a treatment for syphilis, could also be used as a preventative method if administered directly after exposure. Dr.Culter's research team knowingly used prostitutes infected with syphilis to expose the men to the bacteria. In cases, where more disease was needed, researchers injected the male with the syphilis-causing bacteria. Eventually, penicillin was given as a treatment. It is not evident if that was a cure. Recently, a public apology was given by Secretary of State Hillary Clinton and Health and Human Services Secretary Kathleen Sebelius. I am not sure if this would affect the participant views now and this would be an area of exploration for the future. There was not an overall feeling of mistrust of clinical research itself, but more a mistrust of who had access to the results.

When asked about participating in genetic research and mistrust of the government the responses were:

> HISP-021: Some Hispanics don't trust the government. I am sure you have heard that some are not here legally and fear that they will be sent back. America is so much better than other places that they are from. Luckily, I was born here but I am sympathizing with family and friends. There is a lot of discrimination and people are so mean. Why would you trust anyone? My nieces and nephews are more willing to trust because they have been shielded from how cruel the world can be. I am sure when they get a taste of reality they will lose their trust also.

HISP-012: I have family members that are over here that should not be. They will not put their money in the bank, we have to cash their checks, and they refuse to go to the doctor. I mean it is like they are living in hiding because of fear being sent back.

HISP-020: I fear that one day the police will knock on my door and take some of my family away. They have been here for so long, that they should be able to stay. I would not want to participate in anything that will bring unwanted attention to us.

HISP-025: I am not scared of the test itself. I would like to have a genetic test one day. But I know the government will be able to get the test results some way. I fear what will happen with the test results.

This mistrust of the government due to immigration was a view commonly shared by those who were above the age of twenty-nine (10 of 16 above the age of 29). None of the participants who were in the 18-29 age groups had mistrust issues due to immigration concerns.

Religious concerns. In the Hispanic culture there is a saying "Ayudate que Dios te ayudara", which translates to "help yourself and God will help you." Medicines are often shared. Many drugs are available over the counter in Latin American countries that are not in the United States. With the absence of healthcare access, many Hispanic/Latinos use folk healers instead of health care providers or sometimes both. Mexican Americans use the term "curanderismo," which means "God gives the gift of the power to heal to the curandero/curandera." Puerto Ricans use the term "espiritismo," which means the world is populated with spirits and those spirits can heal the ailments of your body.

When asked about the influence of religion on health care decisions, the following responses were received:

> HISP-002: I am just a little uneasy about what to think about making certain health care decisions without consulting God. I mean if we are talking about genetic testing. What happens if the baby is found to have something life-threatening? I am a Catholic and I don't believe in abortion. But I also don't want to bring a baby into this world that will not have a good quality of life. I just don't know what to do. Maybe I just should rely on God and not worry about what the doctors think they can tell me.

> HISP-010: I don't know what to think about genetic testing. There is something inside of me that thinks that it is wrong. I am not sure all of this testing stuff is good. I think it goes against my religion and I will just continue with my prayers.

> HISP-009: God is my healer. I feel that genetic testing will give me small [amounts of] information about health. I am afraid what to do about it. I would not want God to be angry that I am trying to see the future.

The views about religion and health care in general were shared among all ages and genders. Most of the participants also shared something about their religious views concerning genetic testing. A belief in a higher power affected their views, but as stated in the literature, folklore beliefs surround health and healing influence views also. Hisp-005, an older Puerto Rican woman, often referred to herbal healing aids instead of going to the doctor. She shared that she would rather use something from the earth as a possible treatment than use an artificial medicine from the pharmacy. She did not really understand the role of genes in our body, but she did embrace the idea of family history and what it may add or take away from overall health.

These ideas of interactions between religion and genetic testing were slightly different from those in the African American group. The phrase "playing God" was not used specifically, as it was by African Americans, but some of the responses implied the same sentiment. Many of the participants were more concerned with the intense struggle between religion and prenatal testing. What do you do with undesired results from prenatal tests? None of the interviews with African American participants touched on the subject of abortion in response to prenatal testing results.

Lack of knowledge. Another category emerging out of both the African American interviews and the Hispanic/Latino interviews was lack of knowledge of genetic testing. There was a lack of understanding of the terms used in genetics. Especially, for those without a strong English background, translating "gene," "clinical," and "genomics" into Spanish can be difficult. I experienced this when, as part of the interview, the terms would have to be explained further in Spanish in order for the participant to understand. Oftentimes the terms were explained with simple English to Spanish translation and in other instances the terms took longer to explain, which made interviewing the non-native English speakers a tedious process. This lack of knowledge was not dependent of education level or age. This concern was voiced across all categories of stratification.

> HISP-013: I can honestly tell you that I am not confident when talking to the doctor about genes and stuff. I do not understand what a gene is. I mean I didn't do well in my high school science classes.
>
> HISP-006: I don't know enough about genetic testing or research to participate. I feel like I need to take a seminar or a class in order to be a part of a study. I don't understand.

Other responses included:

- "I am not sure if I understand the terms."
- "Sometimes, I think it would be easier if things like this were explained in Spanish, maybe I would understand."
- "Rarely do I find information that is in both Spanish and English. What is a gene?"
- "Because I don't understand, I choose not to do it [genetic testing]."

This category of lack of knowledge did take a different direction than the African American interviews. The Hispanic/Latino interview responses were more concerned with understanding the terms, and did not focus much on research participation. This aspect of lack of knowledge led into the last emerging category of cultural sensitivity in genetic testing and research to participate in medical research.

Cultural competency. A new area emerged out the Hispanic/Latino interviews that was not evident with the African American interviews. Hispanic/Latino participants voiced concern over the lack of cultural sensitivity in medical practice. Many of them, who were not native English speakers, were overwhelmed with grasping certain terms belonging to the English language.

> Hisp007: I am not sure if I understand all the time what the doctor is telling me. I mean I am wondering if should sometimes have a translator in the room when he is giving me a diagnosis or something. It is not fair because I often come away from doctor's appointments confused and not understanding what to do.
>
> HISP-003: It is hard to understand what the doctor is talking about. Sometimes I wish there was something written so that I could understand. I mean I am comfortable with English, but my parents have a hard time during their visits. I don't want to have to go to all of their appointments because they can't understand.

HISP-001: I think medical schools should train more Hispanic doctors. It would be good to have a doctor that shares the same heritage as me. I would feel more comfortable, talking about my medical problems.

HISP-011: I feel that the government spends so much money on blacks that they forget about us. There is more effort to have more black doctors but what about having more Hispanic doctors. It is not fair. We need more Hispanic doctors or more people to speak Spanish in the doctor's offices.

Other key responses were:

- "Everyone should learn to speak Spanish in a doctor's office."
- "We need more Hispanic/Latino researchers."
- "You [Karey M. Sutton] should learn Spanish, so you could translate for yourself."
- "I'd rather have someone who understands my culture to do research on my people."

All of the Hispanic/Latino participants were interested in increased numbers of Hispanic/Latino doctors. A majority of the participants felt that by having someone who understood their culture, they would receive better care. This view was also shared by some of the African American interview participants regarding their preference for an African American doctor.

In Summary

Interviews with African Americans and Hispanic/Latinos showed the same four main thematic areas: financial concern (mitigated when there are clear family benefits), mistrust, lack of

knowledge, and religious concerns. An additional theme emerged in the Hispanic/Latino group: cultural competency. Within these themes, several subsets emerged. Naturally, if these findings are to be used as the basis of health-policy decisions, they will need to be checked and verified on larger samples. It would be appropriate, at this stage, to employ qualitative methods to gauge the full extent to which these identified themes are held within the two minority communities.

Nonetheless, when it comes to promoting the consideration of genetic testing by minority groups, African Americans and Hispanic/Latinos in particular, these findings do offer some tentative insight. In the next chapter, I provide recommendations for policies based upon the information gathered from interview analysis with regard to genetic testing in clinical settings and genetic research in scientific settings.

