

Genetics-Based Research at the Minnesota State Fair: The Impacts of Public Engagement on Participatory Experience

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AMANDA JANE KABAGE

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Abstract

Public engagement and education of science, technology, engineering, and mathematics (STEM) have become prominent topics in politics, just as the broader ethical, legal and social implications (ELSI) of research have become immersed in genetics-based research discourse. While STEM education rates are decreasing in the United States and public opinion of genetics-based research remains somewhat divided, it is important to assess ways in which the scientific community can effectively engage the public. In this analysis, the Gopher Kids Study (GKS) was used to determine the indirect social benefits of participation when conducting research in a public environment, as well as public opinion about the use of genetic information. The GKS is a genetics-based pediatric longitudinal study that has been conducted at the Minnesota State Fair from 2010-2012.

Participants in the GKS were given a survey including questions about their experience with the study and their opinions on the use of genetic information. These questions sought to address three primary questions about the impact of public engagement through the GKS: 1) how does participation in a genetics-based research study influence the participants' views about genetics, research, and science, 2) how do the unique characteristics of conducting research in a public environment impact participants' experience with the study, and 3) how do the GKS participants' opinions about how genetic information should be handled in society differ from those of other fairgoers? The third aim of this study compared GKS responses to a public opinion survey that was used at the 2010 Minnesota State Fair in which fairgoers not involved with GKS completed. The survey results suggested the GKS participants' views on genetics have changed as a result of their participation, through increased knowledge (70%) and interest (60%). About 57% of the children involved in the study have a more positive interest in science, while roughly 44% of the parents have a more positive opinion of genetics since their enrollment in the study. GKS participants have similar opinions about how genetic information should be used and who they would trust with their DNA as other fairgoers.

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Chapter 1: Introduction and Background

Emerging genetics-based research has a history of inciting contention within public and political discourse, prompting an array of ethical considerations regarding the modification of DNA, the creation of genetics-based medical treatments, genetic testing, and the protection of DNA in both research and medicine. In the case of using DNA in research and preventative medical treatment, the primary cause for concern lies in how personal genetic information might be used in harmful ways (Hudson 2007). In reaction to public concerns, policymakers have attempted to keep pace with the rapidly advancing area of genetics-based research by enacting policies to safeguard the use of DNA by mitigating the potential risks associated with new biotechnology and to protect individuals from genetic discrimination. The most substantial piece of legislation to protect genetic information was passed in 2008 at the end of President Bush's term in office called the Genetic Information Nondiscrimination Act (GINA), which protects individuals from genetic discrimination by insurance companies. Additionally throughout President Obama's administration, efforts to increase science, technology, engineering, and mathematics (STEM) education in the United States have been implemented through programs such as Educate to Innovate and the National Science Foundation's (NSF) Transforming Undergraduate Education in STEM (TUES). It is thought that increased education can also help to assuage public fear.

As genetic information is increasingly being used in research as a tool to understand how genes play a role in disease, growth and development, and the overall health of humans, it is important to find effective methods to communicate the benefits of genetics-based research, along with the limitations, to the public. The Center for Public

Engagement with Science and Technology through the American Association for the Advancement of Science (AAAS) aims to provide scientists and scientific institutions with resources to communicate effectively with the public about science and technology research. Alan I. Leshner, the chief executive officer of the AAAS, emphasizes the need for scientists to become more involved in public engagement in order to facilitate public policy and increase support for science research. He argues that it is important for scientists to understand how the public interprets and accepts science, as well as relay the ways in which science can personally impact individuals (Leshner 2012).

In a political environment where the need for understanding the ethical, legal, and social implications (ELSI) of genetics-based research is essential for the continued progression and advancement of genetic knowledge, scientists should play a more significant role in public awareness. Researchers engaging in genetics-based research with human subjects have the opportunity to engage and educate research participants, and because many genetics-based studies require diverse populations, this provides them the opportunity to reach out to a broad range of communities.

The primary aim of this paper is to analyze the experiences of research participants in the Gopher Kids Study (GKS), which is a pediatric genetics-based research study that has been conducted at the Minnesota State Fair annually for the past three years. Parents and their children were recruited for the study while visiting the Minnesota State Fair in 2010, most with no intention of participating prior to their trip to the Fair. While the GKS research team has shown that a longitudinal genetics-based research study can be conducted successfully at the Minnesota State Fair, the unique environment of the Fair has the additional benefit of public engagement, since the

Fair is a highly popular annual event for many Minnesotans. For this project, the parents in the GKS were surveyed about how their knowledge, opinions, and interest in genetics have changed as a result of being involved in the study. The survey also included questions about how the study has impacted their children's interest in science, their views on the risks and benefits of genetics-based research, engagement with the research team, and their opinions about how genetic information should be used in broader society. Through this data, three questions about the participants' experience with the GKS were analyzed.

- 1) How does participation in a genetics-based research study influence the participants' views about genetics, research, and science?
- 2) How do the unique characteristics of conducting research in a public environment impact participants' experience with the study?
- 3) How do the GKS participants' opinions about how genetic information should be handled in society differ than from those of other fairgoers?

These survey data were combined with additional data collected through the previous years of the study, and portions of the survey were compared to a survey that was conducted with self-selected fairgoers not involved with the GKS.

The secondary aim of this paper focuses on addressing the ELSI component of the GKS. During the launch of the study, a number of bioethicists criticized the GKS, citing ethical concerns about the recruitment and consent of research participants at an environment like the Minnesota State Fair. These public criticisms led to a number of media stories from local media outlets, as well as national and international outlets such as the Wall Street Journal and Nature News. The overall sentiment was that the Fair is

not a serious enough environment for individuals to make such an important decision like giving their DNA for research purposes. While the ethical concerns posed are warranted, this paper will address each point raised and show that not only has the GKS proven highly successful as a longitudinal genetics-based study because of the environment, but also that the unique opportunity for public engagement serves the greater purpose of autonomy and informed consent.

This chapter will present background on the policies that have been enacted to protect genetic information, as well as the programs that have been developed to increase STEM education in the United States, to demonstrate the importance policymakers have placed on protecting and educating the public on emerging scientific matters. The final section of this chapter will discuss public opinions about genetics-based research, which will be used as context for comparison to the GKS participant and non-GKS participant fairgoers' opinions.

Federal Policies to Protect Individuals from Genetic Discrimination

While it may not seem apparent to the general public, laws influencing current genetic discrimination protection laws can be dated back the 1964 Civil Rights Act (CRA), which stipulates that individuals cannot be discriminated against based on race, color, religion, sex or national origin. One of the most well-known sections of the CRA is Title VII which mandates that employers cannot discriminate based on the aforementioned characteristics. Title VII does not contain language directly discussing genetic discrimination; however, it could be interpreted that minimal protection could be provided regarding genetic disorders that are linked to race or ethnicity. If an employer discriminated against a particular race or ethnic group based on a genetic characteristic or

disease that is linked to race or ethnicity, then this could serve as a violation of Title VII (NHGRI 2012). Seeing that protection against genetic discrimination would be limited to this particular circumstance, the CRA is not an effective policy to cover genetic discrimination in its entirety.

In 1983 the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research issued a report that addressed the protection of genetic information from an ethical perspective, rather than a legal one. The report dedicated an entire section to the ELSI of Genetic Screening, Counseling, and Education Programs, which summarizes conclusions about the ethics of confidentiality (Federal Register 1983). Genetic information should not be released to third parties without informed consent, specifically mentioning insurance companies and employers. Genetic information can only be released to relatives of a patient if voluntary consent is not obtainable by the patient and the potential for harm that would occur if the information withheld is determined to put the patient at high risk (Federal Register 1983). The Commission also address the use of biobanks by private and governmental organizations, expressing the need to code individuals' genetic information in such a way to protect their identity. This report was significant considering that at the time there were no laws prohibiting the release of genetic information to insurance companies or employers, but the Commission attempted to illustrate that there are ethical guidelines that should be followed despite the lack of legal regulation.

Another landmark piece of legislation was enacted in 1990 with similar mandates to the CRA. The Americans with Disabilities Act (ADA) was passed to protect individuals with physical or mental disabilities from discrimination. Similar to the CRA,

the ADA devotes a significant amount of attention to the protections against employment discrimination. Employers cannot discriminate against a qualified individual on the basis of disability in regards to any hiring, training, compensation, job advancement, or firing practices. Additionally the ADA included a section prohibiting employers from mandating medical examinations or inquiries about medical conditions or disabilities prior to or during employment, unless an examination or inquiry is necessary for job-related functions (ADA 2009).

While the ADA sufficiently protects individuals from discrimination against having a disease, including genetic diseases, it does not provide absolute protection for genetic discrimination. Individuals with symptomatic genetic disabilities have the same protections as individuals with other disabilities, but those with genetic disorders that are not expressed are not offered the same protection. Unexpressed genetic disease or risk could include individuals that are carriers but never actually develop a disease, or individuals that are carriers of a late-onset genetic disease but are identified as high risk candidates early in their lives (NHGRI 2012). Likewise, family history could mistakenly assign high risk of a disease to an individual. In these situations, if an employer requires genetic testing of potential or current employees, anti-discrimination protection under the ADA would not cover the employees. To make matters worse, the ADA does not prohibit mandatory genetic testing or the storage of genetic samples by employers, which means they could potentially discriminate against high risk individuals for a particular disease due to their genetic makeup since they would not be offered protection under the ADA (NHGRI 2012). This once again illustrates the gaps in the protection of genetic information from discrimination.

To supplement the anti-discrimination laws to protect genetic information, the Health Insurance Portability and Accountability Act (HIPAA) was enacted in 1996 in order to protect the privacy of identifiable health information and included provisions to protect health insurance coverage. HIPAA provides rights and protections for participants in group health plans by limiting exclusions for pre-existing conditions. The intention of HIPAA was to reduce the ability for insurance companies to deny or limit individual coverage based on genetic or non-genetic factors. Regarding genetic discrimination protection, HIPAA prohibits insurance plans from considering genetic information, or genetic carrier status as a pre-existing condition, and therefore insurance companies could not impose pre-existing condition exclusions based solely on genetic information (DOL n.d.). While HIPAA decreased the potential for genetic information to be used in determining health care eligibility, the law still left room for possible genetic discrimination.

In order to address many of the significant gaps in the protection of genetic information, the Genetic Information Nondiscrimination Act (GINA) was created and put into law in 2008. In conjunction with the provisions set by HIPAA, GINA extends the protection of genetic information from insurance companies. Title I of GINA prohibits health insurers from using genetic information to make eligibility, coverage, underwriting, or premium-setting decisions, and also bans them from requiring individuals or their family members to undergo genetic testing or provide genetic information (Federal Register, Part II 2009). One notable and important component to GINA is the extended and more detailed definition of genetic information, which includes information about: an individual's genetic test results, the genetic tests of any

family member of such individual, the manifestation of a disease or disorder in a family member of such individual, and the request of or receipt of genetic services by the individual or his or her family members (Federal Register, Part II 2009).

The stipulations in Title I specific to health insurance information are applied similarly to Title II, which protects individuals' genetic information in the work place. Similar to the provisions set in the CRA and ADA, Title II of GINA prohibits discrimination on the basis of genetic information in all aspects of employment, including hiring, firing, promotions, salaries, training, job assignment, and benefits. Title II also makes it illegal to harass an individual because of his or her genetic information in the workplace; defining harassment as any action that is so severe or pervasive that it creates a hostile work environment or interferes with employment decisions (Federal Registrar, Part III 2009). While Title II makes it unlawful for employers to obtain genetic information on employees, there are a number of exceptions to this rule. Since genetic information can also include family medical history, most of the exceptions regard this type of genetic information. One example is referred to as the "water cooler problem". Congress determined that employers cannot be held liable for obtaining genetic information by inadvertently overhearing employees discuss family medical history with co-workers (Federal Registrar, Part III 2009). Likewise, employers are not culpable for acquiring family medical history through volunteer wellness programs, certification for FMLA leave, or publicly available documents such as newspapers. Employers can, however, be held accountable if they are intentionally searching public documents for genetic information on a particular employee. The final exception pertains to obtaining genetic information through genetic monitoring programs that monitor the biological

effects of toxic substances in the workplace (Federal Registrar, Part III 2009).

Additionally if employers do acquire genetic information on employees, they must adhere to confidentiality guidelines defined by the ADA.

Since the inception of GINA, the U.S. Equal Employment Opportunity Commission has maintained data on the total charges filed under GINA, a total of 586 charges between 2010 and 2012. Roughly 17% of cases have reached a successful settlement or conciliation for the charging party, while almost 63% of the cases were deemed to have no reasonable cause for discrimination under GINA based on available evidence (EEOC 2013a). A lack of understanding of the guidelines set forth by GINA may explain the high number of disregarded cases. In one particular case, *Poore v. Peterbilt of Bristol, LLC* the plaintiff, Mark Poore alleged that he was wrongfully terminated from his job on account of his age and in violation of GINA. Poore explained that he completed a health insurance questionnaire that asked about family medical history, in which he provided information about his wife's multiple sclerosis. Three days later his employer asked when his wife was diagnosed and about her prognosis, and three days after that conversation Poore was terminated without sufficient explanation (*Poore v. Peterbilt of Bristol, LLC* 2012). The charges of genetic discrimination were dismissed because while GINA broadened the definition of genetic information to include family medical history, the intention is to protect *employees* from the potentially predictive nature of genetic information. Poore's wife's medical conditions in no such way provide predictive information regarding the future of his health, and thus this case was clearly not an example of a violation of GINA.

Despite the low number of cases filed in violation to GINA, the EEOC specifically filed its first two lawsuits in May 2013. The first lawsuit has already been settled, in which Fabricut, Inc. requested family medical history and then subsequent medical testing of a temporary employee, Rhonda Jones. Fabricut refused to hire Jones after they received a diagnosis of carpal tunnel syndrome (CTS) from their contract medical examiner, despite the fact that Jones's personal physician conducted more thorough tests which concluded she did not have CTS (EEOC 2013b). The focus was on the illegal request of family medical information which can be construed as genetic information, and thus Jones was awarded \$50,000 in a settlement. The EEOC's second lawsuit claims a similar violation of requesting family medical information and is currently pending.

GINA filled in many of the gaps that previous legislation left regarding the potential for genetic discrimination, though GINA is not without its own limitations. Title I is very thorough in protecting individuals from genetic discrimination against health insurance companies, but it does not protect against discrimination regarding other types of insurance such as life, disability, or long-term care. Regardless, GINA was a landmark piece of legislation acknowledging the need for such protection.

The pieces of legislation discussed are the most prominent, but not inclusive of all laws, regulations, and ethical guidelines that have been established to protect individuals from genetic discrimination. The continued emphasis legislators have placed on mitigating the risk of genetic discrimination illustrates that policymakers are listening to the concerns of the public and attempting to ensure the continued use of genetic information in health care and research. The use of individual genetic information in

medicine will be increasingly used in daily life, which is why it is imperative that policymakers, researchers, and the public work collectively to protect genetic information.

STEM Education and Investment in Research

The Obama Administration has placed an emphasis on the need to improve STEM education in the United States so that more Americans will be equipped to fill the increasing number of STEM related jobs in the future. Much of this emphasis is based upon the United States' declining position in the world regarding STEM education. In a 2011 report on global competitiveness, the World Economic Forum ranked the United States 26th highest in terms of a quality educational system, but only 51st regarding the quality of math and science education (World Economic Forum 2011). Furthermore, the NSF conducted an analysis on the recipients of doctoral degrees in the United States over a ten year period, looking at the citizenship status of the students and their major field of study. While the number of doctorates received by United States citizens has remained relatively the same from 1998 to 2008, the number of doctorates received by foreign students has increased significantly, a 61.1% increase in ten years. It is important to note that the percentage of doctorates obtained by foreign students increased for all general degree types: science, engineering, and non-science or engineering (Figures 1-2). The percentage of engineering degrees by foreign students increased from 45.9% to 60.3% from 1998 to 2008 and science degrees increased from 25.3% to 34.3%, illustrating the decline of science and engineering PhD degrees among United States citizens represented in Figures 3-4 (NSF 2011). All of these reports are representative of the reasons

President Obama and his administration have made the investment in STEM education and research a priority.

Figure 1: PhD degrees received by temporary visa holders in the U.S. from 1998-2008

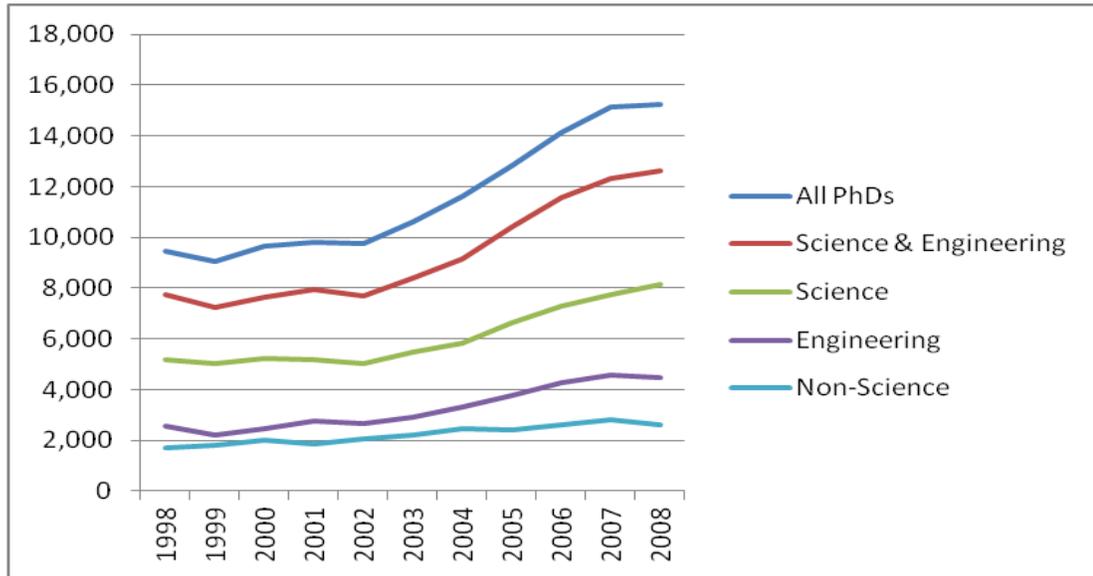


Figure 2: PhD degrees received by U.S. citizens in the U.S. from 1998-2008

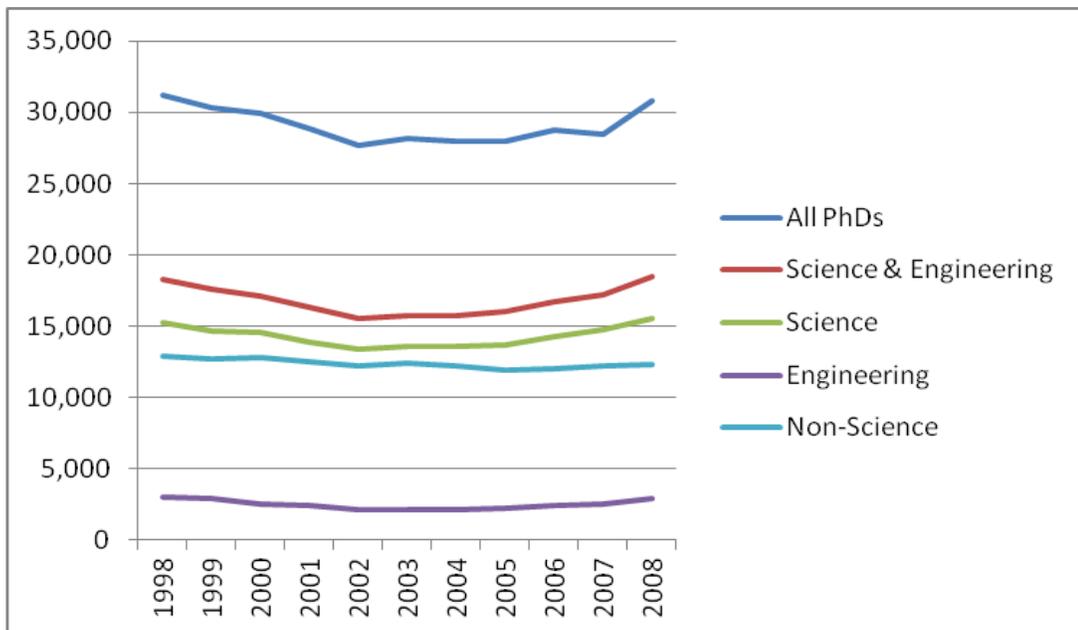


Figure 3: Percentage of science related PhD degrees obtained from 1998-2008

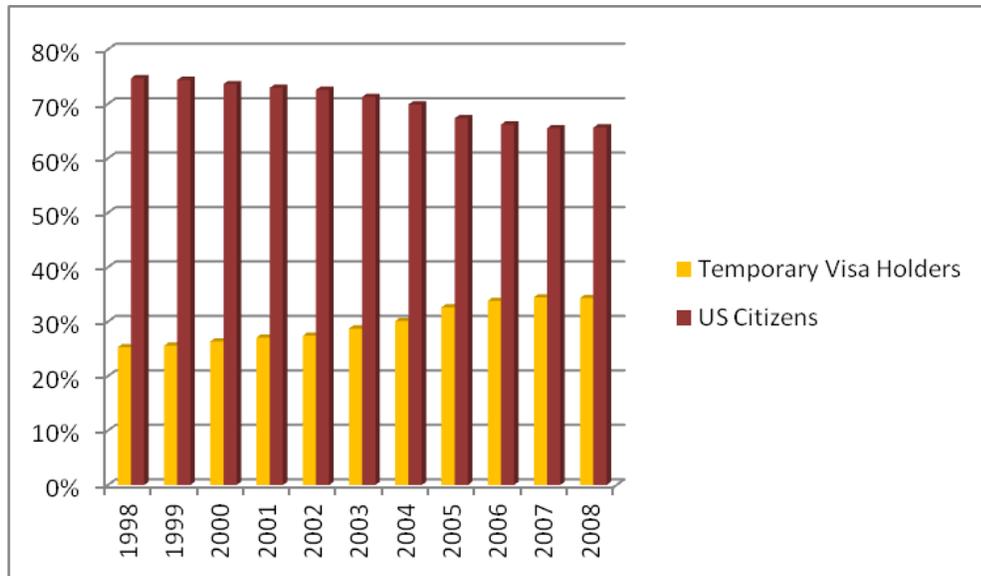
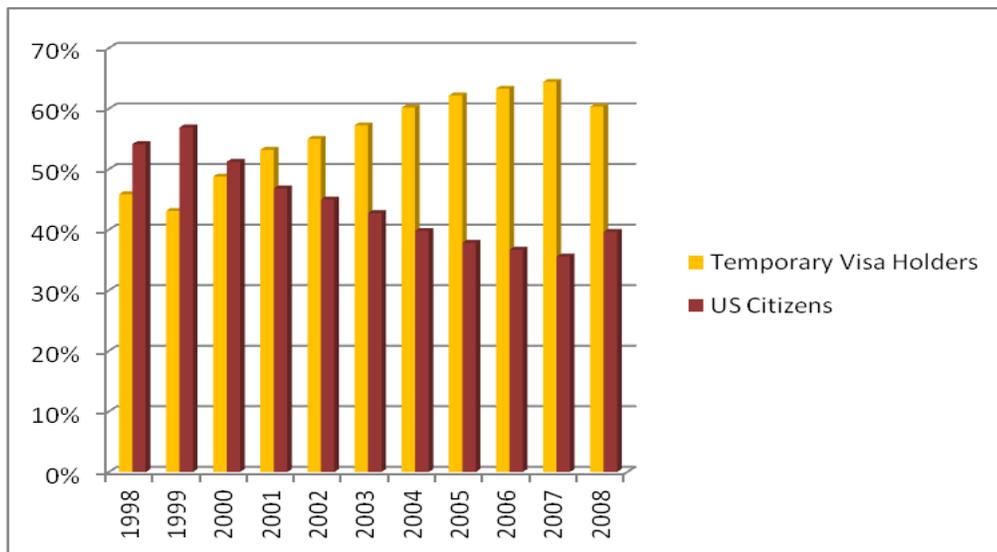


Figure 4: Percentage of engineering PhD degrees obtained from 1998-2008



One of the ways in which the President's focus on STEM has been realized is through the creation of new programs aimed to encourage children's interest in math and science. The Educate to Innovate Initiative was launched in 2009; a campaign designed to move American students from the middle to the top ranks in the world in science and

math over the next decade. The goals of Educate to Innovate extend beyond the Federal Government's aims to increase funding and improve teaching efforts and in STEM, looking to non-profit groups, companies, and educators to invest and join in the mission to improve STEM education by focusing on activities outside the classroom (White House 2013).

The approach of attempting to teach children about math and science outside the classroom has branched out to a variety of organizations, who have committed efforts to reach children in a number of different ways, which to date has raised over \$700 million in public-private partnerships. Sesame Street devoted twenty episodes to focusing on math and science as part of its early STEM literacy initiative, and had First Lady Michelle Obama appear to announce the project (White House 2009). The MacArthur Foundation along with Sony Computer Entertainment America and the Entertainment Software Association launched nationwide competitions to create video games that teach math and science. Discovery Communications created the "Be the Future" campaign which would produce television content across Discovery's 13 U.S. networks, including a commercial-free program on the Science Channel aimed at children (White House 2009). These are a few of the initial examples of how the Educate to Innovate Initiative has developed novel methods to reach and educate children in STEM outside the academic setting. The program has continued to expand with an increase in public-private partnerships and increased funding. The Educate to Innovate Initiative should serve as an example to all professionals in STEM related careers to think outside the box, step outside the lab, and create new ways in which to increase children's and the public's knowledge and perception of STEM related issues.

The allocation of funding of the Federal budget also represents Obama's commitment to the improvement of STEM education and research. The proposed 2014 budget maintains President Obama's commitment to boosting STEM education and research, while simultaneously cutting the number of the existing programs in half in order to decrease fragmentation of these programs in the Federal Government and streamline them for easier coordination. The proposed 2014 budget plans to allocate \$13.5 billion to the NSF, Department of Energy office of Science (DOE SC) and the National Institute of Standards and Technology (NIST) laboratories, which is an increase of \$1 billion, or 8% above the amount allocated in 2012 (Office of S&T Policy 2013a). Additionally, \$3.1 billion has been proposed for STEM education to federal programs through NSF the National Institutes of Health (NIH), the Department of Education (ED), among others. This is an increase of 6.7 percent over the 2012 budget (Office of S&T Policy 2013b). The STEM education budget includes programs for all levels of students, including elementary, high school, undergraduate, and graduate education; some of which are listed in Table 1. One of President Obama's specific goals through the ED's STEM Innovative Initiative is to invest in and prepare 100,000 STEM focused teachers over the next decade. Likewise, Obama wishes to prepare 1 million more STEM undergraduate students over the next ten years through the NSF CAUSE program. Funding for informal methods of STEM education has also become a primary focus by fostering partnerships between Federal agencies and public and private STEM organizations to develop methods to engage and educate children and young adults outside of classroom settings.

Table 1: Proposed 2014 federal funding for STEM education programs

K-12 STEM Education	
\$300 million	Re-design of High Schools and creation of STEM-focused High Schools
\$265 million	ED’s STEM Innovative Initiative
<i>\$150 million</i>	<i>STEM Innovative Networks</i>
<i>\$80 million</i>	<i>100,000 Excellent STEM Teachers</i>
<i>\$35 million</i>	<i>STEM Master Teacher Corps</i>
\$102 million	NSF Discovery Research K-12
Undergraduate STEM Education	
\$123 million	NSF’s Catalyzing Advances in Undergraduate STEM Education (CAUSE)
\$64 million	NSF Advanced Technological Education (ATE) program
Graduate School STEM Education	
\$487 million	NIH Ruth L. Kirschstein National Research Service Award Institutional Research Training Grants
\$325 million	Expand NSF’s Graduate Research Fellowship program
Informal STEM Education	
\$65 million	ED’s Advanced Research Projects Agency for Education
\$48 million	NSF program for Advancing Informal Science Learning
\$25 million	Smithsonian for informal STEM education

The Federal Government has responded to the United States’ decreasing rank in the world regarding STEM education, and the increasing demand for STEM related jobs by making the commitment to improve and invest in STEM education. Investment in STEM spurs innovation which fuels the economy and also creates new jobs; as a result everyone benefits from better STEM education. The ambitious goals of the Educate to Innovate Initiative and other STEM education programs are yet to be fully realized; only time will tell whether the government successfully prepares 100,000 STEM focused

teachers and motivates one million more undergraduates to pursue degrees in STEM. One thing is certain however, and that is to accomplish these aggressive goals it is imperative to continue finding novel ways in which educators, politicians, and STEM professionals can reach the broader public to inform and inspire both children and adults. These are not goals that can be met solely through the classroom, because they have effects beyond the classroom. Increased public knowledge of STEM research can influence policies ranging from environmental protection, to nanotechnology, to emerging biotechnology, such as synthetic biology. Researchers should seize the opportunities of this political environment and seek their own ways to engage with the public and help to increase STEM education and awareness.

Public Opinion of Genetics-Based Research

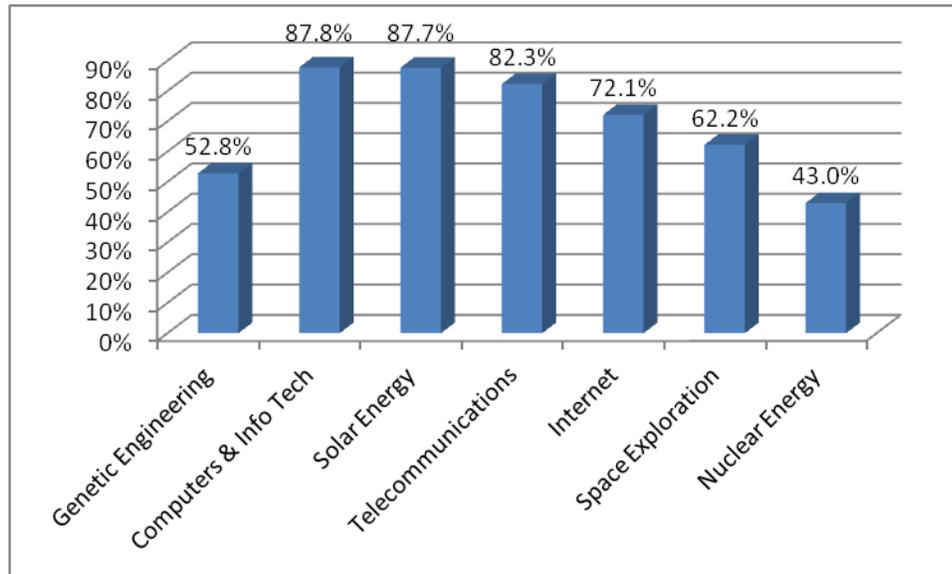
Emerging biotechnology has a long history of stimulating political, ethical, social, and religious debates in the United States. Numerous research studies, polls, and focus groups have analyzed public opinion of genetics-based research and its applications throughout the years. The research overwhelmingly indicates the common links for debate and apprehension to biotechnology are fear, distrust, and a lack of knowledge (Bates et al 2005). Included in this section is a discussion of four research studies which looked at public opinion to highlight some of the recurrent attitudes toward genetics-based research, which are summarized in Table 2.

Table 2: Summary of public opinion literature review

Study	Design	Participants	Purpose	Results
Priest (2000)	Telephone survey conducted between 4/10/2000 - 5/03/2000	N=1,002; nationwide random digit dialing sample of US citizens over 18 years of age	Assess public opinion on biotechnology compared to other emerging technologies and the reasons for these opinions.	US public opinion leans toward a positive view of developments in biotechnology, although support for specific applications is related to moral acceptability. Personal exposure to science seems to make people more accepting of the more controversial uses of biotechnology.
Bates <i>et al</i> (2005)	Nine focus groups divided by self-identified race; conducted from Feb-Mar 2002	N=91; residents of Georgia that were nominated by community advisory boards in three areas across the state	Public understanding of genetics to assess concerns.	The lay public has an informed understanding of genetics. The focus groups identified numerous concerns that could arise from genetics research such as: discrimination, privacy, unequal access to benefits, moral and religious concerns, and the potential misuse of genetic information.
Genetics & Public Policy Center (2007)	18-question online survey conducted between 2/27/07 - 3/4/07	N=1,199; random sample of U.S. adults 18 years or older	To measure public acceptance of the use of genetic information for medical and non-medical purposes, and to examine whom the public does and does not trust with their genetic information.	The American public supports the use of genetic testing to improve health and for medical research purposes. However, the public was concerned about insurance or employer discrimination and do not trust them with their genetic information.
Lemke <i>et al</i> (2010)	Six focus groups; three of which were public and three that included participants of the NUGene biorepository project	N=49; 28 randomly selected adults and 21 adults from the NUGene project	To identify public and biobank participant attitudes toward genetics-based research and data sharing	Five major themes were identified in the focus groups. 1. Wide spectrum of understanding of genetic research. 2. Pros and cons of participation in genetics research. 3. Credibility and trust of the research institution. 4. Concerns about sharing data. 5. The need for increased public awareness.

In 2000 the Public Policy Research Institute at Texas A&M University conducted a telephone survey of 1,002 adults in the United States to assess their attitudes toward various areas of science and technology. Researchers questioned participants about whether they believed their way of life would be improved by seven different areas of science and technology over the next 20 years (Figure 5). They were asked about their views on genetic engineering, which did not specify a difference between the modification of genetics between humans, plants, or animals. While just over half of the respondents gave affirmative responses to genetic engineering, about 30% indicated they believed genetic engineering would make things worse (Priest 2000). Of all the areas of science and technology surveyed, only nuclear energy received fewer positive responses than genetic engineering, and had similar strong negative responses with a third of the participants believing nuclear energy would have detrimental effects in the future (Priest 2000). The study also assessed the participants' attitudes about how different agencies project their points of view on biotechnology. Only 44.4% of the respondents thought the media were "doing a good job" and 36.8% felt their churches were successful. People had more confidence in scientists with a 77.7% approval rating. When asked about the government's role in regulating biotechnology, the results were relatively poor with only 39.5% of participants giving a positive response (Priest 2000). The data from this study suggest that while the American public has confidence in science and technology, attitudes on genetic engineering related issues remain more divided than other areas.

Figure 5: Percent of positive attitudes about whether areas of science and technology would improve the way of life over the next 20 years (Priest 2000).



A study by Bates et al conducted in 2002 sought to assess the public's understanding of genetics-based research by identifying common concerns and benefits. A total of 91 individuals recruited by community advisory boards in Georgia participated and were assigned to nine focus groups based on their self-identified race. Some of the groups were composed of individuals of the same race while others included an equal combination of different races within the same group. All groups agreed there are benefits to genetics-based research, with the majority of participants believing genetics-based research could lead to improved treatments for disease and a better understanding of genetics related diseases, which could lead to earlier detection and prevention (Bates et al 2005).

One of the most prominent concerns of participants of all races was of the potential for discrimination. They addressed fear of discrimination by both insurance companies as well as employers. Many participants drew comparisons between current drug testing policies many employers enforce and the potential for mandatory genetic

testing to be implemented in a similar fashion (Bates et al 2005). They believed this type of consequence would be unavoidable. It is important to note that this study was conducted prior to the enactment of GINA, so there were limited protections against genetic discrimination at this time.

By including a very diverse population in the study, a few issues were addressed that were specific concerns to the African American population based upon their unique historical experiences. Besides the overall fear of employment discrimination based upon genetic testing, the African American participants also indicated they were fearful of genetic discrimination would lend itself to racial discrimination (Bates et al 2005). Whereas Caucasian participants were more concerned with being discriminated against for their predisposition to specific disease or health related traits, many African American participants seemed more concerned with the potential for correlating negative traits or characteristics with race, and therefore adding to the preexisting racial discrimination they feel they already encounter. A quote by one of the participants emphasizes this sentiment by saying, “People discriminate for lots of reasons. So of course, they would justify it if they had some medical basis or some genetic, hereditary thing that they could tie into” (Bates et al 2005). This line of reasoning led to a discussion about the lack of trust in medical research and specifically research that is conducted or regulated by the government. Throughout history African Americans have been given ample reasons to distrust the medical research community, with numerous participants pointing directly to the Tuskegee Syphilis Study, in which research participants were left untreated for syphilis for 25 years after finding an effective treatment. These past ethical violations have long lasting effects on particular population groups, resulting in a distrust of

government, the medical community, and the research community. Regarding genetics-based research, those participants that expressed this type of distrust indicated they would not like the idea of the government having access to their genetic information (Bates et al 2005).

Genetic discrimination may have been at the forefront of the participants' concerns, but there were a few other prominent issues a significant proportion brought up. They cited ethical arguments about how genetic research should be applied and when it crosses the line into "playing God" or "messing with Nature". The notion of "designer babies" was unsettling to a number of the Caucasian participants, more so than other racial groups. They felt the value of genetic diversity was more important than the potential benefits selecting traits could bring to society (Bates et al 2005). Privacy of genetic information and religious ideology were cited as concerns as well. African American participants expressed a fear that genetic testing or genetics related treatments would only be available to those of a higher socioeconomic status, placing a significant discrepancy in available health care between the poor and the rich (Bates et al 2005).

This study serves to remind educators, researchers, and policy makers that in order to reach individuals from all populations and communities, it is imperative to identify the reasons for apprehension to research participation. If the population sample for a study is too homogeneous or heterogeneous, important issues that should be addressed will be missed. Intersectionality is a method of understanding the unique experiences of multidimensional identities of a group of individuals, which is essential for understanding the barriers to supporting or participating in genetics-based research.

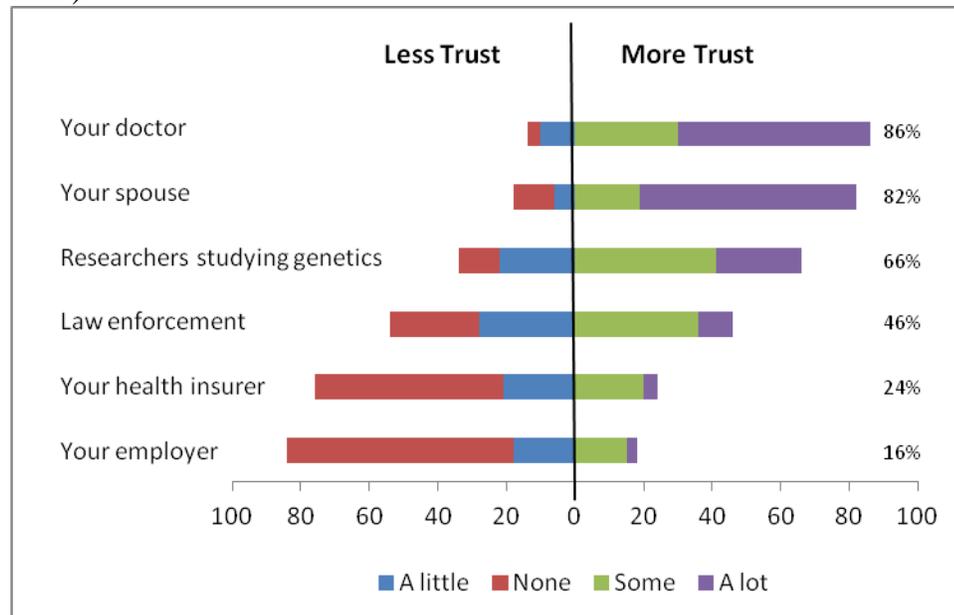
Johns Hopkins Genetics and Public Policy Center surveyed 1,199 American adults in 2007 about public acceptance of genetic testing for medical and non-medical purposes. They also sought to identify which individuals or agencies the public trusts to use DNA for genetic testing and gauge their support for laws to protect genetic information. An overwhelming majority of the participants supported the use of genetic testing for research and health related purposes (Table 3). Participants were not, however, supportive of the use of genetic testing by employers to make employment decisions or insurance companies for setting insurance premiums. At the same time, 92% of individuals expressed concerns about taking individual genetic tests that could predict an increased risk for a disease. They felt this could bring harmful psychological distress to the individual and his or her family (Genetics & Public Policy Center 2007).

Table 3: Support for the uses of genetic testing (Genetics & Public Policy Center 2007)

	Use of genetic testing	Percent in support
Researchers	To find new ways to diagnose, prevent, or treat disease	93%
Doctors	To identify a person's risk of having a bad reaction to a particular medicine	93%
Doctors	To identify a person's risk of a disease where treatment or medicine exist	91%
Doctors	To identify a person's risk of having a child with a serious genetic disease	86%
Doctors	To identify a person's risk of a disease where there no treatment or medicine exist	79%
Employers	To make decisions about hiring and promotion	19%
Insurance Companies	To determine whom to insure or how much to charge	15%

The support or lack thereof for the use of genetic testing also reflects the participants' trust in various individuals to have access to their genetic information (Figure 6). Surprisingly more individuals trust doctors over their own spouses, to have access to genetic information. Despite the fact that 93% of participants expressed support for allowing researchers to use genetic testing in order to study disease, only 66% of the participants indicated they trust researchers some or a lot (Genetics & Public Policy Center 2007). This suggests either a lack of support for studying genetics beyond understanding disease, or that while individuals support genetic testing research, they may not themselves be comfortable with providing their own DNA for such studies. A lack of trust in law enforcement could parallel distrust of governmental access to genetic information, as discussed previously in the Bates et al study. Finally, 68% of all respondents indicated support for creating laws to minimize the potential for genetic discrimination (Genetics & Public Policy Center 2007).

Figure 6: Trust in individuals to use genetic information (Genetics & Public Policy Center 2007)



The final public opinion study that will be discussed is a study by Lemke et al, which analyzed attitudes toward participation in genetics-based research and data sharing. Participants were placed into six focus groups; three groups consisted of random adults, where the others consisted of individuals that had already agreed to participate in a biobank project. The study was conducted in May 2008, at the time GINA was signed into law, although it could be argued that the majority of Americans were unaware of GINA and still are. A study in 2009 surveyed physicians to assess their awareness and knowledge of GINA, a group that would be assumed to be more aware of laws protecting health information. The study found over half (54.5%) of the physicians had no awareness at all of GINA, suggesting the public awareness of GINA at that time was even lower (Laedtke et al 2012).

Through the focus groups five overarching themes were identified. The first theme was about participants' understanding of genetics-based research. They found participants were both excited and hopeful for the potential role genetics could play in healthcare, but they were also fearful and had concerns over how genetic information could be misused in potentially detrimental ways. The most cited concerns were of "playing God", genetic discrimination, the government acting as "big brother", and the privacy of genetic information (Lemke et al 2010). Their research also indicated a significant lack of understanding about genetics-based research.

The focus groups discussed the pros and cons to participating in genetics-based research. The participants shared an overall sentiment of altruism, that a desire to help would persuade them to participate, but they also believed most people would not feel motivated to participate in a genetics-based research study unless they had personal

reasons to help; i.e. a loved one that suffered from a genetic disease or a personal interest in genetics (Lemke et al 2010). The list of barriers to participation mirrored many of the concerns already discussed. Fears in general, as well as a fear of discovering a familial predisposition to a disease were referenced. Genetic discrimination once again was cited as a barrier, including specific concerns regarding insurance companies, government, the health care system, and employers. They also indicated that a lack of knowledge and understanding about genetics could dissuade individuals from participation.