CHAPTER VI
CONCLUSIONS AND POLICY RECOMMENDATIONS

As evidenced by my research and previous studies, African Americans and Hispanic/Latinos are hesitant to participate in both genetic testing and genetic research studies for various reasons. With the information learned about these influential factors of mistrust, financial concerns, and religion I address these major concerns with policy recommendations and also indicate areas for improvement. The policy recommendations are separated into two sections, one pertaining to recommendations concerning genetic testing and one section pertaining to recommendations concerning genetic research. In each section I provide not only programmatic suggestions that deal with the concerns which arose in the interviews with the African American and Hispanic/Latino participants, but I also include strategies on effective recruitment of members from minority communities for research studies. Furthermore, because of the swift progression of the field of genetic, I conclude with how researchers, medical clinicians, and public policy makers can collaborate to create more effective policies with genomic applications.

Genetic Testing Recommendations

When promoting consideration of genetic testing by minority groups, African Americans and Hispanic/Latinos in particular, the findings from Chapter 5 offer some insight. Four identical thematic categories emerged from both the African American and Hispanic/Latino community interviews. They were mistrust, financial concerns, lack of knowledge, and religious concerns. One additional category of cultural competency emerged from the Hispanic/Latino interviews. The interview findings provide a link toward policy recommendations for genetic testing.

Mistrust

There were varying levels of mistrust among African Americans. This mistrust was directly dependent on age. The younger age bracket, those from 18 to 29 years of age, were less attached to the experiences of the Tuskegee Syphilis Study and therefore did not express high levels of mistrust related to it. In contrast, over half of the participants who were 30 years old and above knew some history of the Tuskegee Study. These findings suggest that the Tuskegee Syphilis Study is not the main reason for mistrust among all African Americans. It would seem to be inappropriate to throw up one's hands and say that the legacy of Tuskegee is an insurmountable barrier keeping African Americans away from genetic testing. Awareness about other issues such as the existence of racism, discrimination, age and other societal determinants can also be factors associated with mistrust. Health-care professionals, including doctors, nurses, and genetic counselors would be remiss in counting out African Americans because of mistrust. Because of the age difference in levels of mistrust, the medical institution could tread lightly when dealing with individuals who are older than 30 years old. Genetic counselors should be cognizant that the Tuskegee Syphilis Study may still be lingering in the minds of older African American individuals. To bridge this mistrust of genetic testing, especially for older African Americans, having a trusted person involved would seem to be crucial. Hence the pre-testing education with a trusted individual involved can be essential to establishing the rapport with African American individuals of all ages.

Most of the participants regardless of age had some form of mistrust of white doctors. The presence of more African American genetic counselors, doctors, and nurses can potentially bridge the trust. Such a recommendation would also apply to Hispanic/Latino individuals. The development of programs that promote the increased numbers of African American and Hispanic/Latino doctors can be beneficial. A typical pipeline program for increasing the number

of minorities in medicine would begin during the 7-8th grades. It is during those grades that students begin to take their prerequisites for high school science and math courses. Also it is during 7 and 8th grade that an interest into a medical career can be cultivated by summer programs and additional after school mentoring. After interested students are indentified, then during the high school years an intensive mentoring process should begin. African American and Hispanic/Latino students who show an interest in the medical field are then placed in programs to expose them to different medical careers and paths. As an incentive for participating in such programs, financial aid for college might be given to those students who graduate from high school and attend a 4- year college. Such a pipeline program would be similar to that of the U.S. Department of Education program, Upward Bound. Upward Bound is a collegiate preparatory program that serves, low income families, and high school students' families where neither parent holds a bachelors degree. The goal of Upward Bound is to provide these students with experiences and training to get them prepared for the collegiate level. An unique component of Upward Bound programs, is that they are administered and housed at particular universities. Therefore, students completing the Upward Bound program at a particular university, for example Virginia Tech, are often given scholarships and financial aid for them to attend (U.S. Department of Education, 2010). I propose that these types of programs should reach students before reaching high school. And furthermore, provide additional experiences during their collegiate years.

While in college African American and Hispanic/Latino students could be placed in programs where they can continue receive mentorship from minority doctors and genetic counselors. The African American and Hispanic/Latino doctors and genetic counselors already in practice could provide educational resources to the students about medical training and tools

needed for study at the next level. Hence this pipeline approach will potentially allow for interested African American and Hispanic/Latino students to be identified at an early age and provide them with training, and tools to move into a medical career.

Both African Americans and Hispanic/Latinos had concerns about trusting White doctors and medical institutions, in general. During the past five years, direct to consumer (DTC) genetic testing has emerged as a viable (Genetics Public Policy Center, 2006). Direct to consumer genetic testing is genetic testing completed in the absence of genetic counselors or medical advice. The tests are as the title suggests, from the supplier to the consumer, without the middleman (Javitt, Stanley, & Hudson, 2004). Because of the existence of such mistrust among African Americans and Hispanic/Latinos of medical doctors, DTC genetic testing may become more popular for minority groups. DTC genetic testing will allow those minority individuals who are concerned about a particular genetic disorder to obtain their genetic information without ever seeing a doctor. Of course, DTC genetic testing does present dilemmas to both the medical consumer and doctor. As indicated in my findings in the previous chapter, understanding genetic information was extremely difficult for both African Americans and Hispanic/Latinos, Thus, the difficulty would remain for deciphering the information provided from a direct to consumer genetic test. I propose more comprehensive regulations be developed so that individuals are protected against potential misuse from direct to consumer genetic testing companies. These regulations would include protections for privacy of information, protections from the misuse of results, and mandatory educational component to accompany all DTC genetic tests.

The Hispanic/Latino interview participants shared that their mistrust exists due to concerns about immigration. This fear was widely felt by those 30 years old and above. None of those in the 18 to 29 year old bracket voiced concern about immigration. To alleviate this

concern, Hispanic/Latino individuals must be reassured that their genetic and personal information will not be shared with government agencies. This reassurance can be accompanied by providing information about the Genetic Information Non-Discrimination Act of 2009. The Genetic Information Non Discrimination Act of 2009 (GINA), is one of the first federal laws proposed to protect consumers from discrimination in the areas of the workplace and health insurance (Genetic Information Nondiscrimination Act of 2007 , 2007). GINA addresses the concerns raised about the gaps in the Health Insurance Portability and Accountability Act (HIPAA) guidelines. It prohibits the usage of genetic information by health insurance plans to adjust the premiums costs and coverage. It imposes high monetary penalties against companies who violate the law. However, GINA does not cover disability insurance or long-term care insurance. Even with GINA in place, there is still apprehension towards genetic testing. However, this federal regulation is a starting point for protecting those individuals who may be fearful about the misuse of genetic information (Genetic Information Nondiscrimination Act of 2007 , 2007).

Financial Concerns versus Overall Benefit

The African American participants voiced concerns about the adequacy of their health insurance coverage. This view was widely consistent among those belonging to the 18 to 29 year-old age bracket. Hispanic/Latino interviews revealed similar concerns about finances. The details about health insurance can become difficult to understand for medical consumers. As part of the genetic counseling pre-test assessment information, a guide can be developed on how to claim genetic testing procedures on health insurance. Another part of this guide would include an overview of what genetic testing procedures major health insurance companies cover. This

guide would be similar to the summary of benefits which is provided as part of any health insurance plan.

Many of the African American and Hispanic/Latino participants stated that they could not justify spending money for genetic testing. However, both African Americans and Hispanic/Latinos also said that they would participate in genetic testing[put a comma here] regardless of cost, if there was a clear perceived benefit for their family or children. Genetic counselors, nurses, and doctors should outline what are the possible risks for genetic testing but also explain the benefits, if any, for both the individual and family. These risks and benefits should be clearly outlined during the pre-test counseling so that the minority individual leaves with an understanding of what can be gained from genetic testing for a particular disorder and how it may impact one's family.