The third and fourth themes both revolved around trust, that of the credibility of the research institution, transparency of how genetic information is being used, and how genetic information is shared among research institutions. Participants expressed distrust of institutions that are out for profit, citing insurance and pharmaceutical companies as the worst culprits. The government did not receive high accolades either, but participants discussed their distrust of the government as a credible oversight body for genetics-based research, preferring an independent group to oversee genetics-based research instead (Lemke et al 2010). In order for the participants to feel comfortable with their genetic information being shared with other researchers, they would prefer their information would be used for studies with similar purposes and would prefer to be re-contacted for consent. The assurance of adequate security and privacy practices was as important as trust in the institution receiving their genetic information.

The final theme identified in the focus groups was a need for increased public awareness. The participants overwhelmingly argued that in order to increase participation and reduce fear of genetics-based research, more education is necessary. One participant said in order to build trust, the scientific community needs to “educate

away the fears” (Lemke et al 2010). They felt much of the information they receive about genetics comes from the media, which they felt was biased and increased distrust. More accurate sources of public information and partnerships between the public and research communities were a couple ways in which the participants thought researchers could reach out to the public. Many of them said participating in the focus group itself was a highly educational experience, which validates the argument set forth in this paper about how researchers have the opportunity to educate and inform research participants.

All of these studies express similar concerns among the public regarding their opinions of genetics-based research. Genetic discrimination fears seemed to be the prominent concern among participants, which is not surprising considering the lengthy history of discrimination in the United States and the fact that discrimination against race, gender, and sexual orientation are still issues today. What is surprising however, is that GINA was enacted as a proactive piece of legislation to prevent genetic discrimination from occurring in the future. There is little actual evidence that genetic discrimination was a serious problem in the U.S. Most antidiscrimination legislation address patterns of past discrimination, giving validation for the need to enact such protections, but GINA is loosely based on actual historical accounts of genetic discrimination, and more so on the history of discrimination in general in the U.S. (Feldman 2012). Despite the fact that genetic discrimination fears may be unsubstantiated and protection under GINA exists, many Americans are unaware of the law and therefore fear of genetic discrimination is still a major concern and barrier to participation in genetics-based research and genetic testing. Researchers contacted individuals who were in contact with a Hereditary Breast and Ovarian Cancer Syndrome advocacy group and invited them to participate in a

questionnaire about attitudes and awareness of genetic discrimination post enactment of GINA. What is interesting about this study is that 69.2% of the respondents had undergone genetic testing, but the study found a total of 54.3% of all participants had never heard of GINA (Allain et al 2012). For a group that has been more intimately involved with genetic testing, awareness of GINA is still limited. There is still much researchers, educators, and policy makers can do to address public concerns and distrust of genetics-based research.

Outline of Thesis

The introduction to this paper serves to exemplify the foundation for this project. Through discussions of genetic information protection laws, governmental initiatives to increase STEM education, and public opinion of genetics-based research, the underlying goals are to address fears and concerns while increasing education, awareness, and participation. In the fast paced and ever-changing world of genetics-based research, it is imperative to become innovative not only in the research conducted, but also in education, awareness, and the dissemination of information. In order to bring awareness to the public, education has to extend beyond the classroom setting.

The GKS participants are a great resource to survey about their experiences and opinions due to the manner in which the study was conducted, including the unique environment and longitudinal nature of the study. The study includes both adults and children and for many of them, participation in the GKS has become part of their annual State Fair experience. This population is ideal for analyzing the impact of participation in a genetics-based research study and the effect of public engagement the study has had on fairgoers. Regarding the three questions this project aims to analyze, the overall

hypothesis is that participation in the GKS has increased both the parents' and children's knowledge, and interest in genetics-based research, and influenced their opinions.

Participants are likely to be of the opinion that the environment of the State Fair has offered an ease of participation and created a comfortable environment to interact with the research team. Finally, the GKS participants are more likely than the general public to support uses of genetic information and believe the benefits outweigh the risks to human health.

The next chapter will focus on research studies at State Fairs. The GKS is not the first study to utilize the fair environment for research purposes; the Minnesota State Fair in particular has been home to numerous research projects. The GKS methodology, demographic information about the participating families, and results of participation will be summarized as well in the subsequent chapter. Chapter three will outline the ethical arguments that were broadcasted across various media at the onset of the GKS in 2010. The GKS came under scrutiny by bioethicists predominantly because of the environment, many of them arguing that a State Fair is not a serious enough place to conduct genetics-based research. One of the many goals of Educate to Innovate and similar programs is to find novel ways to reach and educate the public in STEM. Bringing research into the public is a great way to inform individuals about research. While it is good practice to constantly question the ethical nature of human subjects based research studies, simply because a study is attempting something new does not imply the methods are unethical. Therefore it is important to address these ethical concerns to pave the way for future research projects. Chapter four will present the methodology of the public engagement and participation survey sent to GKS participants. Chapter five presents the survey

results, which have also been merged with previously collected data throughout the GKS. The analysis contains results for both the parents' and the children's experiences with the study. The third section of the survey was compared to survey data collected from random fairgoers in 2010. The final chapter will discuss the implications of these results on public engagement, the ways to increase STEM education, and the role researchers can take to aid in these endeavors.

Chapter 2: State Fair Research and the Gopher Kids Study

Past State Fair Research

Conducting health research at State Fairs is not a new concept, although the GKS is unique in that longitudinal research has not been attempted in such an environment. The Midwest in particular has a long history of research at fairs. Many of the studies conducted at fairs included some sort of health screening, which would allow participants to receive a health assessment through their participation. One of the earlier recorded research studies at the Indiana State Fair dates back to 1946 in which over 17,000 individuals visiting the fair in 1946 and 1947 participated in chest x-ray screenings for tuberculosis (Bundy 1947). Ethical guidelines were in place so that if anything of concern was identified through the x-rays, the participants' physicians were contacted.

Research studies providing health assessments have continued to be a part of fairs across the country. At the Wisconsin State Fair in 1954, fairgoers had the opportunity to be part of a hearing survey to assess reasons for hearing loss. About 3,500 individuals participated in the four step study process including: an otologic exam, a personal history of general noise exposure, occupational history to identify noises caused by military service, factory, or farming industries, and an actual hearing test (Glorig 1957). At the Arizona State Fair in 1957, a total of 1220 participants were screened for glaucoma at the public health booth that had previously conducted other health screenings by the Arizona State Department of Health (Lorenzen 1959). The goals of the survey were to screen individuals for glaucoma while also educating the public about the importance of early glaucoma detection and the methods of detection. A total of 21 participants showed warning signs of glaucoma, 17 of these individuals sought further screening by

physicians, and in 10 cases a confirmed diagnosis of glaucoma was made (Lorenzen 1959). The Arizona study illustrates that by bringing research and health screening to public venues like a fair, the researchers are given the opportunity to not only contribute to research, but can also educate the public and bring awareness to health issues.

Finally, the Minnesota State Fair itself has a lengthy history of facilitating research and health assessments. Throughout the 1950's and 1960's the Minnesota Podiatry Association conducted pediatric foot examinations over a seven year period to assess foot disorders (Sabbann 1965). The 1980's saw multiple research projects, including two conducted jointly by the Minnesota Dental Association and the University of Minnesota School of Dentistry. Both studies were administered at a dental exhibit that has been housed in the Education Building at the Minnesota State Fair since the 1970's. In 1985 a total of 988 fair visitors completed a questionnaire on their knowledge of preventative dental care, which allowed researchers to identify areas of misinformation about preventative practices (Bakdash and Peterson 1986). In 1987 researchers sought to evaluate the public's knowledge of oral health once again, this time asking visitors to complete a questionnaire on their knowledge and use of smokeless tobacco products (Hastreiter et al 1990). A total of 5,927 individuals completed the survey, and according to the demographic data obtained, the study population was younger, more highly educated, and visited their dental office more than the general population of Minnesota (Hastreiter et al 1990). Due to the location of the study in the Education Building at the fair, this demographic profile is not surprising.

These are just a few examples of research studies that have taken place at state fairs across the country, but they illustrate that the idea of bringing research into public

events can reach large numbers of individuals and bring education and awareness to the public. While research at fairs is not a new concept, longitudinal research has not been attempted, which makes the GKS unique in its study design.

The Gopher Kids Study Recruitment

The Minnesota State Fair is among the largest and most popular fairs in the United States, with an all-time record of 1,790,497 attendees in 2009 (MN State Fair 2012a). It is only second to the Texas State Fair in attendance numbers, but the Minnesota State Fair only takes place over twelve days versus the month long Texas State Fair, and thus potentially has a higher per capita attendance. While the attendance numbers of the Minnesota State Fair represent visits to the fair rather than unique visitors, with a state population of 5,303,925 in 2010 (U.S. Census Bureau 2012), it is probable the per capita attendance rate is substantial each year. The Minnesota State Fair is conveniently located near the University of Minnesota St. Paul Campus, which made the close proximity to the University, coupled with the significant representation of the population, attractive to attempt a longitudinal research study at the Fair.

The GKS was launched at the 2010 Minnesota State Fair (herein referred to as the State Fair) by pediatric epidemiologists, Dr. Logan G. Spector and Dr. Ellen Demerath at the University of Minnesota. The study was approved and funded as a three year feasibility study to demonstrate the viability of a longitudinal genetics-based research study of children at the Minnesota State Fair. Recruitment and data collection was conducted in the University of Minnesota's permanent building at the State Fair. The research team consisted of University faculty and staff members from a variety of health research departments as well as student volunteers with an interest in the health sciences.

All study members completed human subjects research training and were thoroughly trained on subject recruitment and data collection prior to each State Fair. Special attention was given to the procedures of obtaining informed consent from eligible participants, discussed in Chapter 3.

The primary aim of the study was to identify genes that contribute to the normal growth and development of children. The goal was to recruit 500 children over six days at the 2010 Fair. The inclusion criteria were set to recruit children ages 1-11, families that were residents of Minnesota and two metro-area counties in Wisconsin (Pierce and St. Croix), and at least one biological parent present at the Fair to provide a DNA sample. Limiting recruitment to primarily Minnesota residents allows for a comparison to the state's census and other available data. Initial recruitment for the study was scheduled for six of the twelve days of the State Fair for six hours each day. Prior to the launch and after the first day of the study, local media outlets picked up the story and coined the study as "DNA on a Stick", in reference to the iconic nature of food items served on sticks at the Minnesota State Fair. Due to the media exposure, 35% of parents who participated indicated they planned to visit the GKS during their trip to the Fair. The remaining 65% of participants were approached randomly by the GKS research team as they visited the University of Minnesota building, with no previous knowledge about the study.

At the 2010 State Fair the GKS team successfully recruited 534 families comprising 841 children, far exceeding the original recruitment goal. The research team explained all components of the consent form and participating parents were given a copy to take home. Children aged seven and above were given an assent form to sign to

indicate their understanding of participation in the study. Once consent and assent were obtained, the parents provided their contact and demographic information. They were also asked how many of the past five State Fairs they had attended, in order to assess the frequency of visitation to the Minnesota State Fair, with 67% indicating they had visited all five years. This supports the ability to conduct longitudinal studies at the State Fair since many fairgoers attend annually. After discussing the study procedures and obtaining consent, the families were informed that they would also be given tokens of appreciation for their time in the form of \$5 of ride tickets, free admission to the 2011 and 2012 State Fairs, and a University of Minnesota drawstring backpack as a souvenir.

The participating families then moved on to providing anthropometric measurements and biospecimens. Each child and his or her biological parent(s) gave DNA saliva samples using Oragene collection kits. The children then had their height, weight, waist circumference, and blood pressure measured. Finally the children were asked whether they were willing to participate in two optional biospecimens: fingernail clippings and blood spots obtained through fingerstick. The average amount of time spent per family participating in the study was about 30 minutes. Each child received a couple tokens of appreciation for their participation in the Gopher Kids Study. They each received \$5 worth of ride tickets and a University of Minnesota drawstring backpack.

Six months after the 2010 State Fair, each participating family received a survey that included questions about their children's diet, physical and leisure activities, health and development, and sleep habits. The questionnaire also included questions about the parents' food and exercise habits, including self-reported height and weight, and family medical history. The intent of the survey was to gather additional health information to

supplement the anthropometrics and biospecimens collected at the State Fair, and to evaluate the willingness of the parents to complete the questionnaire and assess their continued participation in the study. Included with the questionnaire was a postcard which parents could return to indicate their desire to withdraw from the study.

The 2011 and 2012 State Fairs were conducted similarly to the recruitment year, with a few minor changes. Several weeks prior to each State Fair, the GKS team mailed reminders to each family to visit the study at the State Fair for updated anthropometric measurements. As an incentive, each child received an admission ticket to the State Fair, along with a ticket for one parent per family. Whereas the GKS was only present six of the twelve days of the State Fair in 2010, in the subsequent years the study was at the State Fair all twelve days, in order to allow participants to return to the State Fair any day they preferred. Due to the difficulty of obtaining reliable results, the GKS team chose to forgo blood pressure measurements. Many of the readings were inflated by environmental conditions of the State Fair, such as significant heat, increased intake of fried and sugary foods, and the loud, chaotic nature of the State Fair. The remaining anthropometrics were taken to see how the kids had grown, and the two optional biospecimens were still included in the study. DNA was collected for any biological parents who were not present at the 2010 State Fair.

Each year a new component was added to the study. In 2011 digit ratio was added, which is the ratio of the lengths of the ring and index fingers. Research indicates that the ratio of these digits is affected by exposure to androgens in utero, which can be linked to numerous traits (Williams et al 2003). In 2012 three-dimensional photographs were taken of the children. The 3D photos allow for the measurement of facial

morphology, and are currently being used in a genome-wide association replication study.

Gopher Kids Study Results and Demographics

As previously stated, the GKS recruited 841 children from 534 families over 36 hours at the 2010 State Fair. DNA samples were collected from 829 children; samples were not collected from 12 of the younger children that were unable to cooperate for a saliva sample. DNA was collected from 476 biological mothers and 267 biological fathers that were present at the fair. Anthropometric measurements were obtained for all participating children, fingernail clippings for 570 (67.7%) children, and blood spots for 288 (34.2%) of the children. Demographic data, including race/ethnicity, marital status, household income, parents' education, and the children's race/ethnicity was collected for all the families. Of the participating children, 51% were identified as female and 49% as male.

While one of the advantages to recruiting for research at the State Fair is the per capita attendance rates, the GKS study population is still limited in its representation of the state population, as many research studies are. The majority of the parents self-identified as non-Hispanic and Caucasian, a much less homogeneous population than compared to the 2010 Minnesota Census data (Figures 7-8). The household income and education level of the parents are higher for GKS participants compared to state averages, but considering the State Fair environment this demographic difference is not surprising, as previously noted in the discussion of dental studies conducted at the State Fair. Firstly, the State Fair can become an expensive family outing when considering the cost of admission, entertainment, food, and transportation, all of which become more daunting

for those traveling hundreds of miles across the state that may also have to pay for accommodations. Based on the 2010 Census data, the median household income for Minnesota was \$58,476, but the income level of GKS participants is significantly higher with about 42% of families earning over \$100,000, illustrated in Figure 9 (U.S. Census Bureau 2012). Secondly, the location of the study takes place inside the University of Minnesota building, which attracts a significant alumni population and thus a highly educated population; in fact at least one parent from 200 families reported they had some affiliation with the University of Minnesota as alumni, students, staff, or faculty. The comparison of GKS education levels to Minnesota’s population is represented in Figure 10, provided by the Minnesota Office for Higher Education (MOHE 2010).

Figure 7: Comparison of race/ethnicity of the GKS and MN Census (MSDC 2010)

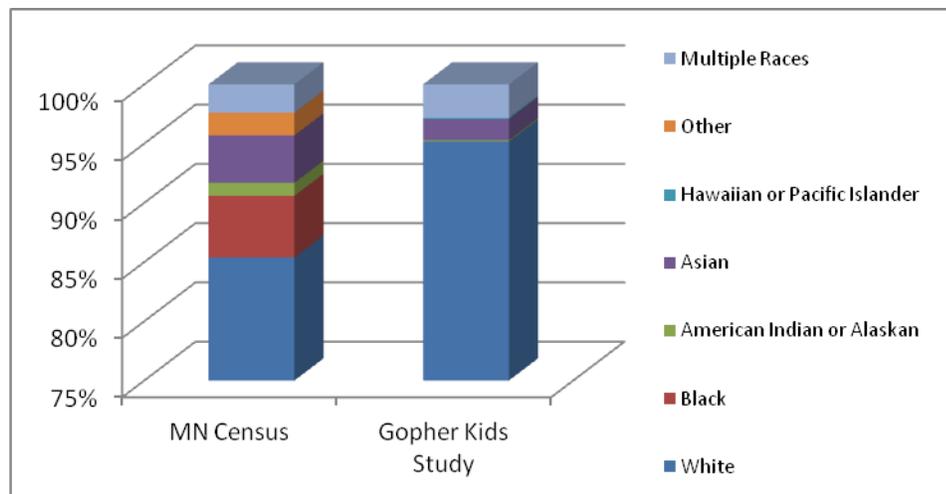


Figure 8: Comparison of Hispanic data of GKS and MN 2010 Census (MSDC 2010)

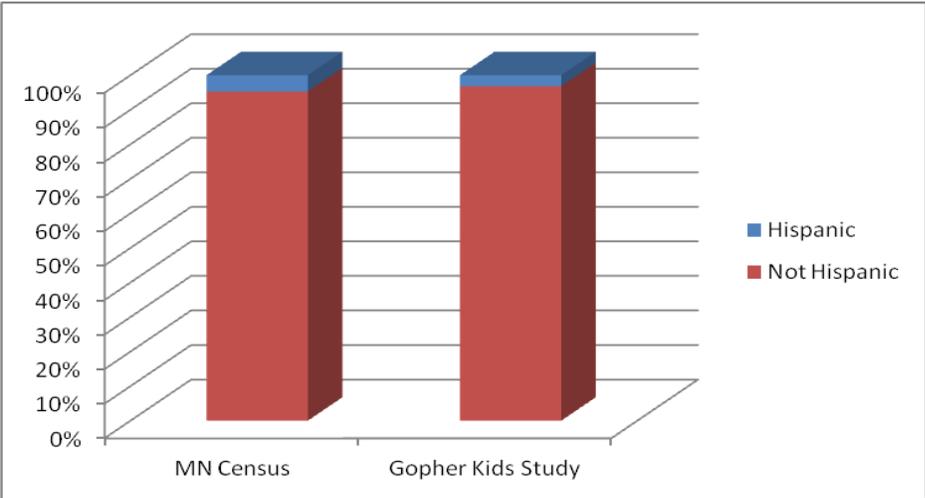


Figure 9: Household income levels for GKS participants

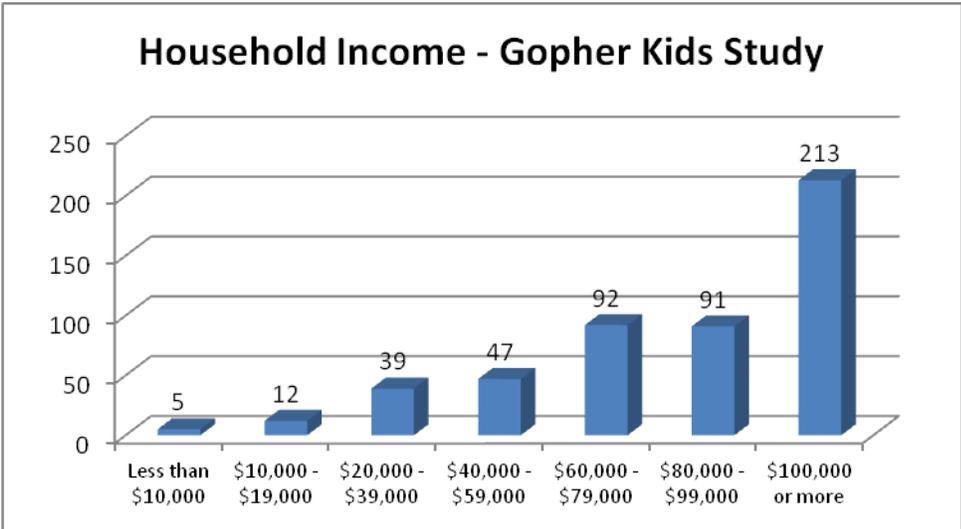
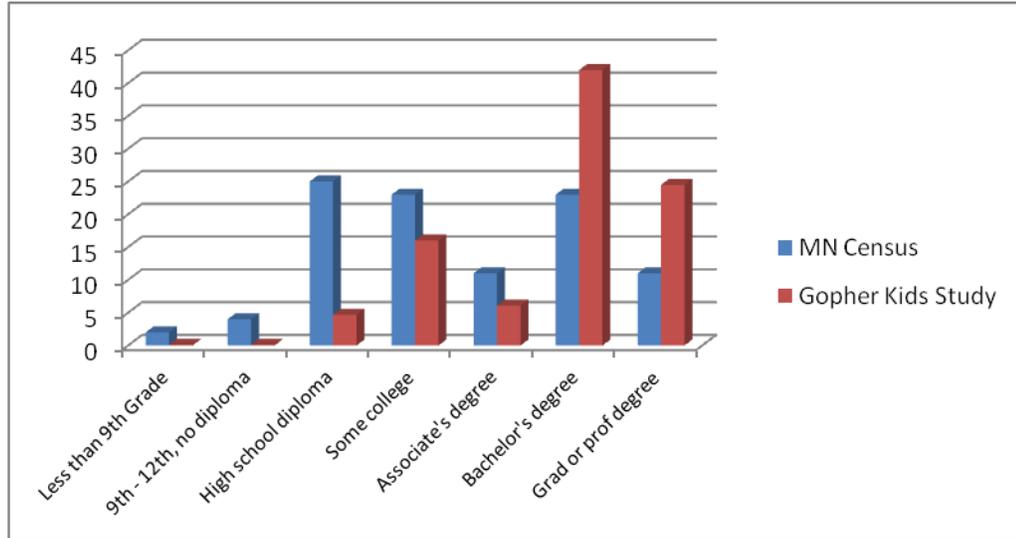


Figure 10: Education level of the GKS participants and the 2010 MN Census data



Six months after the recruitment at the State Fair, GKS participants were mailed a questionnaire that included questions that focused on gathering data about the children's diet, physical and leisure activities, health and development, and sleep habits. It also included questions about the parents' food and exercise habits, family medical history, and their self-reported height and weight. The intention of the survey was to supplement the anthropometric and genetic data collected at the fair, and to also assess the willingness for participants to complete a questionnaire and continue their participation in the study, seeing that it is a feasibility study. Included with the questionnaire was a postcard that families could return indicating their preference to discontinue their participation in the study. Fifteen families returned the postcard, and therefore their personal information and biospecimen samples were destroyed, with the exception of unidentifiable demographic information. By the 2011 State Fair, 457 families (88%) returned the survey, strongly demonstrating their willingness to take part in study components outside of the fair environment.