Assess to genetic testing regardless of income level is important to alleviating health care inequities. As mentioned in Chapter 1, African Americans and Hispanic/Latinos are the most likely to be uninsured of all racial groups. Even if a genetic test was covered by health insurance, for those who are without insurance, genetic testing may not be a feasible option. I propose developing a subsidy program for genetic testing for qualified individuals. Individuals qualify for the program based on health insurance coverage, income level, and the particular genetic test of interest. The program would discount genetic testing for those showing financial needed and without adequate health insurance coverage. An example of an existent genetic screen subsidy program is the one used by the Chicago Center for Jewish Genetic Disorders. The funding for this program comes from the Jewish Federation of Metropolitan Chicago and Integrated DNA Technologies and works in conjunction with various Jewish community organizations across the city of Chicago. This subsidy program offers screening four times a

year for those of Ashkenazi Jewish descent and has not been screened before. Since 2002, the Chicago center on an average screens up to 200 people per year. The program screens for disorders such as Tay Sachs, cystic fibrosis, and Bloom's syndrome, which are disorders that affect large numbers of those of Ashkenazi Jewish descent, but does not screen for cancer genes. As mentioned in Chapter 2, genetic testing can be very expensive. As part of the program, they charge $110 per screening and $54 for full time students. In addition to screening, each person is provided with a dinner and also a genetic counseling session (Jewishgenetics.org, 2010). Similar programs have been established as part of the Jewish Genetic Diseases Center of Greater Phoenix and Pittsburgh. These programs screen an average of 600 to 700 people a year (Tabachnick, T, 2010).

Much can be learned from this community based screening program and is applicable to other minority communities. A program such as this in the African American community could provide screening for diseases such as sickle cell anemia which affects African Americans at disparate rates. Also using a community-based approach to screening, could be an avenue for building trust between clinicians and African American community members. I address this sort of community engagement practice in the latter part of this chapter. The limitation to any type of subsidy program is obtaining and maintaining funding to offer services to those in need. Are there funding agencies that will provide grant money to establish programs such as the one created by the Chicago Center for Jewish Genetic Disorders? In order for a subsidy program to be effective would need the financial backing of either nonprofits, government agencies, or genetic technology companies to ensure as many individuals can receive aid as possible.

Lack of knowledge about genetic testing

Many African Americans voiced concern about their lack of knowledge of genetic testing procedures and technology. The Hispanic/Latino participants were not concerned with the genetic testing procedures, but more with understanding genetic terminology. The educational component about genetic testing can be strengthened in various ways. There is concern about understanding the scientific terms associated with genetic testing. Education about genes, chromosome, and family history can begin before adulthood and be part of the school curriculum. The U.S. Department of Education has implemented the Science, Technology, Engineering, and Math (STEM) education coalition, to promote programs for teachers and students in STEM related fields. The STEM education coalition could be the avenue to promote a more comprehensive approach to teaching about genetics and family history. The overarching goal should be to educate individuals at an earlier age in hopes of when they reach adulthood they have retained some of the information, and are better informed medical consumers concerning genetics.

In addition to the school educational component, doctors, nurses, and genetic counselors should be trained on how to effectively and efficiently communicate highly scientific content to the lay public. One approach would be developing pamphlets and reading materials that carefully explain terms and provide genetic testing case scenarios to which people may relate. In the case that reading may be an obstacle for some individuals; an educational video can be used. The videos and reading materials should be culturally sensitive. For example a video or pamphlet for African Americans should cite genetic disorders that are more prevalent in African Americans i.e. sickle cell. The Hispanic/Latino educational tools should be translated into Spanish and should showcase people of Hispanic/Latino descent.

Religious Concerns

Strong spiritual convictions were expressed by all African Americans regardless of gender and age as they were in the Hispanic/Latino interviews. However, in the Hispanic/Latino interviews the issue of abortion in response to unfavorable prenatal testing results was mentioned a few times. This topic did not arise in any of the African American interviews.

Genetic counselors and clinicians should be constantly aware that religious beliefs do play a role in the medical decision making of individuals. Some would automatically assume that African Americans and Hispanic/Latinos may refuse genetic testing for other reasons such as mistrust and financial concerns, when religion may very well be the most influential factor. Therefore, it is up to genetic counselors and doctors to be sensitive to the religious beliefs of others. As part of the comprehensive health history questionnaire given to a person before medical treatment, a section dealing with religious denomination should be included. In this way the doctors could become aware of the religious background of the patient before testing is discussed. However, it is the responsibility of the medical institution to become educated on the beliefs and practices of different religions so that they are sensitive to the backgrounds of others.

Cultural Competency

As indicated in chapter 5, cultural competency was an additional thematic area unique to the Hispanic/Latino interviews. The participants voiced the need for cultural sensitivity in health care. Cultural competency in genetic testing covers many different areas. Hispanic/Latino participants were concerned about language barriers. In order for this to problem to be rectified I propose that genetic counselors and doctors working with Hispanic/Latino individuals on a regular basis should be able to speak Spanish. To require doctors and nurses to learn Spanish, is an enormous requirement. But according to Glenn Florres, pediatrician at Children's Hospital of

Wisconsin, misinterpretation due to language barriers can have damaging effects. Those who have limited English proficiency often rely on the interpreting skills of a family member, most likely a child under the age of 15 (Florres, 2006). Children have not had specialized medical training in translating and explaining medical terminology, and how to explain sensitive issues. I do not see the benefit and appropriateness in having a child communicate to his/her mother about the risks of having a baby with a genetic disorder. By being able to speak Spanish, genetic counselors and medical doctors can more effectively communicate about the risks and benefits of genetic testing. The language course could be offered as a part of continuing education coursework to remain certified. Furthermore, eliminating the language barrier could in turn alleviate the problem of the lack of understanding about genetic testing because of the scientific terms.

Additionally, under the umbrella of cultural competency regarding genetic testing is training more genetic counselors, nurses, and doctors who are of Hispanic/Latino heritage. A concern from Hispanic/Latinos I interviewed was that there were few doctors that understood their culture. This pipeline approach mentioned earlier in this chapter can be helpful in addressing this concern.

Genetic Research Recommendations

The findings from Chapter 5, also offer some insight into the underrepresentation of African Americans and Hispanic or Latinos in genetic research studies. The thematic areas also point us in the direction of potential policy recommendations that can aid in the increasing the number of minorities in genetic research studies.

Mistrust

The African Americans and Hispanic/Latinos participants were mistrusting of participating in genetic research for various reasons. Once again we cannot automatically attribute the mistrust African Americans have for genetic research studies to the Tuskegee Syphilis Study. When recruiting African Americans for genetic research studies, one must be aware that older generations are more attached to the lingering effects of Tuskegee Syphilis Study than are younger African Americans.

The Hispanic/Latino participants voiced concerns about participating in genetic research because of immigration concerns. In this instance the importance of a well developed informed consent process and document is needed. During the recruitment process the Hispanic/Latino participant must be reassured of what the study will involve, who will have access to the information, and how will privacy be protected. These components of the informed consent process must voiced on paper and verbally prior to any research study.

As I have learned during this research, in minority communities other dynamics are involved that influence the perception of a scientific technology. Moreover, there are numerous factors that play a part in why African Americans and Hispanic/Latinos are underrepresented in genetic testing and research. Some of the barriers to research participation for African Americans are mistrust due to the Tuskegee Study, lack of understanding of the research study, fear of racial discrimination. Hispanic/Latinos are often cited as being mistrusting of research participation because of mistrust of the government due to immigration concerns and the existence of language barriers. To overcome these many barriers, I would suggest that there be a process of "community engagement". Community engagement is not a brand new idea. It is routinely used in public health research. Community engagement models have often been used in

recruitment of participants for studies involving human immunodeficiency virus (HIV). The premise in public health research is to forge a lasting relationship with the community of interest. Such an extended relationship allows the researcher and the community to learn from each other. Additionally, with the partnerships, if there is a direct outcome from the research, the researcher would ensure the community studied would benefit (Alvares, Vasquez, Mayorga, Feaster, & Mitrani, 2006). Active engagement of the community has led to more relevant and successful interventions to improve health. This type of model could be extended to include other forms of research, including genetic research.