The participants' survey return rates appeared to be indicative of their enthusiasm to return to the State Fair in subsequent years. At the 2011 State Fair, 388 families (75%) returned to participate in data collection, and the 2012 State Fair saw an even greater return rate of 413 families (80%). Each year additional DNA samples were collected from biological parents who had not previously attended the fair and a greater number of children chose to participate in the optional fingernail clipping and blood spot biospecimen collections. Whereas in 2010, about 67% of the children gave fingernail clippings, in 2012 77% of them opted in. Likewise with blood spots, in 2010, 34% of children participated; in 2012 the percentage rose to 43%.

This brief summary of the experience of the GKS over the past three years serves as an excellent case study in attempting to conduct a longitudinal study at a public event. The study has many unique advantages that could be taken into consideration when designing large scale studies of this kind. The GKS is incredibly cost effective compared to many longitudinal studies since the study subjects participate while attending an event they already planned to attend. Efficiency of data collection is another benefit, as all annual measurements and biospecimens are collected in twelve short days. Although the demographic data of GKS differs from the demographics of the entire state population, the study does have the opportunity to reach individuals from all parts of the state, instead of focusing solely on the metro population of the Twin Cities. Roughly 15% of the GKS participants reside in towns and cities outside the metro area.

While the GKS has proven successful as a longitudinal genetics-based research study, the unique attributes of the State Fair environment offer opportunities for public engagement by bringing education and awareness of genetics-based research to the

participants the State Fair public. Witnessing firsthand the personal experiences of the children and their parents and the overwhelming positive reaction to the study from fairgoers, led to the motivation for this project. This research project seeks to quantify the participants' experiences with the GKS, to assess how their opinions, knowledge, and interest in genetics-based research have changed as a result of participation. Human subjects research studies are also a great way to educate and inform individuals. Fear and distrust are prominent barriers to individuals' willingness to participate in genetics-based research, and studies like the GKS offer transparency to bring research into the public eye for all to see.

Chapter 3: Ethical Considerations of Research at the State Fair

When conducting human subjects based research studies, it is important to take into consideration and implement ethical practices in order to limit the potential harm to research subjects. Due to the historical exploitation of humans in research, numerous ethical principles, guidelines, and regulations have been implemented to ensure the ethical treatment of humans in research. The Nuremberg Code and the Declaration of Helsinki serve as the foundation for the Code of Federal Regulations Title 45 Volume 46, or otherwise known as the Common Rule. Likewise, the Common Rule is heavily influenced by the Belmont Report which is a report that provides ethical principles and guidelines for the protection of human subjects in research and was created by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report provides the basis for three fundamental ethical principles for all human subjects research, which include: respect for persons, beneficence, and justice; all of which will be described in greater detail throughout this chapter regarding their direct application to the GKS.

The purpose of this chapter is to emphasize the ways in which the GKS adheres to the ethical principles and guidelines established by the Belmont Report and the Common Rule. At the onset of the study local media outlets broadcasted the study, and immediately following the media attention a number of bioethicists across the country aired their criticism, questioning the ethical nature of the study, largely criticizing the environment of the fair as an appropriate venue to conduct research. Because this paper examines the social benefits of conducting research in a public venue like the State Fair

through public engagement, it is important to illustrate how the environment itself helps rather than hinders the application of ethical principles and guidelines. This chapter will address each of the ethical concerns raised through the media over the Internet, and discuss how the GKS addresses each of the ethical principles set forth by the Belmont Report as well as components of informed consent. These arguments will be supplemented by peer-reviewed research articles that support the study design of the GKS.

Bioethicists and the Media

Prior to the launch of the study, the GKS team created a website that contained eligibility criteria, an introductory video about the study created by Dr. Spector, and copies of the consent and assent forms to be used in the study. One of the primary reasons for the study website was to publicize the research project in advance to the 2010 State Fair to allow potentially interested families the opportunity to read through the forms and think about questions they may have about the study. As previously mentioned, about 35% of the participants said they heard about the GKS prior to their attendance at the State Fair and had planned to participate in the study. Although these participants were previously informed about the study, data was not collected to determine whether they read the consent form prior to enrollment. In early August, just weeks before the State Fair, GKS researchers contacted the Star Tribune, the largest newspaper in Minnesota, to give the study some media exposure. To add another perspective to the article, the journalist decided to interview the Citizens' Council on Health Care, a local privacy group that has challenged states' collection of neonatal bloodspots regarding their use in genetic screening. While the Council recognized the

privacy protections the research team put into place, they still questioned the appropriateness of conducting research at the State Fair (Olson 2010). This marked the first of several organizations' criticisms of the ethical nature of the GKS, and the subsequent flurry of media stories and blogs across the Internet and local television news shows.

Just one week after the initial Star Tribune story was published online, Doug Pet, a blogger for the Center for Genetics and Society (CGS) brought up some of his ethical concerns about the GKS through CGS's weblog, the Biopolitical Times. The strongest critique regarded the vagueness of the consent form, citing a lack of specificity of the usage intentions and limitations of the use of DNA samples, and ambiguity over who will have access to the genetic information. A copy of the consent form is included in Appendix A. In his argument Pet focused on the wording in the consent form about participant DNA samples being "kept indefinitely" and made correlations to notable cases where the use of genetic information was unspecified and unrestricted, such as the Havasupai Indian tribe and Henrietta Lacks. Pet went on to question the enrollment site of the GKS by saying, "the chaotic and otherwise jovial atmosphere of a state fair could not be further opposed from a lab, clinic, or other appropriately focused setting for gaining fully informed consent" (Pet 2010). The environment and incentives of ride and admission tickets were called into question and suggested as potentially coercive to participants' consent.

After the CGS blog and the launch of the study at the State Fair, numerous media organizations picked up the story, many of which continued discussion of the ethical concerns of the GKS. This included Minnesota Public Radio, the Wall Street Journal

Health Blog, Nature, the AAAS, and MinnPost, along with several local television news stations. Marcy Darnovsky, the associate executive director for the CGS joined the conversation emphasizing the seriousness of handing over DNA samples, arguing that it requires even more consideration than handing over one's social security number since a person can always get a new SSN (Hobson 2010). Darnovsky mirrored the sentiments expressed by Pet, stressing that the State Fair is not an atmosphere conducive for obtaining meaningful informed consent, especially when "tempting kids and parents with free tickets" (Callaway 2010). Dr. Norman Fost, a bioethicist from the University of Wisconsin Madison, agreed that the State Fair is not the proper place to conduct genetics-based research, and is quoted as saying, "Given the complexity of these issues, the fair seems like the worst place in the world for parents to sit down, discuss these things, have their questions answered, and make thoughtful decisions about very complicated ethical issues" (Schmickle 2010). Concerns about the environment were increased by the incentives given to study participants. A bioethicist from the University of Iowa, Christian Simon, explained that while it is routine to give small tokens for participation, especially in research where there is no direct medical benefit to participating, offering ride tickets to children may have coercive effects. Children, not understanding the nature of their participation in the study may pressure their parents by the sheer desire to receive ride tickets (Schmickle 2010).

The factors of the State Fair environment were not the only components of the study that led bioethicists to question the consent process. The consent form itself was questioned once again. Fost felt the four page consent form and the study website were lacking pertinent details of the study, to the extent that he was confused by the actual

questions the study sought to research (Schmickle 2010). Bioethicists were not the only ones concerned about the details of the consent form. Lee Black, a lawyer with the Centre of Genomics and Policy at McGill University in Montreal, criticized the form for not providing any details about how genetic information would be used in the future. He also believed the GKS researchers underestimated the risk that genetic information could be released publicly (Callaway 2010).

Despite the critiques of the consent environment and process, a few supporters of the study design offered their insight as well. Another researcher from the University of Minnesota, Brian Van Ness from the Institute of Human Genetics, provided an explanation to the criticisms that the consent form did not include enough detail about the potential usage of genetic information. He explained that years ago researchers had to tell people exactly what they were looking for, but with the ability to look at such a large portion of the genome, limiting research to a specific set of genes could potentially miss important information (Schmickle 2010). Dr. Spector supplemented this response by explaining that the study was intentionally left open-ended to leave room for discovery in the future for this longitudinal study. In reference to the concerns about the environment and study methods, Daniel Vorhaus, a biotechnology lawyer, pointed to the fact that new methods of conducting genetics-based research are frequently scrutinized and deemed controversial. By attacking novel methods of research he states, “I think it is an easy way to avoid the much more complicated question of analyzing the benefits and the risks of genetic research, including what can be gained by pursuing new ways to involve and educate members of the public on these topics and to increase public participation” (Callaway 2010).

The quote by Vorhaus captures the essence of the GKS research project which is to embrace new ways to conduct genetics-based research by reaching out to the public. Through this sort of public engagement, researchers and ethicists need to include the indirect benefits of public involvement, education, and awareness that research can bring to the table when assessing the level of risks and benefits to a particular study. The remaining portion of this chapter will speak to the concerns laid out in this section by discussing how the GKS addressed these specific concerns and using other examples in peer-reviewed literature to support the GKS methodology.

Obtaining Informed Consent at the State Fair

To begin this discussion of informed consent concerns, it is important to identify factors that make the process of informed consent ethically sound. According to the Common Rule, the general requirements of informed consent that apply directly to the GKS include the criteria illustrated in Table 4 with examples of the language used in the actual GKS consent form (CFR 2009). The full consent form is included in Appendix A.

Table 4: Common Rule requirements and GKS consent form language

Common Rule Requirements	Example of Language in GKS Consent Form
An explanation of the purposes of the study, the expected duration of the subject’s participation, and a description of the procedures	The main purpose of this study is to understand how genes contribute to children’s normal health and development. During this first phase of the study, we are trying to see if families will participate in research based at the Minnesota State Fair. If it is successful, we will then enroll a much larger group of children. Our goal is to recruit 500 children at the 2010 State Fair and have them visit again for measurement and sample collection at the 2011 and 2012 State Fairs.
A description of any foreseeable risks to the subjects	The risks of this study are minor. There is a small risk that your or your child’s personal information could accidentally be released to someone other than study staff. We would keep all personal information in locked

	<p>file cabinets or in computer databases protected by passwords. Only study staff would have access to these documents and files.</p> <p>Also, because we're getting DNA from parents and child, we may be able to tell if someone was adopted or if their father is different than they think. Our policy is to not reveal this information.</p>
<p>A description of any benefits to the subjects</p>	<p>There is no personal benefit to you or your child for participating. The study may benefit society by discovering genes related to normal growth and development</p>
<p>Disclosure of how confidentiality will be maintained</p>	<p>The records of this study will be kept private. In any publications or presentations, we will not include any information that will make it possible to identify you as a subject. Your record for the study may, however, be reviewed by departments at the University with appropriate regulatory oversight. Your participation in this study will not be noted in your medical record. To these extents, confidentiality is not absolute.</p>
<p>Information about whom to contact for answers to research questions</p>	<p>The researchers conducting this study are Logan G. Spector, Ellen W. Demerath, and their associates at the University of Minnesota. You may ask any questions you have now, or if you have questions later, you are encouraged to contact Dr. Spector at 612-624-3912 or Dr. Demerath at 612-624-1818.</p> <p>If you have any questions or concerns regarding the study and would like to talk to someone other than the researcher(s), you are encouraged to contact the Fairview Research Helpline at telephone number 612-672-7692 or toll free at 866-508-6961. You may also contact this office in writing or in person at Fairview University Medical Center - Riverside Campus, #815 Professional Building, 2450 Riverside Avenue, Minneapolis, MN 55454.</p> <p>You will be given a copy of this form to keep for your records.</p>
<p>A statement indicating the voluntary nature of the subjects' participation</p>	<p>Participation in this study is voluntary. Your decision whether or not to participate in this study will not affect your current or future relations with the University of Minnesota. If you decide to participate, you are free to withdraw at any time without affecting those relationships.</p>

Despite criticisms regarding the length of the GKS consent form, all essential components required by the Common Rule were included in the form and received IRB approval. In conjunction with the legal regulatory requirements of informed consent, there are the underlying ethical principles that extend beyond the consent form itself, as informed consent is process of communication, along with the act of obtaining a signature of consent for legal purposes (Weir and Horton 1995). The principle of respect for persons is imbedded in the informed consent process. This principle maintains that research subjects have a necessary level of information in order to make an informed decision, are competent and therefore aware of the potential risks and benefits to participation, and are participating in a voluntary manner, free of coercion and undue influence (Belmont Report 1979).

While the GKS consent form adhered to the legal requirements set forth by the Common Rule despite the concerns posed by bioethicists, the overall criticisms of the consent process went beyond just the content, or lack thereof, in the form itself. The critics felt the actual environment of the State Fair inhibits the ability to obtain ethically sound informed consent from participants. It is important to recognize the precise ethical arguments that are being posed. One theme identified was a consensus that the State Fair is too distracting to make informed decisions about something as serious as giving one's DNA. Distractibility is not a new concern to obtaining informed consent, nor is it a factor that would make informed consent impossible. Emergency medical research where patients are consented for research in emergency room type settings could be considered one of the most chaotic environments to attempt the consent process; however exemptions and additional considerations are made for these circumstances (Schmidt et al

2004). Decisions made under pressure in an emergency situation could be argued as more serious than giving DNA for health research. These types of decisions are critical for life threatening situations, which differ significantly from the risk/benefit considerations for determining whether to participate in genetics-based research.

The GKS research team was aware of the obstacles of getting informed consent at the State Fair, so much that they anticipated some of the issues and created some unique ways of handling the concerns. The consent form was purposely created to be only four pages in length in order to not overwhelm the enrollees and ensure they comprehended the most important components of study. Comprehension of the consent form requires that the participant must be able to understand the information presented, and have the time to read and evaluate the form. It is argued that using shorter consent forms that a reasonable person could understand and contains specific information that participants would want, may improve comprehensibility (Pandiyaa 2010). With a shorter consent form, it was assumed the GKS research team would have more time to thoroughly explain the consent form rather than rush through a lengthier form. In settings where distractibility becomes an issue for obtaining informed consent, it is important to highlight the essential details to ensure comprehensibility, and remembering that the consent form is only one component to the ongoing consent process.

In addition to the decisions about the design of the consent form, the GKS researchers created signage to display in the study area at the State Fair that included some of the key components to informed consent. All participating families were given a copy of the consent form to take home with them, and a copy of the form was made available on the study website. As required by the Common Rule, contact information

was included in case participants have questions about the study. One of the most significant ways that the GKS researchers addressed the issue of distractibility impeding the consent process was through reminding participants they can opt out of the study. While all study participation is voluntary and subjects can opt out at any time, which was stated in the consent form, few, if any, researchers wish to emphasize this, especially in longitudinal studies when subject retention can be difficult. The GKS team, however, anticipated criticisms about the appropriateness of the environment and included an opt-out postcard with the questionnaire that was mailed to participants six months after the 2010 State Fair and initial enrollment. The postcard specified that if returned, the GKS researchers would remove the subjects from the study and have all of their personal information and biospecimens destroyed. The GKS team wanted to ensure the participants had another chance to consider their decision to enter the study, away from the distractions of the State Fair environment. As mentioned in Chapter 2, fifteen families chose to opt out of the study, and thus their information and samples were destroyed.

While none of the bioethicists pointed directly to issues about the involvement of children in the consent process, some of their concerns alluded to properly consenting children to the study as well. Seeing that children are considered a vulnerable population, additional considerations must be made regarding the consent process. The GKS researchers addressed these issues by empowering the children to have a voice regarding their participation. All children ages eight and older sign an assent form that was explained to them at the time of enrollment. Each additional year of the study, children who turned eight years of age were asked whether they still wanted to participate in the

study, and if they agreed they signed an assent form as well. Two of the biospecimens collected were deemed optional, the fingernail clippings and blood spots, both of which the children, not the parents, made the decision to participate in. Children were never forced into either component of the study, despite any parental preference to do so. The GKS research team actively engaged the children throughout data collection and strove to make them feel they had power over their participation decisions.

The GKS researchers took numerous measures to guarantee proper informed consent would be received by the participants of the study, anticipating potential criticisms of the consent process and the environment. Although the research setting was scrutinized, the unique environment offers a unique opportunity in the consent process many other studies do not provide. The GKS participants have the chance to interact with the GKS researchers on an annual basis in person, and not just a team of data collectors and students, but they get the opportunity to talk directly to the Principal Investigators too. Seeing as though consent is not just a one-time moment of getting a signature on a document, but is an ongoing process, this direct communication with the research team allows the participants to continue asking questions and learn more about the study and its goals. It could be argued that this distinct quality of the study, the environment itself, potentially improves the process of informed consent.

Incentives and the Potential for Undue Inducement

To begin a discussion on incentives, it is important to cite the Common Rule's (CFR 2009) language about obtaining consent, which states:

An investigator shall seek consent only under circumstances that provide the prospective subject or representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.

Criticisms cited throughout the media articles include subjects' intentions for participation and potential undue inducement. Both intentionality and undue inducement are discussed at length by bioethicists and researchers, many of whom believe in order for an action to be truly voluntary these two necessary conditions must be satisfied (Nelson et al 2011). In order to interpret a person's intentions, one must determine first whether their decision is free from potentially controlling situations. According to the Common Rule, in research situations where study subjects are vulnerable to potential undue inducement, additional safeguards must be implemented to protect the rights and welfare of the subjects (CFR 2009). Some of the factors that can lead to undue inducement in research recruitment include monetary incentives, threats, deceit, manipulative advertising, and emotional appeals (Nelson et al 2011). In reference to the concerns over undue inducement in the GKS recruitment, the factors in question regard the ride and admission tickets and the fair souvenir. The arguments posed focused on the potential persuasive nature of these incentives on the children specifically. Seeing as though the parents made the decision to participate or not, it can be suggested that the undue inducement is directed at the children, who then influence their parents' intent to participate.

In bioethics discourse there is discrepancy whether monetary payments for research participation are coercive or used as an inducement versus compensation for time spent, or tokens of appreciation. One definition of coercion is "an extreme form of

influence by another person that completely controls a person's decision" (Bentley and Thacker 2003). Another explanation is that coercion occurs "if and only if one person intentionally either forces another person or uses a credible and severe threat of harm to control another person" (Nelson et al 2011). While interpretations for coercion are more universally defined, what constitutes undue inducement is a little more subjective. "The control of influences found 'irresistible' by an individual" as quoted by Faden and Beauchamp, could be regarded as unduly influential, potentially compromising voluntariness (Grady 2001). Undue influence can thus be thought of as excessive or too much influence. An incentive has been defined in one regard as "that which influences or encourages to action; motive; spur; stimulus" (Rice and Broome 2004). The amount of monetary payments is typically relative to the level of risk research subjects could potentially experience. Clinical trial research with high medical risks can sometimes offer thousands of dollars for participation, whereas minimal risk research such as completing surveys offer smaller amounts such as \$5 (Wendler et al 2002). In studies where actual coercion exists, according to these definitions, the monetary amount is high enough to potentially influence vulnerable populations because the dollar amount is such that participants will minimize the level of risk in their decision making process. The level of risk in a study does not appear to be as critical of a determining factor regarding undue inducement. Undue influence could occur simply if an individual is uninterested or uncomfortable with participation in a particular study, but yet are unable to refuse because of the monetary influence (Grady 2002). In other cases, incentives are considered compensation or tokens of appreciation for time spent participating in a study. Whereas the case with the GKS would probably not be considered coercive, the question

still remains whether the tickets and fair souvenir are an undue inducement or a token of appreciation for participation. That question, more specifically, is whether the GKS incentives compromise the ability to obtain voluntary informed consent from the participants of the study.

The use of incentives for research with pediatric subjects remains controversial due to their highly vulnerable status in research ethics standards, since children cannot weigh the risks and benefits to participation and can be influenced by very small monetary incentives (Rice and Broome 2004). Wendler et al argue that children from 7 to 11 years of age have developed a sense of independence which allows them the ability to provide or decline assent to participation, however while these children may refuse assent because they have no interest to participate, an incentive of just \$5 could be sufficient to influence them in the other direction. While such small monetary incentives may not impact an adult's intent to participate, they may be quite influential to children (Wendler et al 2002).

The question remains whether the GKS incentives are of an undue inducement nature or not. Each child was given \$5 worth of fair ride tickets and a souvenir University of Minnesota backpack for enrollment in the study. Participating families were given free admission tickets to the 2011 and 2012 State Fairs, one for each child in the study and one adult ticket per family; a cost of \$9 per ticket. The actual monetary amount likely does not exceed an acceptable amount for participation. As long as the children attempted to complete the initial participation they were awarded the incentives; 12 children were unable to provide a DNA sample, which was the crucial component of

the study, but still received the backpack and ride tickets. Children were not forced into any component of the study as a requirement to receive the incentives.

Although some of the media concerns alluded to the possibility that children could influence their parents' intent to participate, the ultimate decision of consent is up to the parents, and as previously mentioned, the parents have been reminded that they can opt out of the study at any time. Since enrollment in the study, only fifteen parents have decided to end their participation in the study. While the parents have been greatly appreciative of the free admission tickets, the majority of these families attend the State Fair each year anyway and are of a higher income level, and would potentially be open to participating without the extra incentive. At the time of enrollment over 67% of the parents indicated their family had attended each of the previous five State Fairs, so the tickets may be considered more as compensation or an appreciation rather than an incentive. Rice and Broome point out that many critics of incentives confuse them with recruitment and retention strategies, which is another way to look at the GKS "incentives" (Rice and Broome 2004).

Would bioethicists deem the coercive nature of the GKS incentives differently if parents were given \$5 in cash for each participating child and \$9 cash in replacement of each admission ticket for subsequent years of participation? Likewise it would be good to consider whether bioethicists would have issue with recruitment by telephone or other typical enrollment site, offering the same State Fair related incentives. It is important to recognize the actual reason for concern. Is it the type of incentive itself, the environment where recruitment takes place, or the combination of both? While the actual monetary amount of the incentives was minimal and procedures were implemented to remind

parents and children that their participation is voluntary, the type of incentive is still ethically questionable because of the environment. According to the Belmont Report, an influence could still be considered “undue” not only in terms of whether it is excessive, but whether it is “inappropriate” (Grady 2002). Giving ride tickets at the State Fair could be construed as a very different incentive than giving cash. Children are in an exciting environment filled with rides, games, and candy. When faced with the possibility of receiving ride tickets, children are aware that the incentive will be theirs to enjoy in the immediate future, whereas cash may not be perceived in the same regard. The GKS attempted to minimize the persuasive nature of the incentives through the recruitment process. Parents were approached about whether they would be interested in participating in a genetics-based research study. The study process was described and eligibility was assessed. If the parents expressed interest, then the GKS research team went through the consent form with them and obtained signatures if the parents agreed, and subsequently discussed the assent form with children of age. After consent, the parents were told they would receive the ride and admission tickets and the University of Minnesota backpack as their State Fair souvenir. The GKS team made attempts to obtain consent and assent before describing the incentives in order to mitigate the potential for undue inducement and allow the incentives to be merely a token of appreciation for the participants’ time spent being part of the study.

Vague Usage of Genetic Information

The final ethical concern to address is the ambiguity surrounding the future use of genetic information obtained by the GKS researchers. In recent years numerous research studies have made news headlines about what has been deemed unethical use of genetic

information without consent beyond initial research purposes. Specifically named in the GKS media criticisms was the Havasupai Tribe case against Arizona State University (ASU). Beginning in 1990, members of the Havasupai Indian tribe gave DNA samples to ASU researchers in the hopes of contributing to research that would provide a genetic understanding to the tribe's devastating rate of diabetes (Harmon 2010). Years later some members learned that their samples had been used in other studies including schizophrenia, ancestral migration, and population inbreeding; topics that were all deemed highly taboo to members of the tribe. In 2004 the Havasupai Tribe filed a lawsuit against ASU and the Arizona Board of Regents, and in 2010 they reached a settlement of monetary compensation and the return of DNA samples back to tribe members (Garrison 2012). As a result, the Havasupai Tribe has become distrustful of medical researchers, and tribe members have been discouraged to participate in research in the future. Based on other historical issues of distrust in medical research, as well as the Havasupai case, the Navajo Nation passed a moratorium on genetic research within their boundaries (Garrison 2012).

This case brought into question the application of open-ended language in consent forms allowing for unlimited use of genetic samples for research purposes beyond the initial research goals at the time of consent. It also focused attention to the ethical principle of justice, which questions who ought to receive the benefits of research and bear its burdens. In the Havasupai case, tribe members felt they were exploited for research by stigmatizing their population (Garrison 2012). While blanket consent to use genetic information for unknown future research purposes is increasingly common due to the rapid advancement of the field of research, there are challenges that researchers and

ethicists must consider. One such consideration is whether re-consent is required for studies not related to the original study to which participants consented. Re-consenting participants may not always be feasible, but nonetheless it should remain a consideration and a goal when it is possible. Secondly, while potential social risks associated with genetic findings are often unknown, researchers should attempt to identify these, specifically when researching a designated population to which stigmatization could cause social harm to the individuals of such group (Caulfield et al 2008).

The GKS Principal Investigators chose to leave open the option to use the genetic information collected in future studies, as it has become standard practice in many genetics-based research studies, although whether this standard adheres to ethical guidelines is undetermined at this time. In order to minimize the risks to subjects, the GKS researchers have maintained effective communication with the participants. Each year at the State Fair, the researchers have the opportunity to relay the progress of the study to participants. In the case of longitudinal studies, and especially the GKS where communication is retaining the ability to re-consent individuals for future research is more feasible than for studies that have a onetime consent process. Nationwide studies often have zero direct person to person contact between researchers and participants, which makes it difficult to build a trusting relationship between them. Whereas conducting research at the State Fair allows for both a continual consent process to inform and educate participants and the chance to develop more personal relationships.

Although the GKS has had the ability to interact with participants annually thus far, allowing for the ability to re-consent participants easily for additional research studies, there are still other ethical considerations to be made. The GKS thus far is only

being conducted as a feasibility study with the hope of turning it into a longitudinal study with no distinct end date. If the study comes to an end and the research team no longer communicates with the participants of the study, re-consent to utilize participants' DNA samples for other research becomes more problematic. One option to overcome some of the concerns over future use of DNA is that the GKS researchers could amend the consent form to allow individual participants to choose whether they wish to use their DNA only for the GKS or if they are willing to let their samples be used for other research projects as well. This opt out choice allows participants a stronger voice in how their genetic information can be used. Another option in a similar regard would be to let participants decide whether they require re-consent if their samples are to be used for other studies, even including a brief checklist of types of research the participants are comfortable allowing their DNA to be used without needing additional consent or others they may want to be contacted about. Parents may be willing to forgo re-consent for studies that are researching similar pediatric health questions like the GKs, but may be reluctant to allow for open-ended usage without re-consent for studies with quite different aims than the GKs. The participants' preferences are unknown until they are asked. Moving forward with the GKs, these types of additions to the consent form could reduce some of the concerns about open-ended use of DNA for future research to minimize the potential for another case like the Havasupai Tribe.

As President Obama's Educate to Innovate campaign proposes is that researchers, educators, and policymakers need to create novel ways to educate and motivate this nation's children in STEM. Therein lies the possibility of an increase of using unconventional environments to conduct research, by bringing research into the public.

The GKS serves as an example of the bioethical discussions that will occur in the future, has and the previous analysis makes a strong case that the GKS met all Common Rule requirements and Belmont Report principles, and that the environment and study design itself allow for a highly ethical, and continual consent process. By engaging the public and the participants directly, the GKS participants have given meaningful informed consent.

Chapter 4: Methodology

The previous chapters serve as the foundation for this paper by addressing the public's concerns regarding genetics-based research, specifically highlighting the history of antidiscrimination laws of genetic information in the United States, articulating the ways in which President Obama's administration has made STEM education and research a priority, and discussing the ethical issues that can arise when conducting human subjects research. Due to the continued public fears and concerns, coupled with the decreasing STEM education rates in the United States, it is important to find innovative ways to educate and engage the public about STEM research. President Obama's commitment to programs like Education to Innovate illustrate that the scientific and political communities need to collectively discover new ways to disseminate STEM information to the public, in order to increase education and decrease fear. Researchers have the opportunity to bring awareness to their study participants with very little effort. The success of the GKS feasibility study, the unique environment in which it takes place, and the high participation rates make the GKS participants an excellent study population to assess their experiences with participating in a genetics-based research study, and identify how their opinions, interest, and knowledge about genetics have changed as a result of participation. This chapter will detail the methodology used in this research for addressing these questions, including the survey design, data analysis and study limitations. It will also present the research questions and how they are addressed through the survey materials.

Research Design & Methods

Throughout the three years of the GKS, only fifteen families chose to opt out of the study, leaving 519 remaining families in the study. While another five families had moved out of Minnesota, they still wished to remain in the study in the chance that they may be able to visit the State Fair in the future. For the purposes of this research project, only participants who had provided an email address were included, as the survey and communication was conducted solely via the Internet. Of the 519 families, a total of 485 (93.5%) had at least one email on file; although an additional eleven families' emails were invalid, decreasing the number of eligible families to 474 (91.3%). Upon comparing the demographic information of those included in the study versus those excluded, some significant differences were realized. Race and ethnicity data were similar among the populations with a slightly higher proportion of Hispanic parents without an email address on file, as shown in Graphs 7 and 8 in Chapter 2. Income levels differed among the most extreme household earnings; as those earning less than \$10,000 annually were slightly underrepresented (5% versus 1%) and those earning over \$100,000 annually were overrepresented in the eligible survey population (42% versus 36%). Finally, the education levels differed most significantly in that those with a college degree or higher (70.8%) were more represented in the eligible survey population than those who were excluded (61.4%). Therefore the eligible study population is more highly educated and has a greater income level than the overall GKS population.

An online survey was created consisting of 28 questions for the eligible study participants with valid email addresses on file. The questions were created to address three general themes, including how participation has influenced the participants' views

about genetics, science, and research including their children's experience, the impact of conducting research in a public environment on the participant's experience, and how the GKS participants' opinions about how genetic information should be handled differ than those of non-participants. In order to analyze the differences in the use of genetic information, the GKS participant experience survey was compared to a questionnaire used at the 2010 State Fair by another researcher. The comparison survey was aimed at understanding individuals' opinions and knowledge about genetic testing, and received responses from random fairgoers. Three questions from this questionnaire were used on the GKS participant experience survey so that responses could be compared.

The GKS participant experience survey was approved by the University of Minnesota Institutional Review Board and was created using the Survey Monkey online survey tool. The survey was emailed to eligible participants in December 2012. Although participant responses tend to be lower during holiday seasons, the emails also included 3D video attachments of their children that were taken at the 2012 State Fair, in order to incentivize participants to complete the survey. Participants who had not responded were sent email reminders both at the beginning and end of January. Survey collection was completed by the end of February 2012. A copy of the survey is included in Appendix B.

The survey data was downloaded from Survey Monkey into SAS for analysis. Although all parents were encouraged to complete the online survey, since the questions were focused on individuals' experiences rather than of the family as a whole, the majority of the survey included responses from only one parent per family. In order to simplify the analysis, the data was maintained at the family level versus the parent level,

requiring the removal of one parental response for each of those which had multiple entries. The date of completion was captured, so the parental entry that was completed first was maintained while the latter entry was removed from the dataset. This decreased the survey entries from 310 parental responses 301 individual entries per family. Once the survey dataset was updated and coded, three datasets were exported from the GKS study database in order to match previously collected data with the participant experience survey. The family dataset matched by the unique family ID with the survey data with questionnaire data collected in 2011. The entire survey data was also matched up with the parents' specific demographic information including race/ethnicity, education level, marital status, and household income, as well as the family's fair attendance history. The final dataset created merged the three survey questions pertaining to each individual child's experience with the study, with race/ethnicity, sex, and age. Using SAS, the child dataset was created by matching both the unique family ID and also the first three letters of the child's name, which were provided in the survey. Once all three datasets were created, the frequencies of their responses were analyzed to address the study questions.

One question on the survey was designed for an open ended response that allowed participants to discuss factors that have made their participation easy or difficult. The comments were coded based upon the key words and phrases used and then categorized into general themes, with many participants expressing multiple factors. While the majority of the sentiments expressed in the comments section provided descriptions of the ease or difficulty of participation, the families also utilized the comments section to point out some benefits to participation as well as a couple ways in which their

experience could be improved. Table 3 illustrates the overall themes and the subcategories identified through coding the comments.

Table 5: List of GKS survey participants’ comments by theme and subcategory

Ease of participation	Number of Comments
Well organized	29
Quick process	41
Easy	73
Location of study (at the fair)	124
Free admission tickets	45
Researchers	39
Great communication	19
Flexible timing	22
Difficulty of participation	
Process took too long	1
Not present at the fair all hours	16
Crowded environment	1
Trouble finding the building	1
2011 survey was too long	1
Impartial response	
Neither easy nor difficult	1
Benefits of participation	
Fun	19
Kids' enjoyment	17
Learn about science	3
Altruism	7
Great way to stay connected to the U	2
Suggestions to improve participation	
More time to talk with researchers	1
More information on results of study	3

The analysis also looked at the responses of the similar questions that were present in both the GKS participant experience survey and the 2010 genetic testing public opinion survey. The genetic testing survey was conducted by a University of Minnesota graduate student at the 2010 State Fair, which surveyed random fairgoers that visited the University of Minnesota building. The survey asked respondents questions about their

likelihood of participating in a genetics-based research study, along with their reasons justifying this response. The survey also included questions about the risks and benefits of genetics-based research, whom the respondents would trust with their genetic information, and how genetic information should be used; all of which were questions addressed in the GKS participant experience survey and were compared to assess the difference of opinions between GKS participants and the general public at the State Fair.

Research Questions

The first question this project sought to investigate is how participation in a genetics-based research study influences the participants' views about genetics, science, and research. This question is evaluated through a compilation of eleven survey questions, both of the parents' and the children's perspectives. In one section, parents were instructed to think about how their experience with the GKS may have changed their opinions, knowledge, and interest in genetics. They were first asked how much these perspectives changed in general since August 2010, and then were followed up with a question for them to assess how much of this change was attributed to participating in the GKS, in order to assess the impact research participation can impact individuals' attitudes. This section also included three questions directed at the children's change of interest in science since their participation. Because the children were only aged 1-11 at the time of recruitment, the questions aimed at their experience were more generalized to their interest in science versus being more specific to genetics since most young children may not be able to differentiate individual areas of science. Finally parents were asked whether they had sought out research opportunities if they had not been recruited at the State Fair, if they had participated in other studies since the GKS, and what the likelihood

is that they would participate in future studies. This set of questions evaluates how participation in the GKS has potentially motivated individuals to become more involved with research. By bringing research into a public venue, the public has the opportunity to be exposed to research possibilities that they may not have sought out on their own.

The second aim of this study focuses not only on the participants' experience with the study, but in particular how the characteristics of conducting research at the State Fair have impacted their experience. Because all data collection for the GKS occurs at the State Fair, the participants have had the opportunity of meeting the entire GKS research team, including the Principal Investigators of the study. Therefore questions were included to gauge their interactions with the research team. As mentioned previously, participants were offered the opportunity to provide their own comments about factors that have made their participation easy or difficult, many of which pointed at components of the environment of the State Fair and the study design. Finally participants were asked about the importance of public engagement about genetics-based research and their perception of the frequency in which researchers actually engage the public on such matters. This series of questions examines the additional social benefits of conducting research at a public event like the State Fair, and how those are perceived by those participating in the GKS.

The final set of questions point to the third study question about how the GKS participants' opinions about the risks and benefits of genetics-based research, the use of genetic information, and who to trust with genetic information compare to the opinions of the general public. As mentioned in the discussion of the study design, this comparison utilized the genetic testing survey in order to compare the State Fair population of those

who participated in the GKS versus those who did not. This analysis is important to understand the differences between GKS participants and the public.

Study Limitations

No study is without its limitations, and the GKS, as well as the GKS participation survey are not exceptions. One of the most prominent limitations of the GKS is selection bias. While the State Fair has the highest per capita attendance rate of any fair across the country, attracting visitors from all parts of the state, the environment itself does lead to certain population biases. The State Fair is located in St. Paul, which led to a greater representation of the Twin Cities metro in the GKS population, with over 85% of the participants residing in the metro area. Compared with state averages, about 2.85 million residents make up the Twin Cities metro area according to the 2010 U.S. Census Population bias, of the total 5.3 million Minnesota residents, indicating about 54% of the population is centralized in the metro area (Metro Council 2011). Although the GKS population is heavily represented by metro area residents and did not recruit a proportional sample from outside the Twin Cities metro, without being located at the State Fair, the study may have experienced more difficulty recruiting participants from outside the metro area for an in-person longitudinal study.

Many other demographic characteristics of the GKS participants are not perfectly indicative of the state's overall demographics, as mentioned in the discussion of the GKS in Chapter 2. The study is housed in the University of Minnesota permanent building, which may potentially attract a significant number of individuals with some association with the University, including alumni, former or current staff and faculty, and current or prospective students. Although no quantifiable data on the demographics of visitors that

frequent the University of Minnesota building exists, it could be assumed that the population it attracts may be more highly educated. The education breakdown of the GKS participants reflects this assumption, with roughly 70% of the total GKS population and about 75% of the GKS participant experience survey population having a college degree or higher. This is even further validated by the demographic information obtained by the State Fair, which indicated about 34% of all fairgoers in 2012 had a college degree or higher (MN State Fair 2012b). Additionally, seeing as though roughly 35% of the families planned to participate in the GKS prior to the launch of the study, the GKS may have attracted a population more supportive of genetics-based research. The GKS research team did not obtain public opinion data at the time of enrollment to assess participants' views on genetics-based research.

The cost of fair attendance can be significant, when considering the costs of entertainment, food, admittance, and travel. The State Fair estimated that the per capita spending for the 2012 fair was about \$46.36, without taking into consideration travel costs which is broken down in Table 4 (MN State Fair 2012b). These costs add up quickly when considering a family of four would spend about \$185 for a trip to the State Fair. As a result, the GKS population has a higher household income level than the state average. Roughly 42% of the GKS families earn over \$100,000 annually, whereas the average annual income for Minnesota is \$58,476 (U.S. Census Bureau 2012). The household income level for the State Fair in general is inflated compared to the state average, with 45.2% of households earning over \$75,000 annually (MN State Fair 2012b).

Table 6: Minnesota State Fair per capita spending for 2012

Admission Fee Average	\$10.09
Food & Beverage	\$19.20
Retail Purchases	\$10.38
Carnival/Midway	\$2.77
Other Attractions	\$1.51
Grandstand	\$2.41
Total	\$46.36

The final demographic factor that skews the GKS study population from the state demographics is race. The African American and Asian populations are underrepresented in the GKS, with 5.4% and 2% lower representation respectively. Caucasians are overrepresented in the GKS with 95% of the total population self-reported as white, whereas the Minnesota percentage is at about 87% (U.S. Census Bureau 2012). The Hispanic population in the GKS, however, closely matches state demographic numbers.

There are three other limitations to address regarding the study design of the participant experience survey. Firstly, the survey was conducted retrospectively rather than prospectively. While attempting to assess the impact participation in the GKS has made on the participants' opinions, knowledge, and interest in genetics-based research, it would have been preferable to quantify the actual changes in their perspectives by surveying the participants in the first year when they were initially enrolled and then again at the end of the feasibility study. Participants were asked in many of the questions to think back to the past three years during their time in the study to assess how their views have changed, which could lead to recall bias, in the sense that it may be difficult for them to accurately reflect on how their views have truly changed. The second

limitation to the study design regards the comparison population. Some of the GKS participant responses regarding broader questions about the use of genetic information are being compared to a survey of random fairgoers from the 2010 genetic testing public opinion survey. While it is convenient to utilize the genetic testing survey as a comparison, only a limited number of questions were applicable to the goals of the GKS participation experience survey. It would have been ideal to create a greater number of questions that could be used to survey the general public at the State Fair to gain even more insight into the differences of opinion between the GKS participants and the general public. The final study design limitation is that the analysis used descriptive statistics rather than inferential statistics, and likewise there was no significance testing on the comparison between the GKS participation experience survey and the 2010 genetic testing public opinion survey.

Chapter 5: GKS Participant Experience Survey Results

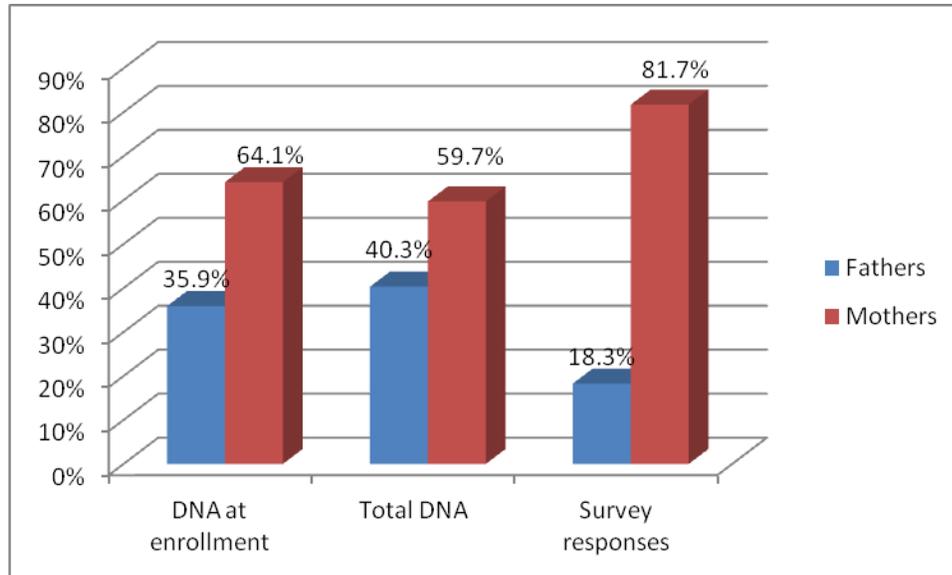
GKS Survey Population

Participants in the GKS were given the option to participate in an online survey about their experiences with the study; the methodology of which was described in Chapter 4. The survey was conducted between December 2012 and February 2013, of which a total of 310 individuals completed the survey. As discussed in the methods section nine families submitted multiple survey entries, and in order to analyze the data at the family versus parent level, only the first completed survey per family was included in analysis. Therefore a total of 301 unique families completed the online survey, out of 474 eligible families, giving a 63.5% response rate. If the survey period had lasted longer than three months, the response rate may have been higher seeing as though the questionnaire submitted in 2011 ended with an 88% response rate over a six month period. Roughly 6% of the respondents of the participant experience survey did not complete the survey in 2011.