When designed properly, community-academic partnerships I am suggesting could overcome historical distrust and begin to bridge cultural gaps by engaging and empowering historically marginalized communities. Community- academic partnerships can draw on the strengths of both partners. Community partners can be seen as the gatekeepers of their community. They are knowledgeable of the needs of their community, what resources are available, and how communicate and research their community members; whereas academic partners exist to provide expertise in research and scientific methods. In this type of research partnership, both the community and academia benefit. Academia can gain knowledge from the community engagement and the community could benefit the outcomes of the proposed research studies (Alvares, Vasquez, Mayorga, Feaster, & Mitrani, 2006).

Partnerships in the African American community can begin with trusted institutions such as the African American Church. Because mistrust is a major issue looming within the African American community, using a trusted place such as the African American Church as an avenue for recruitment may be beneficial. This partnership is essential in engaging the African American community. The black church has historical significance and overwhelming

influences within African American community. It exists as an entity surrounded by the community it serves. The African American Church is unique because it serves as more than a place of worship and spiritual growth. Health disparities are often conditions created due to unequal levels of social power, financial resources, and political influence. Thus, the Church, a known powerful player in social change, can be seen as an essential partner with health-care research. By forming these partnerships with trusted organizations in communities of color it is also important that we are fully aware of historical barriers of distrust with any research institution. Using faith based organizations, such as the African American church, allow for a reach across a broad spectrum of people, to build a foundation of trust with community members, and also it is an avenue for addressing health care concerns such as health disparities in communities of color (Campbell, Hudson, Resnicow, Blakeney, Paxton, & Baskin, 2006).

Though the African American Church may be a valuable location for recruitment, researchers must be mindful of the type of studies for which they are recruiting. For example, recruiting African American participants for a HIV prevention study through the church, may not yield many participants because of stigma associated with HIV and fear of religious persecution. Researchers must also be cognizant of the responses they may receive from those recruited from the church. A limitation of a study using participants recruited from the African American Church is the participant responses may be heavily swayed by religious influence. This is only a slight limitation when faced with the extreme difficulties of obtaining adequate numbers of African Americans to participate genetic research studies.

Financial Concerns

African Americans and Hispanic/Latinos did voice financial concerns about participating in genetic research studies. However, as part of the recruitment strategies I propose later in this

chapter, financial compensation is a useful tool when recruiting subjects from minority communities. Additionally, by offering payment for participation, I was able to make the study more appealing. Each participant was given a $10.00 gift card to stores such as Walmart, Target, or Kroger. Though most particpants stated they would have participated in the research study without payment, they were grateful for some form of compensation. The amount of compensation should be appropriate for the research study and not an amount that can be seen as coercive.

Lack of Information about Studies

In my interviews, the African American and Hispanic/Latino participants shared their views on the lack of information about research studies. In the African American interviews[put a comma here] those in the 18 to 29 year-old age bracket were more eager to participate in a medical research study. They also voiced they would be more willing to participate if only asked. The standard way researchers currently ask those from minority communities to participate (indeed, the ways I used at the beginning of this study) may not be productive. Different approaches such as face to face communication, additional follow-up phone calls, or other forms of contact may be needed in order to effectively recruit minorities for research studies.

Both African Americans and Hispanic/Latinos voiced concerns about their lack of scientific understanding about genetic research studies. Insights into African American and Hispanic/Latino creation of scientific knowledge are offered when exploring models used in the field that has become known as the "Public Understanding of Science".

"The Public Understanding of Science" is a significant area of Science and Technology Studies. As the engrained behaviors of scientists changed, the relationship between science and the public also changed. The traditional laboratory scientist would often isolate him or herself in

the laboratory and communicate only with those in the scientific world, those seen as scientific equals. However, over the last twenty years, scientists have felt compelled to share results with the public. Sociologists Jane Gregory and Steve Miller call this the new commandment of scientist, "thou shalt communicate." Having the public's acceptance of a scientific technology or findings builds legitimacy for the results and can be seen as a tool of accountability for the scientific researcher.

The traditional model for the public understanding of science, for this communication, is linear in design. As it is usually designed, scientific experts meet with lay community members to educate about a new technology or scientific theory. Once a perceived scientific understanding is achieved, it is assumed that the public will be in awe of the marvels of science learned and will be more accepting of the science. Geoffrey Evans, social scientist at Nuffield College, and John Durant social scientist at the Imperial College of London (1995), surveyed over 2000 people in Britain to explore the relationship between scientific knowledge levels and the attitudes towards science. They found in their study that increased scientific knowledge levels can be an indicator of a more supportive level of science. However, this support level was not for science in general, but for scientific issues of moral and personal relevance. Social influences such as class, gender, age did have an effect on the support levels also. In their article, Evans and Durant exposed a key issue: scientists and policy makers cannot rely on the presumption that a better informed public is a public that will be more supportive and accepting of a scientific technology. Social categories in conjunction with knowledge levels certainly play a role in the acceptance. In chapter 3, I presented literature such as the Hipps study and Hughes-Halbert study that suggest lack of information concerning breast cancer genetics in an influential factor for why African Americans are underrepresented in genetic testing. Furthermore in

Chapter 5, the interview analysis yielded results indicating that the lack of knowledge was a barrier to genetic research for both African Americans and Hispanic/Latinos community members.

We are faced with the predicament of how can scientific knowledge effectively be shared with the ALL of the public? There must be more efficient ways than the methods of the researchers in the Harvard Recombinant DNA study of 1977. Scientists wanted to involve the public as a means of input and also as a method for accountability. However, in order to involve the public in such a specialized area of research, the scientists had to educate the lay community about the science. The scientists set up booths every Saturday morning at the Market in Kendall Square to educate the community members about DNA, explain genetics, and molecular structures. "Science was literally taken to the citizen ((Mendelsohn, 1984, p. 324)." This sort of introduction to the science may work for some communities, but may not be applicable to all. In order for all interested communities to be engaged, it is essential that a new model be designed.

In addition to the community engagement models proposed, I also recommend additional strategies for recruitment. Much of what I have drawn from this research is that the voices of minorities are often silent in health care forum. I have learned that recruitment and access to these communities is very guarded. With the new era of genomic medicine arising, it is crucial to identify how to diversify the particpant pool for clinical research. Because of the obstacles faced during recruiting, I developed strategies that may be useful to others for recruiting research subjects in a minority community . Though this is not an exhaustivie list, these are helpful tools I picked up along the way, that may be useful when designing a study where African Americans and Hispanic/Latinos are the target populations. These may well work for other minority populations.

Belonging to the community that you are studying does not automatically grant you access to that community. Being an African American woman, I automatically assumed that recruiting in the African American community would be fairly easy. I found that, though I see myself as being unthreatening and caring, I was not seen that way through the eyes of potential participants. Because they did not know me as a person, I was seen as an outsider to the ethnic community of which I am a member. The role of being an outsider was unsettling and often uncomfortable. I could not understand why people would not want to talk to me. However, the information shared in the individual interviews illustrated that African Americans and Hispanic/Latinos of this study would be more comfortable with someone they could trust and understand. The key point is to treat each person as an individual, while recogonizing cultural and ethnic similiarities.

Sometimes it is more effective to step outside the box. Creativity is key. In research we often become accustomed to operating under set procedures. Methods such as recruitment, survey design, and interview protocols are designed by referring to textbooks and are the same for each study. This can be problematic seeing that all studies are not the same and there are differences among research populations. Concerning the recruitiment of subjects for my reasearch project, I began my journey using the procedures that are typically used for this kind of study. However those traditional methods did not work for me. Therefore, I had to brainstorm and revise how I could effectively reach the African American and Hispanic/Latino communities. I must say that sitting inside hair salons, barbershops, or restaurants was not "typical," but, by doing so, I was able to provide a face and establish trust for those interested in participating in the study.

Gatekeepers are real and are often the best means of access to your desired particpant population. If it were not for the prescence of helpful gatekeepers I wou ld not have been able to

enlist any participants. The institutional gatekeepers granted me access to their constituencies. The church pastors allowed me to talk to their congregations for recruitment. The hair salon owners and barbershop owners allowed me to talk to their patrons. Moreover, restaurant workers and the participants' family members allowed me to talk to those they knew who fit the research criteria. Using the gatekeeper method is extremely effective with minority communities. It is important to first establish rapport with the gatekeeper in order for him/her to help you gain participants.

Religious Concerns

As noted earlier in the chapter, religion plays an influential role in the medical decision making of African Americans and Hispanic/Latinos. Because members from these two communities may opt not to participate in a genetic research study, it does not mean they are not interested. There could be factors such as religion that may sway them not to participate. Researchers should be sensitive to the religious backgrounds of those participating in their research study.

Cultural Competency

The Hispanic or Latino individuals I interviewed raised concerns about cultural sensitivity in medical research. This particular community could also benefit from the addition of a Lay Health Advisor (LHA). Such an individual has been used in the field of gerontology when educating individuals about Alzheimer's disease. Also LHAs have been utilized as part of a model for community health promotion. This model argues that for health conditions to change there must be interventions on the individual, social, and organizational level. LHAs are informal advice givers. The premise behind a LHA is that individuals are more willing to seek out advice from someone resembling them, rather than approach a professional. A LHA serves

in the role to use their expertise and knowledge to benefit the health care of their community. A LHA may organize community activities, collaborate with the professional medical community, but most importantly bring awareness to their respective communities about health. LHAs help develop culturally appropriate interventions and also are a means of activating social change because of their inherent role of being the liaison between their community and the medical community (Rhodes, Kristie, Zometa, & Bloom, 2007).

Implications for Future Genetics Policies

Science policy in the area of genomics is constantly changing. With the progressions in genomic research, there are concerns about the applications of the old and the newly developed genetic technologies. Even with federal legislation in place, there is still concern that employers may use genetic tests to discriminate against their employees. Additionally, there are concerns about the protections for human subjects involved in the use of some genetic technologies (Sharp, R.R., Yudell, M.A., Wilson, S.H., 2004). Without this assurance of proper protections, it will be difficult to recruit minority participants, where mistrust is already problematic. Human subjects' regulations as outlined in the Belmont report and codified into federal regulations (45CFR46) were developed before the rapid advancement in genomics. These concerns fuel the need for regulations and policies in the area of genetics.

The National Human Genome Research Institute (NHGRI) of the National Institutes of Health has a division devoted to studying the ethical and societal implications of genetic applications. This division, the Ethical, Legal, and Societal Implications (ELSI) research program, plays a pivotal role in NHGRI. There is much to be learned from ELSI researchers about implications of a particular genetic technology such genetic testing. Thus, I propose that policy makers and laboratory scientists work in conjunction with ELSI researchers in developing

genomic policies. These policies could include protections for vulnerable populations, regulations against potential misuse of information gained, and also policies ensuring equal access for all populations. Scientists, policy makers, and ELSI researchers must have a mutual understanding of each other's work so that research can translate from clinical application to community practice in hopes of improving the health conditions for all, regardless of race or ethnicity.

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APPENDIX A: African American Focus Group Flyer

Focus Group Participants Needed!!

Interested in speaking with those of the **African American heritage group, of any age about a wide variety of topics dealing with the United States health care system.**

When: April 4th, 2007 at 7:00-8:00pm

Where: The Graduate Life Center at Virginia Tech
Room C.

$15.00 Gift Card will be awarded for your time and efforts. Pizza will also be provided

If you are interested please contact Karey Sutton, 3rd year doctoral student in the Department of Science and Technology in Society at Virginia Tech, by phone at **540-443-1267**, by email **sutton04@vt.edu**, or by mail **221 Lane Hall, Virginia Tech, Blacksburg, VA 24061-0247**

No real names in this work and any personal details will be altered to preserve privacy. The Virginia Tech Institutional Review Board has determined that this research meets the federal standards for the protection of the study participants.

APPENDIX B: African American Focus Group Recruitment Email/Letter

03/26/2007

Dear Friend,

My name is Karey Sutton. I am a 3rd year graduate student in the Department of Science and Technology in Society at Virginia Tech. I am working on a research project dealing with how people in ethnic and heritage groups get and use genetic information.

One portion of the study is to hold focus- group sessions. I am looking for African Americans eighteen years and older to participate in sessions that will last no longer than one hour, to discuss a wide range of topics dealing with the health care system. The session will be held on Wednesday, April 4th at 7pm in Room C of the Virginia Tech Graduate Life Center.

No real names in this work and any personal details will be altered to preserve privacy. The Virginia Tech Institutional Review Board has determined that this research meets the federal standards for the protection of the study participants. Compensation of a 15.00 gift card will be given for your time and efforts. Also pizza will be provided during the session.

If you are interested in participating in this study, please contact me by **Monday, April 2nd,** by phone at 540-443-1267, by email at sutton04@vt.edu, or by writing to Karey M. Sutton, 221 Lane Hall, Virginia Tech, Blacksburg, VA 24061-0247

Sincerely,

Karey M. Sutton

APPENDIX C: Focus Group Informed Consent Form

VIRGINIA POLYTECHNIC INSTITUTE AND STATE UNIVERSITY
Consent for Participants in a Research Project Involving Human Subjects

Title of Project: Understanding the Views of Minority Groups: Hearing Their Voices through Focus Groups

Investigator: Doris T. Zallen, Ph.D
Professor of Science and Technology Studies
Department of Science and Technology Studies
Virginia Polytechnic Institute and State University (Virginia Tech)

Co-Investigator: Karey Sutton, B.S., B.A.
Graduate Student
Department of Science and Technology Studies
Virginia Polytechnic Institute and State University (Virginia Tech)

I. Justification for the project

Generally, voices within the minority communities are often unheard in health research concerning genetics. Therefore, one of the purposes of this study is to hear the voices a small portion of the African American and Hispanic communities concerning health care issues in general and genetic issues in particular, through the use of focus groups.

II. Procedures

Participation in this study is purely voluntary. If you agree to participate in the focus group the discussion will be lead by Karey Sutton. The discussion will be held in a group setting and also it will audio-taped. The focus group session will last no longer than one and half-hours. An optional pizza dinner will follow the session.

III. Risks

One may experience psychological discomfort when discussing health care research issues or concerns about genetic testing especially if it involves some personal experience.

IV. Benefits

There is no personal benefit from participating in this study. However, this study could contribute to the improvement of health-care and genetic testing policies in the future by informing the government and the medical community of the experiences and concerns of consumers.

APPENDIX C: Focus Group Informed Consent Form- Continued

V. Extent of Anonymity and Confidentiality

The focus session audiotapes will be transcribed by Karey Sutton. The transcripts will be kept in a locked file cabinet accessible only to the investigators. The tape itself will be erased after a transcript has been prepared. Any information that could identify the subjects will be altered or removed from any publications or research talks based on this research project.

VI. Compensation

Compensation will be provided for participation in this study. Participants will be given $15.00 at the conclusion of the focus group session. In addition to the monetary compensation, an optional pizza dinner will be provided after the session has concluded.

VII. Freedom to withdraw

You are free to refuse to answer any of the questions during the focus group session and you may also with withdraw from the focus group at any time without penalty.

VIII. Approval of Research

This research project has been approved, as required, by the Department of Science and Technology in Society and by the Institutional Review Board for Research Involving Human Subject's at Virginia Tech.

In case you have any pertinent questions about this research or its conduct, research subjects' rights, or in the event of a research- related injury, you should contact:

Doris T. Zallen, Ph.D. 540-231-4216
Investigator
Email: dtzallen@vt.edu
Department of Science and Technology in Society

Karey Sutton 540-231-9064
Co-Investigator
Email: sutton04@vt.edu
Department of Science and Technology in Society

David M. Moore, DVM 540-231-4991
Chair, Institutional Review Board

APPENDIX C: Focus Group Informed Consent Form- Continued

Office of Research Compliance
Email: moored@vt.edu
Research and Graduate Studies

Subject's Permission

Based on the information presented in this document and on discussions with the investigators, I give my voluntary consent to participate in the research project described. I have had my questions answered and I have received my own copy of this consent form.