A greater number of mothers completed the survey versus fathers, with over 80% of the survey entries completed by mothers. While the gender distribution is highly skewed, mothers have been more involved with the GKS from the onset of the study. At the time of enrollment, more biological mothers were present to provide DNA samples than biological fathers, and while the GKS research team made efforts to obtain more DNA samples from the fathers over the final two years of the study, about 60% of the total DNA samples received by the parents have come from the biological mothers (Figure 11). Other demographic characteristics, such as race, ethnicity, and household income, were very similar between the total GKS population and the survey respondents.

Education levels differed slightly, with a more highly educated population in the survey group versus the total GKS population. As mentioned in the methodology, the exclusion of families without email addresses on file led to a higher educated eligible population for the participant experience survey.

Figure 11: Comparison of parental participation in the GKS



Impacts on Participant Perspectives and Experience

The first aim of this project is to determine how the participants' involvement with the GKS has impacted their perspectives on genetics and genetics-based research. One way to assess how the parents feel about research is by asking whether they have become involved in additional research projects since the GKS and what their likelihood of future participation in research may be. A total of 54 parents (18%) indicated that they have participated in other research studies since being part of the GKS. In the 2011 survey, families were asked whether they had ever been involved in a research study prior to enrolling in the GKS, and roughly the same number of individuals (17%) had previously participated in research studies. What is most important to point out,

however, is that of the 54 families that have become part of other studies in the past three years, 38 (70.4%) had never participated in research until the GKS, and now have become involved in other research opportunities. Participants were also asked about the likelihood that they would have sought out research opportunities on their own had they not been approached by the GKS at the State Fair and whether they foresee themselves becoming involved in more research studies in the future. A majority of parents (70%) expressed that they were either somewhat or very unlikely to seek out research studies on their own (Figure 12). Regarding the parents' interest in participating in future studies, an overwhelming majority (83.3%) indicated they would be somewhat or very likely to engage in research in the future (Figure 13).

Figure 12: Likelihood GKS participants would seek out research opportunities on their own

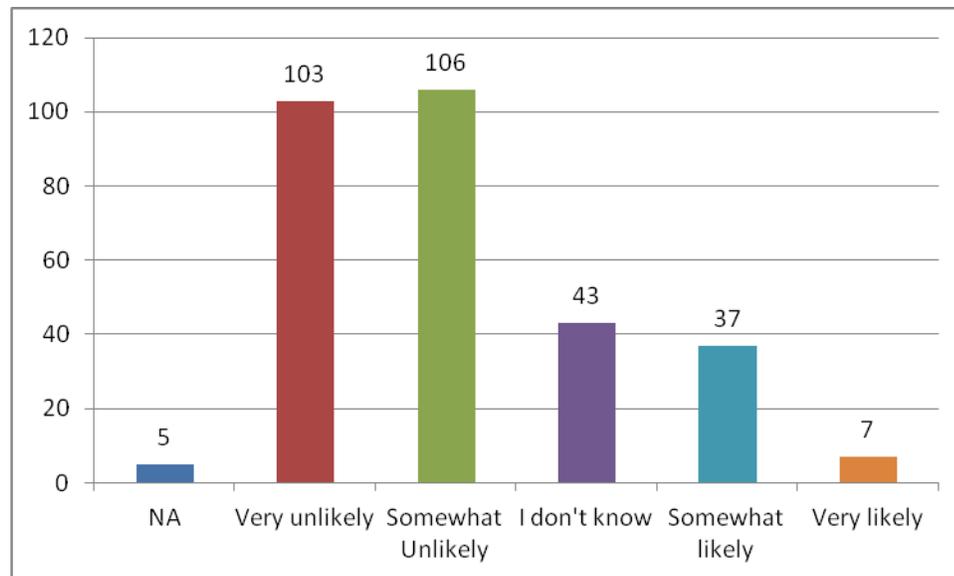
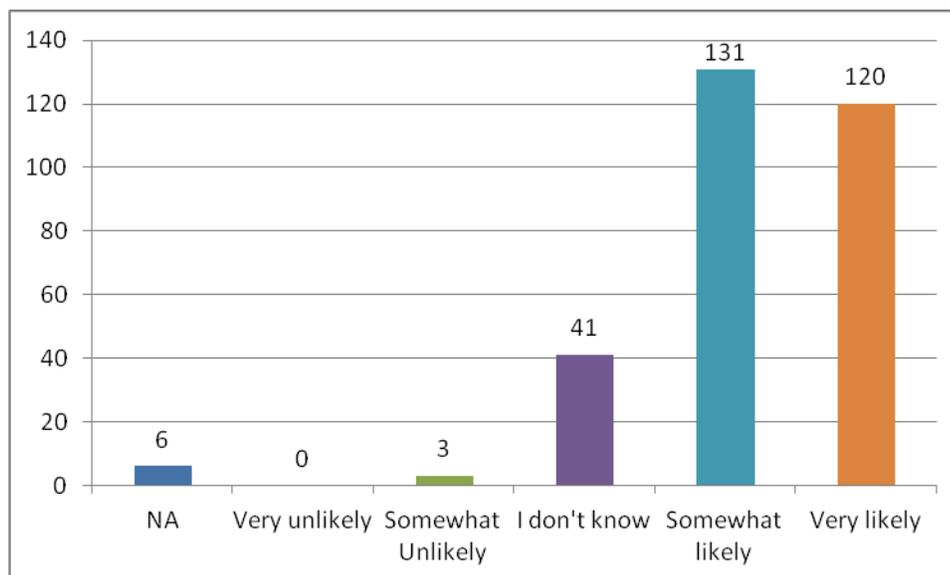


Figure 13: Likelihood GKS participants will participate in research in the future



These results suggest that the GKS and the fact that recruitment was conducted at the State Fair have impacted the participants' willingness to be involved in research. Some participants have already sought out other research opportunities, and many more indicate they would be willing to consider being part of another study. The parents were asked how they felt about their experience with the study on a scale of 1-5 (1=very dissatisfied, 5=very satisfied), which averaged a satisfaction rate of 4.73. By creating a very satisfactory research project and environment, participants are left with a good impression of research and are more likely to participate in the future. This is validated by the incredibly high retention rate of the GKS, with 85% of the families returning to the study in 2011 or 2012.

Participants were asked to think about how their opinions, knowledge, and interest in genetics have changed since August 2010, the time since their enrollment in the GKS. They were then asked follow-up questions to equate how much of the change in their perspectives they believed was a result of being involved with the GKS.

Regarding their opinions toward genetics-based research, 54.5% of the respondents indicated their opinions had not changed in the past three years, whereas 43.9% said they had a slightly or much more positive view of genetics research, and 1.7% of respondents did not answer the question (Figure 14). It is important to note that the survey did not assess the general opinions of those participants that indicated their opinions had not changed in the past three years. As mentioned in the limitations in Chapter 4, there is the possibility the GKS may have attracted a pro-genetics crowd, in which therefore their opinions may already be quite high regarding genetics-based research. Of those whose opinions did change, more than 65% of the parents owed the majority or all of this change in opinion to their participation in the GKS, and all of them attributed at least some of their change of opinion to the GKS (Figure 15). Roughly 70% of the participants have learned more about genetics since 2010, and over 93% credited the GKS with providing some level of education or awareness that contributed to their increased knowledge of genetics (Figure 16). Finally, about 60% of participants said they have an increased interest in genetics because of their participation in the GKS.

Figure 14: Change in GKS participant opinions toward genetics-based research in the past three years

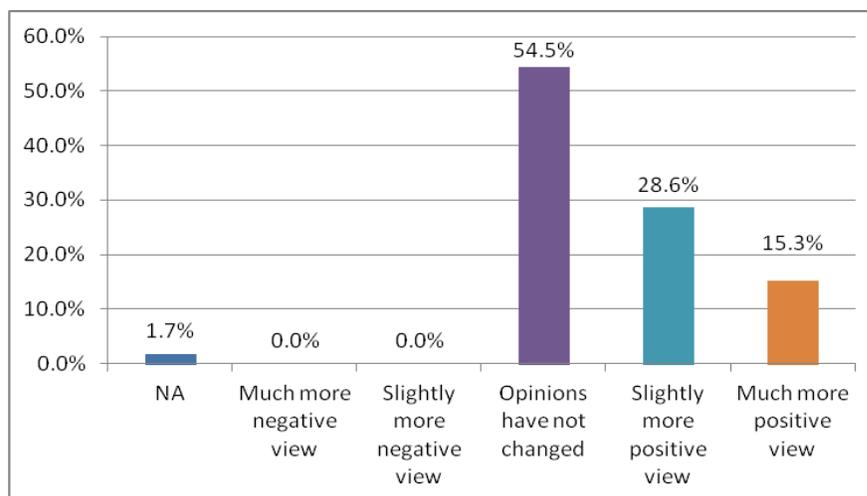


Figure 15: Impact of GKS participation on the change of participant opinions toward genetics-based research

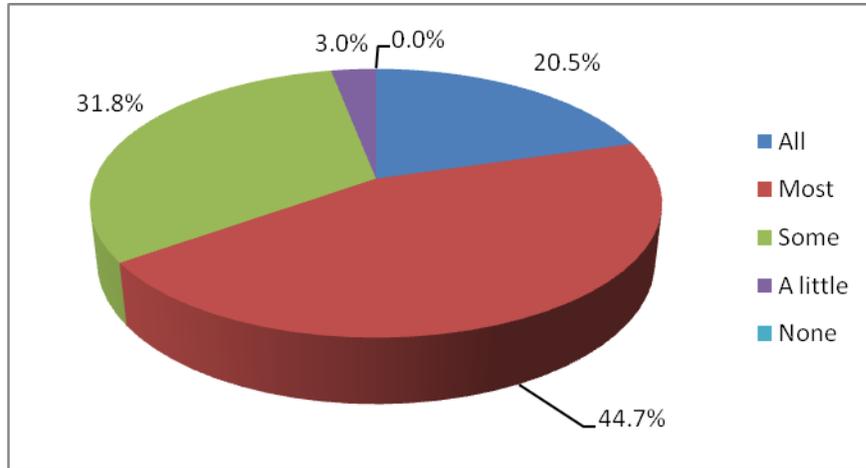
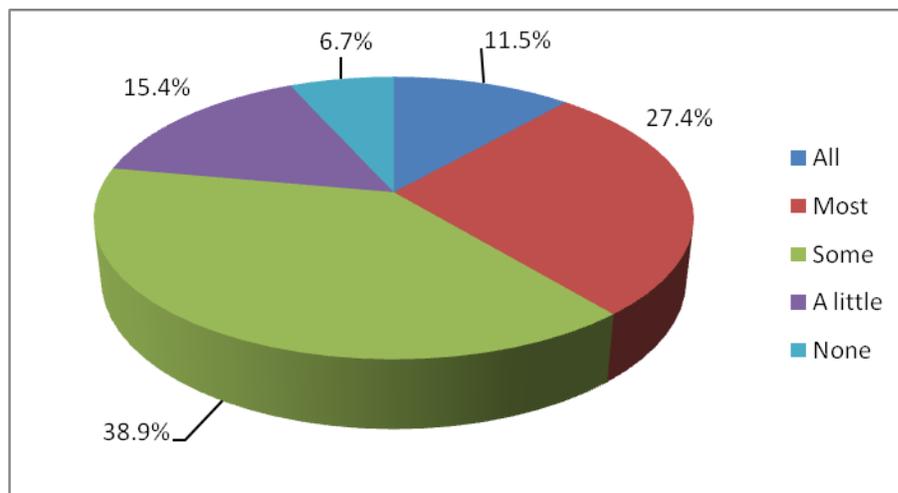


Figure 16: Impact of GKS participation on participants' increased knowledge of genetics



Because the GKS is a pediatric research study, it is important to assess the impact the study has made on the children as well. The 301 families included in the survey population, consists of 445 total children. Parents were asked to describe how each of their children's interest in science has changed since enrollment in the GKS. Due to the fact that the children were aged 1-11 at the time of recruitment, the assessment of their interest was focused more generally on science as a whole, rather than more specifically

about genetics. Parents determined about 4.5% of the children were too young to have an interest in science, another 38.4% stated that their children’s interest in science has not changed in the past three years, and just less than 1% of the children developed a decreased interest (Figure 17). Of the children that developed an increased interest in science, about 83% of parents attributed some of the increase to their children’s participation in GKS (Figure 18).

Figure 17: GKS children’s change of interest in science

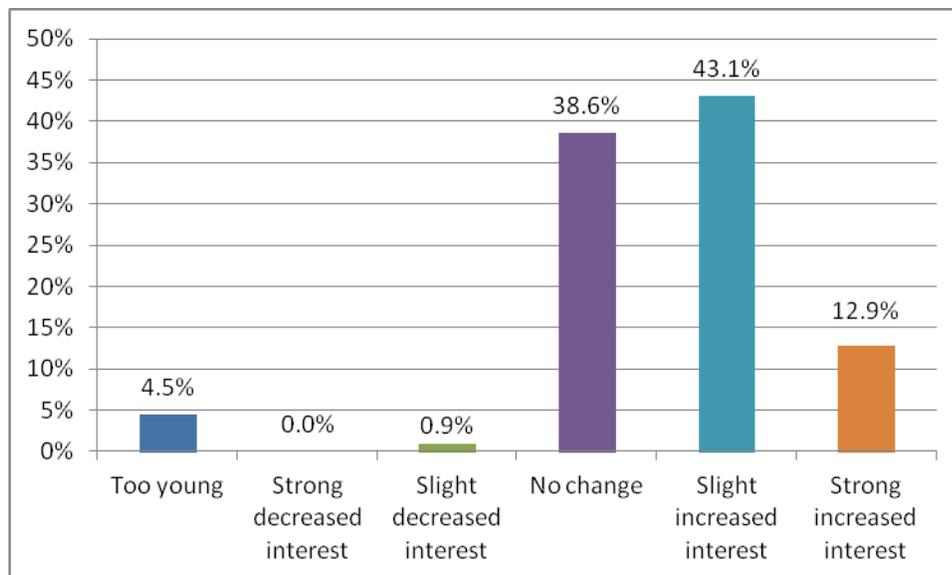
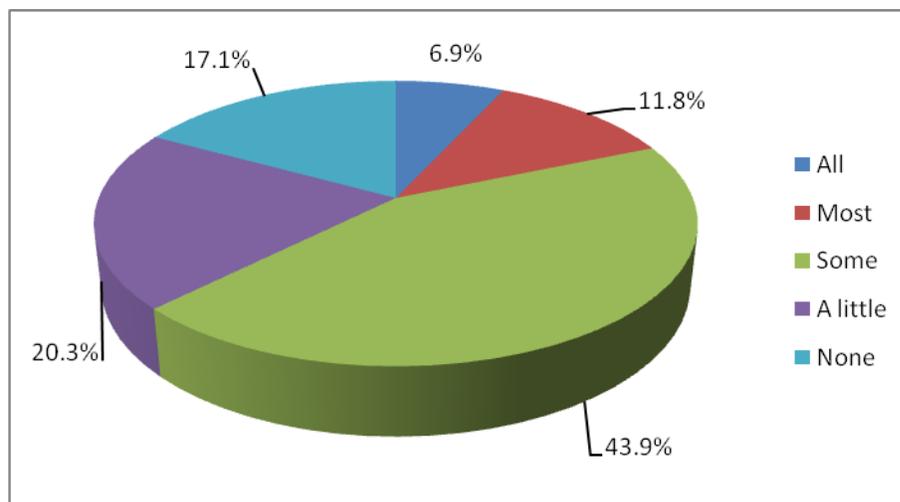
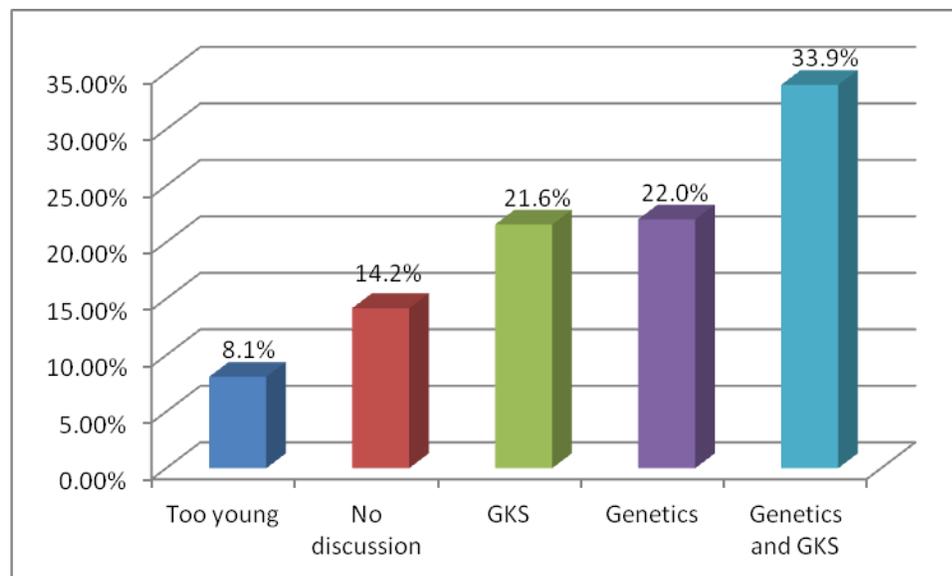


Figure 18: Impact of GKS participation on children’s increased interest in science



The parents were also asked whether they have engaged in discussions about genetics and the GKS with their children in order to determine whether participation in the GKS has spurred the families as a whole to talk about the study and about genetics in a more general context. A total of 78% of the parents have engaged their children in conversations about genetics or the GKS since their initial enrollment in the study, with only 14% of parents indicating they have not had such discussions (Figure 19).

Figure 19: Percent of parents that have engaged in conversations about genetics and the GKS with their children



The Impacts of Research in a Public Environment

The second aim of the study is to determine how the unique components of conducting research in a public environment like the State Fair impacts the participants' experience with the study. One the characteristics of bringing research into the public is that the participants have the opportunity to meet and engage with the research team in person, and as for the GKS this had included significant presence by even the Principal Investigators of the study. Because this is a longitudinal study as well, the families have the chance to create relationships with the research team. This is unique for multiple

reasons, since many research studies are conducted through the telephone and mail which decreases the level of personal involvement, and oftentimes Principal Investigators are not directly involved with the recruitment of study subjects for their studies. Therefore the GKS parents were asked a series of questions about their interactions with the research team, including their views on researchers' level of responsibility to engage participants and the public. Over 67% of the participants said they believe it is important or very important that they are able to meet the GKS researchers in person, with about 3% indicating it is not important to them (Figure 20). When questioned about their comfort level with interacting with the GKS research team, over 95% said they feel comfortable or very comfortable asking questions about the GKS and about 87% responded that they feel comfortable asking questions about genetics (Figure 21). The ability to interact with researchers and to feel comfortable asking questions minimizes some of the ethical concerns posed about the environment not being a serious enough place to conduct research and obtain proper informed consent. Overwhelmingly, the participants are comfortable asking about the study.

Figure 20: Importance of being able to meet the GKS research team in person

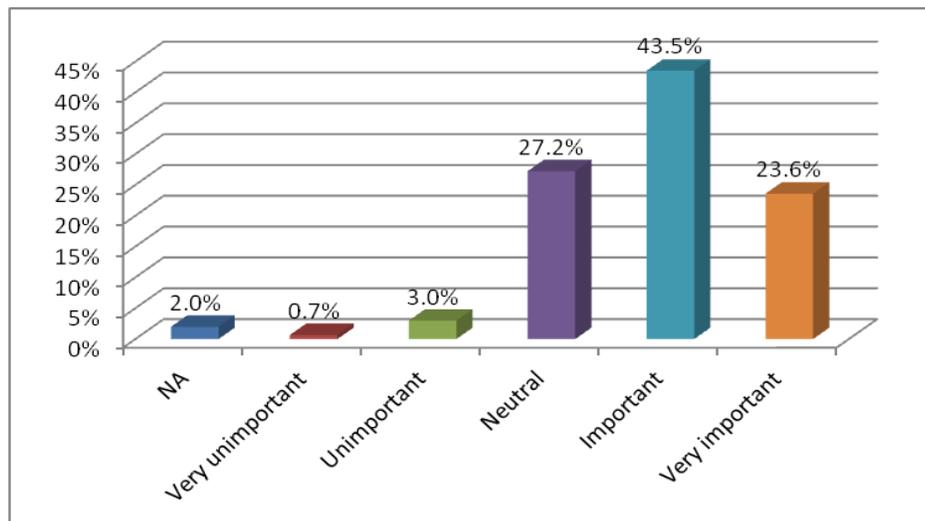
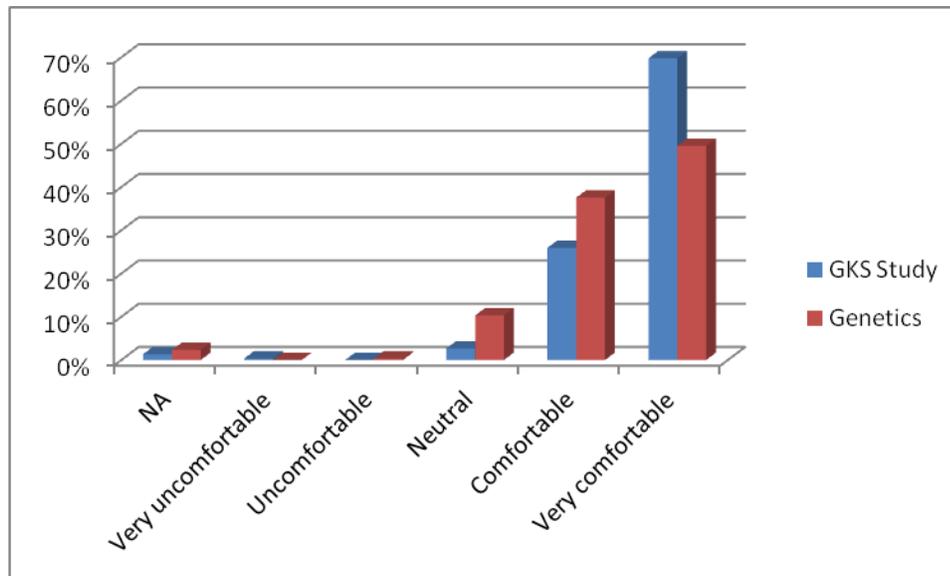


Figure 21: Participants' comfort asking the GKS team questions about the study and genetics.