_____ _____

Subject Signature Date

APPENDIX D: Consent to Audio-Tape Form for the Focus Groups

VIRGINIA POLYTECHNIC INSTITUTE AND STATE UNIVERSITY

Consent to Tape the Interview

Title of Project: Understanding the Views of Minority Groups: Hearing Their Voices through Focus Groups

Investigators: Doris T. Zallen, Ph.D
Professor of Science and Technology Studies
Department of Science and Technology in Society
Virginia Polytechnic Institute and State University (Virginia Tech)

Karey M. Sutton, B.A., B.S.
Graduate Student
Department of Science and Technology in Society
Virginia Polytechnic and State University (Virginia Tech)

I agree to allow an audio-tape to be made of the interview between myself and Dr. Doris Zallen or Karey Sutton that is being conducted on _____.

I understand that I am free to not answer any of the questions and can ask, at anytime, that the tape recorder be stopped. I am also free to withdraw my permission for the taping of our conversation.

The tape will be erased after notes are taken or a transcript has been prepared. None of the tapes will contain my name or location. All interview records will be stored in a locked file cabinet accessible only to the investigators.

_____ _____

Participant's Signature Date

APPENDIX E: Focus Group Demographic Information Form

DEMOGRAPHIC INFORMATION

Age: _____

Gender (circle answer): Male Female

Race/Ethnicity:

Highest Level of Education Completed:

Marital Status (circle answer): SINGLE MARRIED DIVORICED WIDOWED

Any Children? (circle answer): YES or NO

Health Insurance (circle answer): YES or NO

If you answered yes, please give the name of your provider_____

Appendix F: Focus Group Session Guide

- Current evidence shows that African Americans and Hispanics are under-represented in health-care research. Do you have an explanation of why Hispanics/African Americans do not participate in health care research?
- What is your opinion about health care research?
- (For African Americans) What do you know of the Tuskegee Study?
  - Has this study influenced your views of participating in health care research?
- What could the government or any agency do to get more Hispanics/African Americans to participate in research?
- Is anyone aware of what genetic testing is?
- What is your general opinion about genetic testing?
- Has anyone here been faced with a decision about genetic testing?
- Would you participate in research leading to genetic testing?
  - Why would you? Or Why wouldn't you?
- I know this is an assumption, but could anyone comment on his or her parent's view of genetic testing? Is there a difference in opinion?
  - Could you explain why there is such a difference or why it may be the same?

APPENDIX G: Focus Group Flyer for Hispanic/Latinos

Focus Group Participants Needed!!

Interested in speaking with those of the **Hispanic/Latinos heritage group, of any age about a wide variety of topics dealing with the United States health care system.**

When: September 13th , 2007 at 7:00-8:00pm

Where: The Graduate Life Center at Virginia Tech
Room C.

$15.00 Gift Card will be awarded for your time and efforts. Pizza will also be provided

If you are interested please contact Karey Sutton, 3rd year doctoral student in the Department of Science and Technology in Society at Virginia Tech, by phone at **540-443-1267**, by email **sutton04@vt.edu**, or by mail **221 Lane Hall, Virginia Tech, Blacksburg, VA 24061-0247**

No real names in this work and any personal details will be altered to preserve privacy. The Virginia Tech Institutional Review Board has determined that this research meets the federal standards for the protection of the study participants.

APPENDIX H: Focus Group Recruitment Letter/Email for Hispanic/Latinos

09/03/2007

Dear Friend,

My name is Karey Sutton. I am a 3rd year graduate student in the Department of Science and Technology in Society at Virginia Tech. I am working on a research project dealing with how people in ethnic and heritage groups get and use genetic information.

One portion of the study is to hold focus- group sessions. I am looking for Hispanic/Latinos eighteen years and older to participate in sessions that will last no longer than one hour, to discuss a wide range of topics dealing with the health care system. The session will be held on Wednesday, April 4th at 7pm in Room C of the Virginia Tech Graduate Life Center.

No real names in this work and any personal details will be altered to preserve privacy. The Virginia Tech Institutional Review Board has determined that this research meets the federal standards for the protection of the study participants. Compensation of a 15.00 gift card will be given for your time and efforts. Also pizza will be provided during the session.

If you are interested in participating in this study, please contact me by **Monday, September 10th** , by phone at 540-443-1267, by email at sutton04@vt.edu, or by writing to Karey M. Sutton, 221 Lane Hall, Virginia Tech, Blacksburg, VA 24061-0247

Sincerely,

Karey M. Sutton

APPENDIX I: Interview Demographic Information Form

DEMOGRAPHIC INFORMATION

Age: _____

Gender (circle answer): Male Female

Race/Ethnicity:

Highest Level of Education Completed:

Marital Status (circle answer): SINGLE MARRIED DIVORICED WIDOWED

Any Children? (circle answer): YES or NO

Health Insurance (circle answer): YES or NO

If you answered yes, please give the name of your provider_____

Please return this form along with a signed copy of your consent forms.
**You may return the all of the forms via mail to 221 Lane Hall (0247) Blacksburg, VA 24061, via email at sutton04@vt.edu, or by faxing the forms to 540-231-7013, Attn: Karey Sutton.
If you have any questions please feel free to call me at 336-254-7994. Thank you

APPENDIX J: Individual Interview Question Guide

Sample Questions

Ice Breaker:
So how long have you lived in this area?
And you are originally from?

General Genetic Test Questions

Is there a health problem that you believe you or your family may be at a higher risk of developing?

Do you think that a tendency toward this health problem is inherited in your family, that it may be related to your genes?

How did you first become aware that you were at risk for _____?

Can you tell me about when you received information explaining that this condition may be passed along in your family?

Where did you get that information? (doctors, websites, family, etc.)

Did you ever receive any information about genetic testing or do you know what it is?

- If no, are you aware that there are genetic tests for (insert the appropriate term or terms: breast cancer, colon cancer, ovarian cancer, Alzheimer's disease)?
- If yes, where did you get that information?
- If yes, did you understand the information?
- Did you understand that you would be able to get a probability or prediction, but a not a definitive yes or no about developing the condition later on in your life?
- So what are your views about having the genetic test?

Carrier Testing
- Have you received information concerning carrier testing?
- If yes, where did you receive that info and what did you do with that information?
- Would you participate in testing to know if you were a carrier for (i.e Sickle Cell, or Thalassmia (Hispanics)?

Prenatal Testing
- Do you have children? Or do you plan on having children?
  - If yes, did you participate in any form of prenatal care?
  - If yes, what type and where did you get that information?
  - If no, is there a reason why you did not want to participate?

APPENDIX J: Individual Interview Question Guide- Continued

- **<u>If no, Why?</u>**

  - Do you have insurance through your employer?
  - Is it financial reasons?
    - If you had the financial resources to participate would you still refuse genetic testing?
  - What has it influenced your view of the health care system and health care research?
  - Are there other factors that have influenced your decision to decline genetic testing?
  - Do you trust your doctor?
  - Do you trust health care researchers?
    - And your reasoning is?
    - How has that trust or lack of trust influenced your decision about genetic testing?

- **<u>If yes, why?</u>**

  - Has there been any effect on your job or with your employer or your insurance coverage as a result of this decision?
  - Were other members of your family informed about the disorder and of the possibility of testing to see who might be at risk? Were they willing to participate in the testing process?
  - Are you aware of the Tuskegee study?
    - How did this study influence any of your views towards health care research? (maybe it didn't so this question might be irrelevant)
  - Do you trust your doctor?
    - Why or why not?
  - Do you trust health care researchers?
    - Why or why not?

Were you satisfied with the assistance you received from the counselors (support group, family physician, specialist) while you were considering genetic testing?

If you could participate in research that would help in the development of a genetic test for (diabetes) would you participate? Why or why not?

What are your fears if you have any of participating in genetic testing in order to tell you the probability you one day getting a disorder?

What are your fears if you have any of participating genetic/health care research?

Have your religious beliefs ever influenced your health care decision. If so in what way? And if not why did you separate the two?

APPENDIX J: Individual Interview Question Guide- Continued

Is there anything I didn't ask that would be helpful for my research?

May I contact you again if I have further questions?
What would be the best way to do this?

Remember to thank them for their time and efforts.

APPENDIX K: Interview Recruitment Flyer for African Americans and Hispanic/Latinos

Research Study Participants Needed

I am interested in speaking with people of either **African-American or Hispanic/Latino** heritage, aged 18 and above, who have a family history of common disorders such as heart disease, cancer, diabetes, and Alzheimer's, or who have considered genetic testing for common diseases, genetic testing before birth of a child, or genetic testing to help determine treatment.

The research involves participating in a one-on-one interview lasting from thirty minutes to an hour to discuss access to your genetic information, your experiences or lack of experiences with genetic testing. How you have gotten genetic information or if you have had problems getting genetic information, and what your experiences if any, has been with genetic testing.

A $10.00 Gift Card will be given to compensate you for your time and effort.

To hear more please contact Karey Sutton, doctoral student in the Department of Science and Technology in Society at Virginia Tech, by phone at **540-443-1267**, by email **sutton04@vt.edu**, or by mail **221 Lane Hall, Virginia Tech, Blacksburg, VA 24061-0247**

In any publications or talks based on this research no real names will be used and any personal details will be altered to preserve your privacy. The Virginia Tech Institutional Review Board has determined that this research meets the federal standards for the protection of the study participants.

APPENDIX L: Interview Recruitment Letter for African Americans and Hispanic/Latinos

03/27/2009

Dear Friend,

My name is Karey Sutton. I am a doctoral student in the Department of Science and Technology in Society at Virginia Tech. I am working on a research project dealing with how people in ethnic and heritage groups get and use genetic information.

One portion of the study is to conduct one-on-one interviews. I would like to conduct interviews lasting thirty minutes to one hour with people in either the African American or Hispanic/Latino heritage groups who have histories in their families any common disorders such as diabetes, heart disease, cancer, stroke, high blood pressure or Alzheimer's disease. Also I would like to speak with people who have considered genetic testing before the birth of a child, or genetic testing for treatment purposes.

Compensation of a 10.00 gift card will be given for your time and efforts.

In any publications or talks based on this research no real names will be used and any personal details will be altered to preserve privacy. The Virginia Tech Institutional Review Board has determined that this research meets the federal standards for the protection of the study participants.

If you are interested in learning more about this study, please contact me by May 1, 2009, by phone at 540-443-1267, by email at sutton04@vt.edu, or by writing to Karey M. Sutton, 221 Lane Hall, Virginia Tech, Blacksburg, VA 24061-0247

Sincerely,

Karey M. Sutton, M.S.

APPENDIX M: Article for African American Church Bulletins

My name is Karey M. Sutton a 23 year-old native of Greensboro, NC and a graduate of Howard University. I am currently a graduate student in the department of Science and Technology in Society. The best way to describe me is to write about my present passion, which is the research of which I am involved.
Before I was born my grandmother lost her battle with breast cancer. At the tender age of eight years old, I observed my aunt fight and win the same battle against breast cancer. By the age of fifteen I witnessed my mother undergo surgeries to prevent the onset of the same cancer. Now at the age of twenty-three I am faced with the strong risk of someday having breast cancer. Some would say that it is coincidental that my graduate research project is dealing with genetic issues and testing, but I believe that it is divine intervention.

While Black citizens are a minority of the population in the United States, we are even more a minority when it comes to participating in genetic research and testing. I conduct interviews so that I may hear and understand the views of the black community concerning genetic information and genetic testing. I would like to conduct interviews with those who have histories in their families of disorders such as cancer, stroke, heart disease, diabetes, high blood pressure or Alzheimer's disease.

The purpose of my research is to give a voice to blacks in health care research concerning genetic issues and to include black citizens views when genetic policies are made. I hope to someday be an influential member of the political community and make a difference somewhere.

APPENDIX N: Spanish Translation of the Informed Consent Form

VIRGINIA POLYTECHNIC INSTITUTE AND STATE UNIVERSITY

El consentimiento para los participantes en el proyecto de investigación que incluye participación de seres humanos

Título del Proyecto: Explorar las opiniones minoritarias en pruebas genéticas y de investigación

Investigador: Doris T. Zallen, Ph.D
Profesor de Estudios de Ciencia y Tecnología
Departamento de Ciencia y Tecnología en la Sociedad
Virginia Polytechnic Institute and State University (Virginia Tech)

Co-Investigador: Karey M. Sutton, MS
Estudiantes de Posgrado
Departamento de Ciencia y Tecnología en la Sociedad
Virginia Polytechnic Institute and State University (Virginia Tech)

I. Justificación del proyecto

En general, las voces y las decisiones de política dentro de las comunidades minoritarias a menudo son desconocidas en las investigaciones del bienestar de salud, sobre todo de investigación y de políticas relativas a la genética. El objetivo principal de este estudio es escuchar las voces de los miembros de las comunidades Africanas Americanas e hispanas sobre sus puntos de vista sobre los diferentes tipos de pruebas genéticas, a través de la utilización de entrevistas personales. Todos los participantes de este estudio deben tener al menos 18 años de edad.

II. Procedimientos

La participación en este estudio es totalmente voluntaria. Si usted acepta participar, la Sra. M. Sutton Karey dirigiría una entrevista que dura entre treinta minutos a una hora en un momento y lugar mutuamente aceptable. En el caso de que la distancia es un factor, una entrevista telefónica puede ser programada. La discusión será grabada si usted ha dado permiso para hacerlo.

Durante la entrevista se le harán preguntas sobre sus experiencias en la adquisición de información genética. También, si ha considerado alguna vez pruebas genéticas o la participación en la investigación genética, la entrevista explorada que fue su experiencia y que cambios sugiere

APPENDIX N: Spanish Translation of the Informed Consent Form-continued

III. Riesgos

Es posible que sientas incomodidad psicológica como la ansiedad o la tristeza cuando se discuta datos personales o familiares sobre la enfermedad o posibles preocupaciones sobre las pruebas genéticas. En un estudio llevado a cabo previamente relacionado con entrevista con la participación de unas 150 personas, este tipo de problema ocurrió muy pocas veces, pero es uno que usted debe tener en mente al considerar este estudio.

IV. Beneficios

No hay ningún beneficio personal por participar en este estudio. Sin embargo, este estudio podría contribuir para mejorar la asistencia médica y las políticas de las pruebas genéticas en el futuro, informándole al gobierno y la comunidad médica de las experiencias y preocupaciones de sus consumidores.

V. Alcance de Anonimato y la Confidencialidad

Los registros de la entrevista serán guardadas en un archivo cerrado sólo accesible a los investigadores. Grabaciones sólo se harán con su previo consentimiento. Las grabaciones serán destruidas y borrada después que las notas se han tomado o una transcripción ha sido preparado por el Dr. Zallen, la Sra. Sutton, o un asistente de investigación. Si usted no desea que la entrevista sea grabada, notas escritas a mano que se usaran.
Cualquier información que pudiera identificar a las personas que fueron entrevistadas será alterada o retirada de cualquier publicación o conversaciones basadas sobre este proyecto de investigación.

VI. Compensación

Para ayudar y compensar su tiempo se le dará una tarjeta de alguna tienda de cadena local con valor de $10.00 a la conclusión de la entrevista.

VII. Libertad Para Retirarse

Usted es libre de negarse a responder a las preguntas durante la entrevista y también puede detener la entrevista en cualquier momento sin penalización. Aún recibirá la tarjeta de regalo.