To supplement the analysis of the participant experience being involved in research at the State Fair, parents were surveyed about how easy or difficult they feel participation has been thus far, and were given the opportunity to provide reasons for their opinions. A strong majority (74.8%) of the parents responded that participation has been very easy, with another 20.3% stating that it has been easy. After analyzing the participant comments, five general themes emerged, including comments about: ease of participation, difficulty of participation, impartial responses, benefits to participation, and suggestions to improve the participatory experience (Figure 23).

Half of the parents (51.2%) mentioned the fact that the study was conducted at the State Fair made participation easy. Participants felt the design of the study made their experience easy, expressing that the data collection was quick and well organized. They felt the GKS research team was welcoming and made their children feel at ease, and the GKS research team communicated well prior to each State Fair. About 18% of the

participants indicated receiving free admission tickets also contributed to the ease of participation. While the parents noted the admission tickets as a factor that contributed to the ease of participation, they were not specifically questioned about whether the tickets influenced their decision to enroll or continue their participation in the study. Regarding the ethical concerns cited in Chapter 3, it would be helpful to understand whether the admission tickets have impacted their participation beyond making it easy to participate. Parents discussed the available hours at the State Fair, with almost equal numbers stating that it made their experience easy or difficult. Seeing as though the study only takes place six of the twelve hours of the State Fair each year, some parents found the hours constricting to their schedules, with the limited hours being the most cited criticism of their experience. A crowded environment, difficulty finding the University of Minnesota building, and the length of participation were also given as criticisms. Parents also cited numerous benefits to participation, responding that the experience is fun and enjoyable for their children, that the study has become a family tradition of their State Fair experience, and also alluded to the altruistic and educational values the study offers. Four participants expressed that they would either like to receive more information on the results of the study or have more time to talk with the researchers.

The final series of questions about unique components to conducting research in a public environment were aimed to assess how the participants felt about public engagement of research. They were asked of the importance for researchers to engage both the participants of their research studies and the general public about their research, with the majority conveying that public engagement is important or very important (Figure 22). This set of questions was followed up with an assessment of how

successfully researchers actually do engage the public about genetics-based research in their opinion. Just over 65% respondents felt researchers are not engaging with the public enough, while about 20% felt their public engagement was sufficient.

Figure 22: Importance of participant and public engagement about research

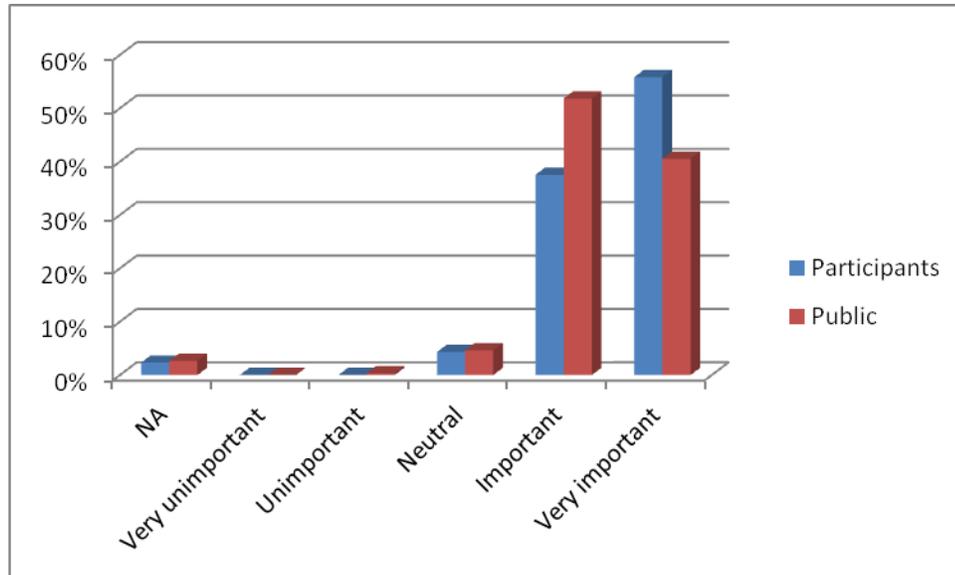
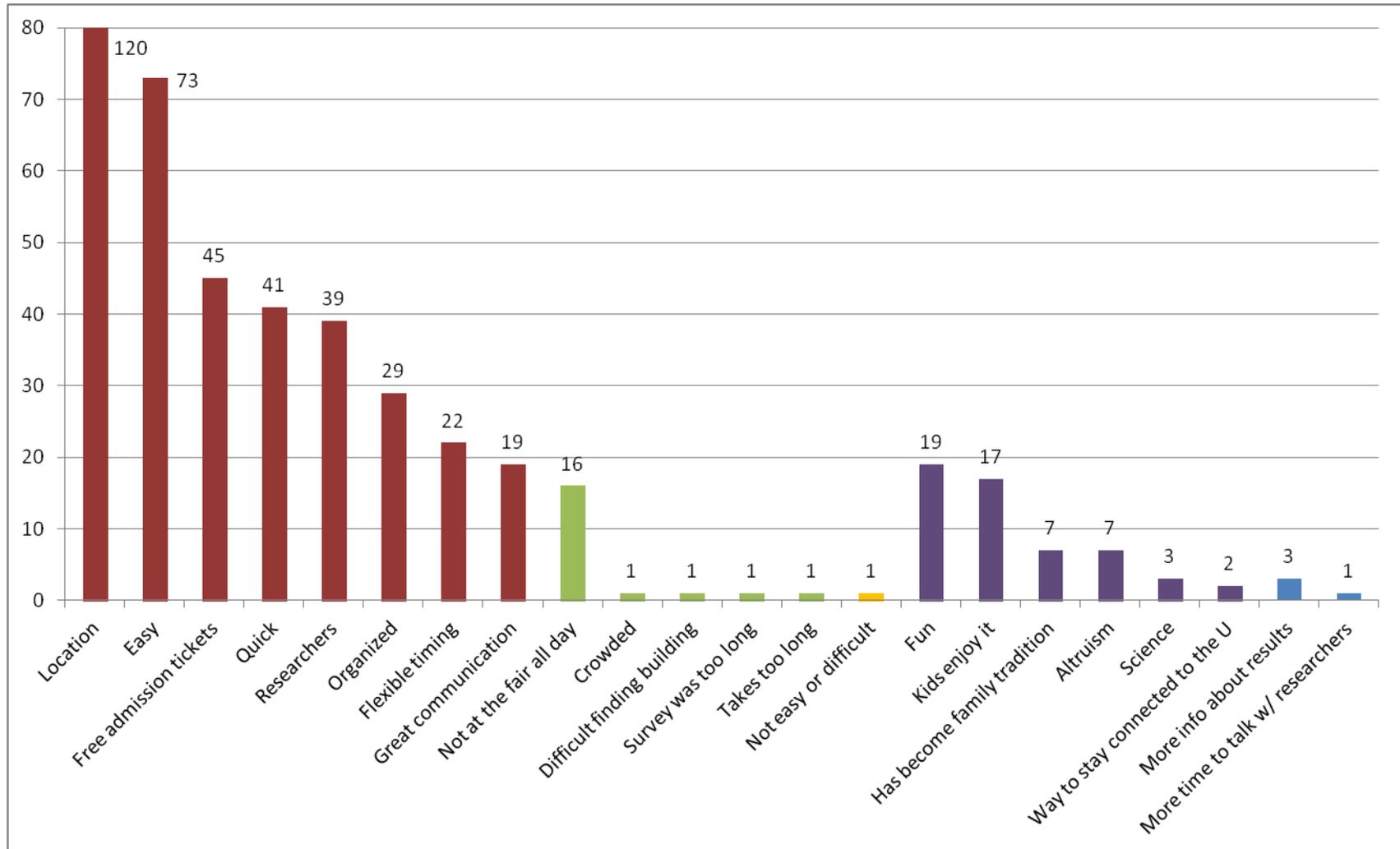


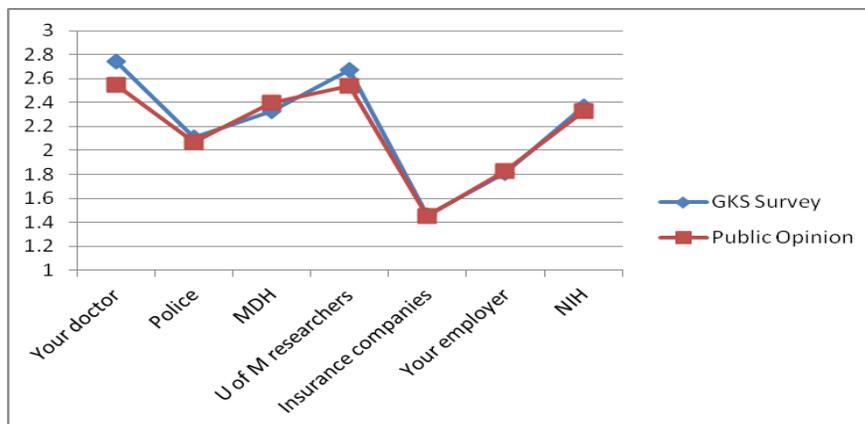
Figure 23: Participant comments regarding the ease or difficulty of GKS participation



GKS Participant Opinions about Genetics-Based Research vs. Public Opinion

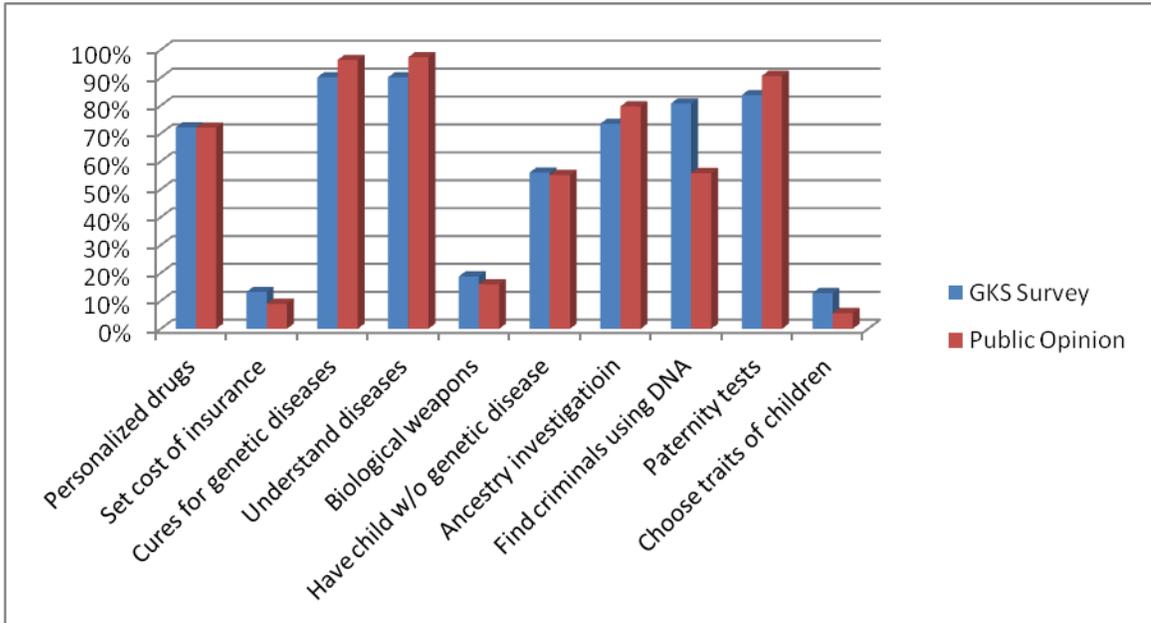
The third and final aim of the study was to compare the opinions about genetics-based research of the GKS participants to public opinion, through comparing the GKS participant experience survey to the genetic testing opinion survey from 2010. Three questions were designed identically to the survey from 2010, regarding risks and benefits of genetics-based research, who is trust worthy to use personal genetic information, and how genetic information should be used. Similar results were found between the two datasets for all questions. Both populations strongly believed the benefits to genetics-based research outweigh the risks, consisting of 84.4% GKS participants and 81.2% of the public. Of the survey participants that provided a response about how much they trust a variety of individuals and organizations with their genetic information, the responses were quantified in such a way to average their attitudes (1=do not trust, 2=somewhat trust, 3=completely trust). As Figure 24 illustrates, the survey results are almost identical, with GKS participants trusting their doctors and University of Minnesota researchers slightly more than the public, and could potentially be significant.

Figure 24: Comparison of trusting organizations with genetic information



Survey participants were asked whether genetic information should be used for numerous different reasons. Their responses reflecting acceptance of the use of genetic information are illustrated in Figure 25, comparing the two study populations. Once again, many of the attitudes are quite similar between the GKS participants and the public, with the only stark difference in using DNA to find criminals (80.8% for GKS and 55.8% for the public). It is interesting to point out that the least supportive uses of genetic information, setting insurance costs, developing biological weapons, and selecting the characteristics of children, all received higher support from GKS participants than the public. These data suggest there are few differences in the general opinions about genetics-based research between the two populations, although it is important to note that both populations were recruited in the University of Minnesota building at the State Fair, so demographically they may be quite similar and could explain some of the similar results. The participants' level of education was obtained for both populations; 67.4% of GKS survey participants and 65.9% of the public respondents have a college degree or higher. The similarities could also potentially suggest that these are relatively stable opinions among Minnesota residents. Overall, the data is not conclusive to illustrate that participants in a genetics-based research study have extensively different opinions about the use and trust of genetic information than the public.

Figure 25: Comparison of acceptance responses to the use of genetic information



Chapter 6: Discussion of Results

The previous chapters have provided the foundation for this research study through a discussion of many ELSI considerations of genetics-based research including the historical progression of genetic antidiscrimination laws, STEM education and research initiatives created by the Obama Administration, public opinion of genetics-based research, and an ethical framework of conducting research in a public environment like the State Fair. Subsequent chapters outlined the methods and study design of the GKS feasibility study and the methodology used for the participant experience survey, and concluded with a presentation of the survey results. This chapter will interpret the results of the participant experience survey and discuss how these findings provide social benefits to research participants through the means of public engagement. This discussion serves to illustrate the indirect benefits of genetics-based research; those of which are beyond the scope of scientific benefits.

Public Engagement and Research

What exactly is public engagement? The National Coordinating Centre for Public Engagement defines it as, “the myriad of ways in which the activity and benefits of higher education and research can be shared with the public. Engagement is by definition a two-way process, involving interaction and listening, with the goal of generating mutual benefit” (NCCPE n.d.). Through this process the goal is to build public trust in risk decisions and decision makers. Overall public trust can spur social trust, defined as finding commonality through cultural values that lead people to trust those who they conceive are like them. Social trust is important because it can facilitate cooperation and

coordination within society, and reduce uncertainty (Petts 2008). Thus, turning public trust into social trust occurs when experts, policymakers, or researchers can personalize the message or goal they wish to communicate through public engagement. In general, people tend to trust those they know more so than those with whom they do not have a relationship. Public engagement can help build more personal relationships between researchers and the public.

Regarding genetics-based research, public engagement can be achieved by several ways, some of which include: identifying factors that motivate or inhibit research participation through discussions with the public, educating the public about genetics and STEM, and informing the public about advances in research to increase awareness. Mutual benefits arise through these interactions between the research community and the public. Identifying public concerns about participation can allow researchers to address these issues, find ways to mitigate their concerns through their study design, and therefore increase participation rates. Thus, the public will be more willing to participate, in which they receive benefits such as education, awareness, and altruism. Increased education and dissemination of study results can build trust in the public, through a better understanding and transparency of research activities. This increased public trust can have significant positive impacts on policies that affect scientific research, one of which is the potential for greater allocation of federal funds for STEM research. This mutually beneficial relationship makes public engagement essential for the successful progression of STEM research.

Public engagement may be more important than ever due to the changes in science communication in the past decades. Schäfer defines this change as a shift from “Public Understanding of Science” to “Public Engagement with Science and Technology”. Instead of merely attempting to communicate scientific matters by translating science to the public, this shift represents a change to a dialogue model; a more transparent and egalitarian way of communicating science (Schäfer 2008). The reason this change is necessary is a result of the “medialization” of science, a term coined by Peter Weingart, which describes the increase of media coverage of science over time. Although certain topics have permeated across the media for many decades, like NASA research, nuclear research, and space exploration, science coverage in general has increased significantly over time, especially with the advent of the Internet which made access to science so easy. One of the reasons it is important for scientists to make public engagement more of a priority is that actors other than scientists have increased their media presence regarding scientific matters, to such an extent that scientists are becoming underrepresented in the mass media (Schäfer 2008). As a result, media coverage of scientific issues has become more controversial, leading to greater public distrust of certain scientific matters. But scientists have the opportunity to change public opinion and increase trust through public engagement.

The GKS effectively engages with the public because the State Fair environment is highly conducive to building trusting relationships. While the divide between the research team, or the “experts”, and the public exists, the atmosphere of the State Fair helps to alleviate the hierarchical nature of the researcher-participant relationship. One

type of vulnerability bioethicists discuss is how environments can potentially create a perceived difference in power in the relationship between researchers and participants. This is often cited in cases where research is conducted in hospital settings where participants are also patients and may be wearing hospital gowns and lying in bed, which may leave participants feeling vulnerable (Koffman et al 2009). This type of ethical vulnerability is not limited to hospital settings. The GKS research team, however, dresses in shorts and t-shirts with the study's logo imprinted on them, they are interacting with both the parents and children in the spirit of the State Fair, and making the experience fun and enjoyable, reducing the hierarchy of the relationship. Building this social trust is represented in the survey responses. The majority of the participants felt it was important to them that they are able to meet the GKS research team in person. Participants in research studies may not often consider whether it would make a difference to their participatory experience if they were able to meet the researchers responsible for the study, but the GKS participants get to see the research team year after year and have deemed it important to their experience. Overwhelmingly, the GKS participants said they feel comfortable asking the researchers questions about the study and about genetics in a more general context (95% and 87% respectively). One of the greatest benefits to building trust with research participants, is that they feel more comfortable asking questions. While comfort with the study does not equate the study to being ethical, it can reflect the potential for open communication between researchers and participants. Where informed consent is questioned, the GKS participants have indicated they have little hesitation to ask a question if they have one, which suggests their intent to

understand more about the study and their participation in the study. The participants become more educated on genetics and more knowledgeable about the study itself, both significant benefits to conducting research in the public.

The GKS participants were asked specifically for their opinions about the responsibility of researchers to engage their research participants and the public. Roughly the same number of participants (93%) believed it was important or very important for researchers to engage both the participants of their studies and the public, with only one individual indicating engagement was unimportant. Additionally, about 65% of the participants believed researchers are not doing enough to engage the public. This should serve as a message to scientists, that people think communication and discussions with the public is very important, either that be in the form of disseminating study results or through education, and they also feel scientists could be doing a much better job. The public wants to hear from scientists, especially when there can be so many conflicting opinions across various media, especially when news stories about science are sensationalized by the media to invoke controversy and debate. The public is eager to hear from the actual experts, and one of the first and easiest ways scientists can reach out to the public is by engaging their own research subjects. Bringing research into the public, like the GKS has done utilizing the most highly attended event in the state of Minnesota, can be an example to other researchers to show how this type of public engagement is easy and can bring about significant social benefits to the participants.

Willingness to Participate

Low participation rates are a constant problem in research, and in particular as genome-wide association studies, and other large scale studies that require sizable study populations, become more popular, low participation rates can be a significant barrier to reliable results. As a result, numerous research studies that have delved into understanding the reasons that inhibit participation in genetics-based research studies, particularly focusing on groups that are often underrepresented in study populations. A study by Sterling et al conducted a literature review of public willingness to participate in genetic variation research, in which they analyzed the factors that caused potential subjects to decline participation (Sterling et al 2006). Many of their results mirrored the discussion on public opinion of genetics-based research discussed in Chapter 1. Lack of trust, genetic discrimination by insurance companies, employment discrimination, racial discrimination, misuse of genetic information, and confidentiality concerns were the most highly cited reasons for decline. Certain reasons for declining to consent to research are highly specific to distinct populations. For example, African Americans are more likely to decline participation because of distrust of government and medical researchers and fears of discrimination, whereas Caucasians often cite concerns over confidentiality, privacy, and the potential misuses of genetic information (like creating “designer” babies (Sterling et al 2006).

While there can be significant challenges to motivating individuals to participate in genetics-based research, once they have been identified, researchers can work to minimize these barriers. The continued political involvement of mitigating risks of

genetic or racial discrimination is essential in order to protect the public from potentially devastating consequences. If the public is going to feel safe giving DNA samples for research or medical purposes, they need to be protected, and become aware that protections are in place. Unfortunately, as noted in Chapter 1, many Americans are unaware of the existence of GINA. Researchers can do their part to inform participants in genetics-based studies about GINA and other such protections. The GKS research team had informational sheets about GINA on hand to distribute to any participant with concerns about genetic discrimination.