VIII. Aprobación de la Investigación

Este proyecto de investigación ha sido aprobada, según se requiere, por la Junta de Revisión Institucional para la Investigación de Seres Humanos en la Universidad Virginia Tech.

En caso alguna pregunta sobre esta investigación usted puede ponerse en contacto con:

APPENDIX N: Spanish Translation of the Informed Consent Form-Continued

Doris T. Zallen, Ph.D. 540-231-4216
Investigador
Correo electrónico: dtzallen@vt.edu
Departamento de Ciencia y Tecnología en la Sociedad

Karey Sutton, MS 540-443-1267
Co-Investigador
Correo electrónico: sutton04@vt.edu
Departamento de Ciencia y Tecnología en la Sociedad

David M. Moore, DVM 540-231-4991
Presidente, Junta de Revisión Institucional
Oficina de Investigación de Cumplimiento
Correo electrónico: moored@vt.edu
De Investigación y Estudios de Postgrado

IX. Permiso del Sujeto

Basándose en la información presentada en este documento y en las discusiones con los investigadores, doy mi consentimiento voluntario para participar en el proyecto de investigación que se descrito. He tenido mis preguntas y dudas contestadas y he recibido mi propia copia de este formulario de consentimiento.

_____ _____

Firma del Participante Fecha

APPENDIX O: Spanish Translation of the Consent to Audio-tape Form

VIRGINIA POLYTECHNIC INSTITUTE AND STATE UNIVERSITY

El consentimiento para grabar la entrevista

Título del Proyecto: Explorar las opiniones minoritarias en pruebas genéticas y estudios.

Investigadores: Doris T. Zallen, Ph.D
Profesor de Estudios de Ciencia y Tecnología
Departamento de Ciencia y Tecnología en la Sociedad
Virginia Polytechnic Institute and State University (Virginia Tech)

Karey M. Sutton, MS
Estudiantes de Posgrado
Departamento de Ciencia y Tecnología en la Sociedad
Politécnico de Virginia y Universidad Estatal (Virginia Tech)

Estoy de acuerdo en permitir la audio grabación de la entrevista entre yo y la Dra. Doris Zallen o Karey Sutton que se va llevar a cabo el _____.

Entiendo que soy libre de no responder a ninguna de las preguntas y puede solicitar, en cualquier momento, que se detenga la grabación. También estoy libre de retirar mi permiso para grabación de la conversación.

La cinta se borrará después que las notas han sido tomadas o la transcripción se ha preparado. Ninguna de las grabaciones tendrá su nombre o localización. Todos los registros de las entrevistas se almacenarán en un archivo cerrado y sólo accesible a los investigadores del proyecto.

_____ _____

Firma del Participante Fecha

APPENDIX P: Spanish Translation of the Demographic Information Form

INFORMACIÓN DEMOGRÁFICA

Edad: _____

Género (marque con un círculo la respuesta): Masculino Femenino

Raza / Etnia:

Más alto nivel de educación completado:

Estado civil (marque con un círculo la respuesta):
Soltero/a Casado/a Divorciado/a Viudo/a

¿Tienes hijos? (marque con un círculo la respuesta): SI o NO

Seguro Medico (marque con un círculo la respuesta): SI o NO

Si usted contestó sí, indique el nombre de su proveedor _____

Por favor devuelva este formulario junto con una copia firmada de los formularios de consentimiento.
** Usted puede devolver la totalidad de los formularios por correo a la dirección, 221 Lane Hall (0247) Blacksburg, VA 24061, vía correo electrónico a sutton04@vt.edu, o por fax a el número 540-231-7013, con atención a: Karey Sutton.
Si usted tiene alguna pregunta no dude en llamarme al 336-254-7994. Muchas Gracias

APPENDIX Q: Consent Form Letter for Individual Interviews

October 24, 2008

Dear

As you requested, I am enclosing two copies of the consent form for my interview study as well as a copy of a consent-to-audiotape form.

I will contact you on _____ to arrange a time that I can answer any questions you have about the study and the informed consent form. If you are still interested, I ask that you return a signed copy of the informed consent form via fax, email, or mail and we can set up an appointment to complete the interview session over the phone. (The second copy is for your own records.) The interview should take about a half-hour to an hour. If you also send back a signed consent-to-audiotape form, I will be able to tape our conversation. This makes it easier for me since I don't have to take complete notes while we are talking. You can always refuse audio-taping (in which case I will take notes) and you are free to ask me to turn off the tape recorder at any time.

I appreciate your interest in this study. If you have any questions or suggestions, please let me know.

Sincerely,

Karey M. Sutton, MS

APPENDIX R: Informed Consent Form for the Individual Interviews

VIRGINIA POLYTECHNIC INSTITUTE AND STATE UNIVERSITY

Consent for Participants in a Research Project Involving Human Subjects

Title of Project: Probing Minority Views on Genetic Testing and Research

Investigator: Doris T. Zallen, Ph.D
Professor of Science and Technology Studies
Department of Science and Technology in Society
Virginia Polytechnic Institute and State University (Virginia Tech)

Co-Investigator: Karey M. Sutton, MS
Graduate Student
Department of Science and Technology in Society
Virginia Polytechnic Institute and State University (Virginia Tech)

II. Justification for the project

Generally voices and policy decisions within the minority communities are often unheard in healthcare research especially research and policy concerning genetics. The main purpose of this study is to hear the voices of members of the African American and Hispanic communities concerning their views on different types of genetic testing, through the use of one-on-one interviews. All participants of this study must be at least 18 years of age.

II. Procedures

Participation in this study is purely voluntary. If you agree to participate, Ms. Karey M. Sutton will interview you from thirty minutes to an hour at a mutually agreeable time and place. In the event that distance is a factor, a phone interview may be scheduled. The discussion will be audio taped if you give permission to do so.

During the interview session you will be asked questions concerning your experiences acquiring genetic information. Also if you have considered genetic testing or participating in genetic research, the interview will explore what your experience was like and what changes you would suggest.

APPENDIX R: Informed Consent Form for the Individual Interviews

III. Risks

You may experience psychological discomfort such as anxiety or sadness when discussing personal or family issues about illness or discussing concerns about genetic testing. In a related interview study conducted previously and involving about 150 people, this type of problem rarely occurred, but it is one you should think about when considering this study.

IV. Benefits

There is no personal benefit from participating in this study. However, this study could contribute to the improvement of health-care and genetic testing policies in the future by informing the government and the medical community of the experiences and concerns of consumers.

V. Extent of Anonymity and Confidentiality

The interview records of the session will be kept in a locked file cabinet accessible only to the investigators. Audiotaping will only be done with your prior consent. The tape will be destroyed and erased after notes have been taken or a transcript has been prepared by Dr. Zallen, or Ms. Sutton, or a research assistant. If you do not wish to have the interview audiotaped, hand-written notes will be taken.

Any information that could identify the people who were interviewed will be altered or removed from any publications or research talks based on this research project.

VI. Compensation

To help compensate you for your time you will be given $10.00 gift card to a local chain store at the conclusion of the interview.

VII. Freedom to withdraw

You are free to refuse to answer any of the questions during the interview and you may also stop the interview at any time without penalty. You will still receive the gift card.

VIII. Approval of Research

This research project has been approved, as required, by the Institutional Review Board for Research Involving Human Subjects at Virginia Tech.

APPENDIX R: Informed Consent Form for the Individual Interviews

In case you have any questions about this research you should contact:

Doris T. Zallen, Ph.D. 540-231-4216
Investigator
Email: dtzallen@vt.edu
Department of Science and Technology in Society

Karey Sutton, MS 540-443-1267
Co-Investigator
Email: sutton04@vt.edu
Department of Science and Technology in Society

David M. Moore, DVM 540-231-4991
Chair, Institutional Review Board
Office of Research Compliance
Email: moored@vt.edu
Research and Graduate Studies

IX. Subject's Permission

Based on the information presented in this document and on discussions with the investigators, I give my voluntary consent to participate in the research project described. I have had my questions answered and I have received my own copy of this consent form.

_____ _____

Subject Signature Date