Trust is a prevailing theme when potential participants choose whether to hand over their DNA to researchers. Kerath et al surveyed individuals about their attitudes toward genetics-based research and participation in biobanks. Their results indicated a generally positive view of genetics-based research in general, with an emphasis on the importance of such work, but there was a disconnect between the support for research and the respondents' actual willingness to participate (Kerath et al 2013). A lack of understanding about the consent form and concern over the use of DNA samples led many respondents to be somewhat distrustful of biobanking their own samples, despite how important they felt the research was. Researchers in turn, can make the consent process more engaging to lessen this distrust. A study focusing on the effective recruitment of minority populations found one of the most effective ways to build trust with potential research subjects is through community involvement. By reaching out to community-based organizations in minority neighborhoods and building trusted relationships with respected community leaders, researchers can assuage many

participant fears that hold people back from participation (Yancey et al 2006). And yet another study that focused on the impacts enrollment sites and recruitment processes have on participation rates, has similar findings. Enrollment site processes could improve participation rates and retention through open, frequent, and personalized communication between researchers and participants. They specifically stressed the importance of personal communication in the retention of participants for longitudinal studies (Helgesson 2011).

Whereas the study by Kerath et al found a disconnect between the importance people place on genetics-based research versus their willingness to participate, the GKS did not have a very significant distinction. Over 97% of the agreed that it was important or very important to participate in research, and about 83% indicated they would be willing to consider participating in future research studies, beyond their participation in the GKS. Participation in the GKS has already inspired 54 families to become involved further research. While their willingness to participate prior to enrolling in the GKS is unknown, the GKS participants have been overwhelmingly satisfied with their experience with the study thus far, and that positive experience is reflected through their willingness to participate again in the future. On the contrary, other research has been able to illustrate that negative experiences with research can deter individuals from participating in other studies (Yancey et al 2006).

After addressing barriers to participate in attempts to increase willingness to participate, researchers are then faced with finding study subjects. This burden rests on researchers' shoulders, because finding research opportunities is not easy from an

interested potential participant's perspective. Bringing research into the public makes people aware of participation possibilities, and may draw interest from individuals who may have never considered becoming involved with research before. This argument is supported by the fact that the majority of the GKS participants indicated that the likelihood they would have sought out research opportunities on their own was small. Because they were approached at the State Fair, they have now become involved as research participants. Other fairgoers stopped by the GKS display, inquiring what the GKS was all about. After explaining the study, many individuals followed up with questions about how they could become involved with research, whether there was a website through the University of Minnesota that could inform them of research opportunities. If more research were brought into public venues and events, or research opportunities were easier to locate through websites, more people may be willing to participate than researchers realize. The GKS was designed to take advantage of the State Fair for recruitment in research, and thus far it has been deemed highly successful.

Changing Attitudes about Genetics

One of the aims of this study was to assess how the GKS participants' opinions, knowledge, and interest in genetics-based research have changed as a direct result of their participatory experience. According to the results of the survey, the participants attributed much of their change in attitudes to their experience with the GKS. Roughly 44% of the participants indicated their opinions about genetics-based research have become more positive in the past three years, but more importantly all of these participants said at least some of the change in their opinions has come from being

involved with the GKS. A majority of the participants have learned more about genetics since their enrollment and 93% expressed that the GKS experience has taught them at least a little more about genetics than they previously knew. Finally, around 60% of the parents said their interest in genetics has increased due to their involvement with the GKS. Likewise, a similar percentage of the GKS children have more interest in science than they did three years ago, with the majority of parents attributing this change in interest to the GKS.

These results illustrate the social benefits of participatory experience in research studies. There is a serious lack of research looking at the benefits participants receive as a result of their experience in research studies. The focus of participation has been on the reasons why a person chooses or declines to participate as previously mentioned. The data from this survey shows that about 44% of parental opinions about genetics-based research became more positive as a result of their experience with the study. Although 55% of parents had no change in their opinions, their overall attitudes about genetics-based research were not evaluated. A majority of the parents have become more knowledgeable as a result of participation, but above all else, a majority the parents and children have developed a greater interest in genetics and science. Through this increased interest, a majority of the parents said they have become involved in discussions with their children about genetics and the GKS. At a time when STEM education is waning and there is a greater demand for STEM related jobs, it is essential to find new and innovative ways to reach out to children, as well as adults to foster an interest in STEM. While this study retrospectively measures the change of participants'

attitudes, future longitudinal genetics-based research studies could integrate processes to measure how the participatory experience changes people's opinions, knowledge, and interest.

Although the comparison of the GKS participant responses to those of the genetic testing public opinion survey did not differ greatly in their trust or use of genetic information, future research studies could attempt similar comparisons to determine if participant opinions differ significantly from the general public. One of the limitations to the comparison in this study was that both populations were very similar demographically and were recruited in the same location at the State Fair, which already illustrated a biased population, particularly in regards to education level.

ELSI and Opportunities for Researchers

When planning and designing a genetics-based research study, the notion of public engagement or the participatory experience is not often put into the equation. Researchers are typically interested in the results of their study and the scientific contribution they can make to society, weighing risks and benefits to their participants, implementing procedures to mitigate risks, and discovering ways to maximize the benefits. Very little focus is directed at maximizing the indirect social benefits to participants; usually the benefits that receive attention are related to potential health benefits. According to the ethical principle of beneficence, researchers have an ethical duty to minimize harms while maximizing benefits. Despite the ethical responsibility of maximizing clear, direct benefits, the question is whether researchers are also ethically responsible to attempt to maximize indirect benefits, such as education and awareness.

Whether or not they have an ethical duty to do so, researchers who conduct human subjects research have the unique opportunity of educating groups about their research without considerable effort.

This notion of the responsibility to educate the public while conducting research is not held only by bioethicists. The National Science Foundation implemented a criterion for their research grants called the Broader Impacts criterion. This requires researchers to think more broadly about how their research impacts society beyond their own personal scientific goals. This requirement can be met in several ways such as provided on their website: promoting teaching, training, and learning, broadening participation of underrepresented groups, enhancing infrastructure for research and education, broaden dissemination to enhance scientific and technological understanding, and directly benefiting society (NSF n.d.). This criterion emphasizes the current culture surrounding STEM research, that there is a responsibility of researchers to become involved with attempts to increase STEM education in this country and recognize the greater societal benefits their research can have on society. Many of the results of the analysis on GKS participation can illustrate some of the Broader Impacts goals. The GKS has increased genetic knowledge in a large percentage of the parents involved in the study, and has exposed both parents and children to research, and has also increased many participants' interest in genetics and science. The purpose of the Broader Impacts criterion is to get researchers to think beyond just the scientific goals of their research. Through the GKS study design, including the environment, the GKS is conducive to informing not only participants but the State Fair fairgoers about genetics-based research.

Throughout this paper trust has been a recurring theme. Many factors play a role in how individuals evaluate their trust of another person or an organization, including history, integrity, transparency, as well as the relationship created between two entities. An interesting view on trust argues that people distrust *someone*, not *something*, which gives power to the public engagement process (Petts 2008). People may not actually fear emerging genetics research, they might just fear who is handling their DNA, who is conducting the research, because ultimately who has the responsibility for using DNA determines *how* it will be used. This is an interesting concept to consider when trying finding ways to build public trust. Policymakers have amended and created laws to protect individuals from genetic discrimination, and while people may point to historical examples of various types of discrimination that have occurred, ultimately people are distrustful of specific individuals. As noted in the GKS survey results as well as many of the public opinion surveys mentioned in this paper, people are predominantly distrustful of insurance companies, government, and employers when it comes to determining who they are comfortable giving their genetic information to. While there still remains skepticism over the usage of genetic information, people are more willing to allow individuals or organizations they trust have more leeway with how their genetic information can be used. Public opinion surveys have often asked respondents to indicate their support for various uses of genetic information. An opportunity for future research could discover whether the apprehension or comfort with a particular use is because of the intended use itself or potentially the result of what sort of organization comes to mind when thinking about who would use genetic information in that manner.

ELSI has become deeply imbedded in research methodology and practices that researchers cannot escape the broader implications of their research. Particularly in this social climate, coupled with the rapid advancement of genetics-based research, it is not only important, but essential for researchers to become more involved in the development and adherence to ethical principles of human subjects research. Whole-genome sequencing can be done at a fraction of the cost only years ago, genetic testing is expanding in the medical arena, and an increasing number of direct-to-consumer genetic testing companies offer health and ancestry information to consumers. The ethical principles currently in place will continue to be challenged by attempting to integrate them as genetics technology expands. It is important for researchers to work collectively with bioethicists in order to continue mitigating risks to research subjects.

In the same regard, laws protecting and regulating the usage of genetic information need input and support from the research community. Scientists are the experts and can serve policymakers when designing new laws to keep up with advancing science and technology. But most importantly, researchers have the opportunity to educate, build trust, and bring awareness to genetics-based research by engaging the public. In a political climate that is highly supportive of developing novel and innovative ways to education individuals outside the classroom, now is the time for researchers to think out of the box, think creatively about how they can integrate education and awareness in their research projects. The GKS has shown by bringing research to the public in an environment like the Minnesota State Fair, researchers can reach a greater

population of individuals and can make lasting impacts on the participants of their studies; and all the while gain important data to advance genetics-based research.

Bringing research into the public is only one example of how researchers can effectively engage the public. The AAAS developed the Center for Public Engagement with Science and Technology in order to provide scientists the resources and tools to improve communication with the public (AAAS 2013). Scientists can develop broader communication methods of disseminating their research directly to the public, beyond peer-reviewed publications, which are not easily accessible to those outside of academia. Researchers can become more involved in political events, such as town hall meetings, in order to discuss pertinent scientific matters directly with the public, such as climate change or evolution. Scientists working with human subjects can create informational materials that they can provide to participants to give them a better understanding of the science behind a particular study and what other research has been conducted thus far. The ways in which researchers can engage the public are endless, and organizations like the AAAS have created centers to facilitate to assist researchers in these types of endeavors. The social benefits to increased public engagement of scientific research can be realized through public and political opinion, policy, and even on research itself.

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Appendix A

CONSENT FORM **Gopher Kids Study**

*Logan G. Spector, Ph.D. and Ellen W. Demerath, Ph.D – Lead Investigators
University of Minnesota*

The Department of Pediatrics and the Division of Epidemiology and Community Health at the University of Minnesota are conducting a large study of children at the Minnesota State Fair. We would like to gather data from healthy children to better understand the growth, development, and health of Minnesota children.

Logan G. Spector, Ph.D., of the Department of Pediatrics at the University of Minnesota and Ellen W. Demerath, Ph.D., Division of Epidemiology and Community Health, School of Public Health are responsible for this study. We would like your child to participate in our study because he/she is between the ages of 1 and 11 and resides in Minnesota. We would like track the health and development of children these ages and relate it to their genes.

We ask that you read this form and ask any questions you may have before agreeing to be in the study.

Study purpose

The main purpose of this study is to understand how genes contribute to children's normal health and development. During this first phase of the study, we are trying to see if families will participate in research based at the Minnesota State Fair. If it is successful, we will then enroll a much larger group of children. Our goal is to recruit 500 children at the 2010 State Fair and have them visit again for measurement and sample collection at the 2011 and 2012 State Fairs.

Study procedures

If you agree to participate in this study, we would ask you and your child to do the following at the Fair:

- Have your child's height, weight, waist, and blood pressure measured.
- Donate a sample of your and your child's cheek cells. Cheek cells will be obtained by depositing saliva into a plastic Oragene container. Younger children's cheek cells will be obtained by rubbing a soft brush on the inside of his or her mouth.

- Collect nail clippings (OPTIONAL).
- Collect blood spots by a fingerstick from your child (OPTIONAL).
- Complete a short, general survey about your family.

In addition to the parts of the study taking place at the Fair right now, we will ask that you:

- Complete a 45-minute questionnaire that will be mailed to you in the next 4-6 months.
- Return to the Minnesota State Fair in 2011 and 2012 year for additional sample collection.

You may choose to participate in all or some of the procedures. Your participation in this study will last until the final sample collection at the 2012 State Fair. You can stop participating at any time. The study investigators may also decide to take you off this study, if they feel it is in your best interest not to continue.

What will happen with your and your child's DNA samples? The cheek cells and blood spots we collect will be used to study you and your child's DNA. DNA is the genetic material in a person's cells that makes them unique. There are thousands of genes in each cell which are made up of DNA. By studying the DNA, scientists can discover what genes might be involved in normal growth and development. We ask for a parent's DNA sample, although we are studying children, to tell which genes the children inherited.

In this study we will be looking at millions of variations in the collected DNA sample. So little is known about the factors being studied, including your and your child's DNA, that the results will not provide useful information to your family. This information is for research purposes only and you will not be informed of your individual results. However, if you wish, you will be informed of the overall findings from the study once it is over.

Research that uses your and your child's DNA might be done a long time after they are collected. These samples will be used for research by Logan G. Spector, Ph.D. and his associates for the purposes of learning more about genetics in growth and development. You will not be identified in any publication or reports of this data.

What will happen with your child's blood spot and fingernail samples? These samples may be used to look at hormones or other substances that they body naturally produces, or they may be used to look at chemicals present in the environment. Again, any tests performed on these samples are for research purposed only and you will not be informed of your individual results.

How long will your and your child's DNA and other samples be kept? Your and your child's DNA and other samples will be kept indefinitely, unless you request destruction. We will contact your child when he or she turns 18 to see if we can continue storing his or her samples. You can request that your or your child's samples be destroyed at any time by contacting Dr. Spector or Dr. Demerath at the number provided below.

Risks of Study Participation

The risks of this study are minor. There is a small risk that your or your child's personal information could accidentally be released to someone other than study staff. We would keep all personal information in locked file cabinets or in computer databases protected by passwords. Only study staff would have access to these documents and files.

Also, because we're getting DNA from parents and child, we may be able to tell if someone was adopted or if their father is different than they think. Our policy is to not reveal this information.

Benefits of Study Participation

There is no personal benefit to you or your child for participating. The study may benefit society by discovering genes related to normal growth and development. .

Study Costs/Compensation

There is not cost to you for participating in this study. You will receive a University of Minnesota fair souvenir and \$5 worth of kids' ride tickets at the Fair each year that you participate. In addition, a few weeks before the 2011 and 2012 Fairs we will mail your family one free ticket for each participating child and one for a parent.

Confidentiality

The records of this study will be kept private. In any publications or presentations, we will not include any information that will make it possible to identify you as a subject. Your record for the study may, however, be reviewed by departments at the University with appropriate regulatory oversight. Your participation in this study will not be noted in your medical record. To these extents, confidentiality is not absolute.

Voluntary Nature of the Study

Participation in this study is voluntary. Your decision whether or not to participate in this study will not affect your current or future relations with the University of Minnesota. If you decide to participate, you are free to withdraw at any time without affecting those relationships.

Contacts and Questions

The researchers conducting this study are Logan G. Spector, Ellen W. Demerath, and their associates at the University of Minnesota. You may ask any questions you have now, or if you have questions later, **you are encouraged to** contact Dr. Spector at 612-624-3912 or Dr. Demerath at 612-624-1818.

If you have any questions or concerns regarding the study and would like to talk to someone other than the researcher(s), **you are encouraged to** contact the Fairview Research Helpline at telephone number 612-672-7692 or toll free at 866-508-6961. You may also contact this office in writing or in person at Fairview University Medical Center - Riverside Campus, #815 Professional Building, 2450 Riverside Avenue, Minneapolis, MN 55454.

You will be given a copy of this form to keep for your records.

Statement of Consent

I have read the above information. I have asked questions and have received answers. I consent to participate in the study on behalf of myself and my child.

Name of child _____

Signature of Parent _____

Date _____

Appendix B

Gopher Kids Study: Experiences at the Fair

Section 1. Please answer the following questions about your experience with the Gopher Kids Study over the past three State Fairs.

1. How do you feel about your overall experience with the Gopher Kids Study?

<input type="radio"/>	Very satisfied
<input type="radio"/>	Satisfied
<input type="radio"/>	Neither satisfied or unsatisfied
<input type="radio"/>	Unsatisfied
<input type="radio"/>	Very unsatisfied

2. How important is it that you are able to meet the researchers in person?

<input type="radio"/>	Very important
<input type="radio"/>	Important
<input type="radio"/>	Neither important or unimportant
<input type="radio"/>	Unimportant
<input type="radio"/>	Very unimportant

3. How comfortable are you asking the researchers questions about the study?

<input type="radio"/>	Very comfortable
<input type="radio"/>	Comfortable
<input type="radio"/>	Neither comfortable or uncomfortable
<input type="radio"/>	Uncomfortable
<input type="radio"/>	Very uncomfortable

4. How comfortable are you asking the researchers question about genetics in general?

<input type="radio"/>	Very comfortable
<input type="radio"/>	Comfortable
<input type="radio"/>	Neither comfortable or uncomfortable
<input type="radio"/>	Uncomfortable
<input type="radio"/>	Very uncomfortable

5. How easy or difficult do you feel participating in the study has been for your family?

<input type="radio"/>	Very easy
<input type="radio"/>	Easy
<input type="radio"/>	Neither easy or difficult

<input type="radio"/>	Difficult
<input type="radio"/>	Very difficult

6. Why has participation been easy or difficult?

Please specify:	
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Section 2. Please answer the next set of questions about how the Gopher Kids Study has impacted you and your family.

7. Have you participated in any other research studies since being part of the Gopher Kids Study (since September 2010)?

<input type="radio"/>	Yes
<input type="radio"/>	No

8. How likely is it that you would have sought out research opportunities on your own had you not come across the Gopher Kids Study at the fair?

<input type="radio"/>	Very likely
<input type="radio"/>	Somewhat likely
<input type="radio"/>	I don't know
<input type="radio"/>	Somewhat unlikely
<input type="radio"/>	Very unlikely

9. How likely is it that you or your family will participate in future research studies?

<input type="radio"/>	Very likely
<input type="radio"/>	Somewhat likely
<input type="radio"/>	I don't know
<input type="radio"/>	Somewhat unlikely
<input type="radio"/>	Very unlikely

When answering questions 10-19, think about how your experience with the Gopher Kids Study may have changed your opinions or knowledge of genetics.

10. Do you think your opinions toward genetics based research have changed since August 2010?

<input type="radio"/>	I have a much more positive view of genetics research
<input type="radio"/>	I have a slightly more positive view of genetics research
<input type="radio"/>	My opinions toward genetics research have not changed
<input type="radio"/>	I have a slightly more negative view of genetics research
<input type="radio"/>	I have a much more negative view of genetics research

11. How much of the change in your opinions is a result of participating in the Gopher Kids Study?

<input type="radio"/>	All
<input type="radio"/>	Most
<input type="radio"/>	Some
<input type="radio"/>	A little
<input type="radio"/>	None

12. Have you learned more about genetics since August 2010?

<input type="radio"/>	I have learned a lot more about genetics
<input type="radio"/>	I have learned some more about genetics
<input type="radio"/>	I have learned a little more about genetics
<input type="radio"/>	My knowledge about genetics has not changed
<input type="radio"/>	I don't know anything about genetics

13. How much of the change in your knowledge is a result of participating in the Gopher Kids Study?

<input type="radio"/>	All
<input type="radio"/>	Most
<input type="radio"/>	Some
<input type="radio"/>	A little
<input type="radio"/>	None

14. How has participation in the Gopher Kids Study changed your interest in genetics?

<input type="radio"/>	I am much more interested in genetics
<input type="radio"/>	I am a little more interested in genetics
<input type="radio"/>	My interest in genetics hasn't changed
<input type="radio"/>	I'm not very interested in genetics
<input type="radio"/>	I am less interested in genetics

15. How many of your children are part of the Gopher Kids Study?

<input type="radio"/>	1
<input type="radio"/>	2
<input type="radio"/>	3
<input type="radio"/>	4
<input type="radio"/>	5

16. Name of child:

First name:	
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17. How would you describe the change in your child's interest in science since August 2010?

<input type="radio"/>	My child has significantly stronger interest in science
<input type="radio"/>	My child has a slightly increased interest in science
<input type="radio"/>	My child's interest in science has not changed
<input type="radio"/>	My child has a slightly decreased interest in science
<input type="radio"/>	My child has a significantly decreased interest in science
<input type="radio"/>	My child is too young to have an interest in science

18. How much of the change in your child's interest do you think is a result of participating in the Gopher Kids Study?

<input type="radio"/>	All
<input type="radio"/>	Most
<input type="radio"/>	Some
<input type="radio"/>	A little
<input type="radio"/>	None

19. Since participation in the Gopher Kids Study, have you engaged in discussions about genetics with your child? (*Think about whether you have talked to them about what the Gopher Kids Study is about or genetics in general.*)

<input type="radio"/>	We have had multiple conversations about genetics and the Gopher Kids Study
<input type="radio"/>	We have talked about genetics and the Gopher Kids Study
<input type="radio"/>	We have only talked about genetics more generally
<input type="radio"/>	We have only talked about the Gopher Kids Study
<input type="radio"/>	We have not discussed genetics
<input type="radio"/>	My child is too young to understand genetics

Section 3. Please answer the next set of questions about research in a more general context.

20. How important do you think it is to participate in research?

<input type="radio"/>	Very important
<input type="radio"/>	Important
<input type="radio"/>	Neither important or unimportant
<input type="radio"/>	Unimportant
<input type="radio"/>	Very unimportant

21. How important do you think it is for researchers to engage the participants of their research studies?

<input type="radio"/>	Very important
<input type="radio"/>	Important

<input type="radio"/>	Neither important or unimportant
<input type="radio"/>	Unimportant
<input type="radio"/>	Very unimportant

22. How important do you think it is for researchers to engage the general public about genetics-based research?

<input type="radio"/>	Very important
<input type="radio"/>	Important
<input type="radio"/>	Neither important or unimportant
<input type="radio"/>	Unimportant
<input type="radio"/>	Very unimportant

23. Do you think researchers engage the public often enough about genetics research?

<input type="radio"/>	I think they engage the public a lot
<input type="radio"/>	I think they engage the public enough
<input type="radio"/>	I think they should engage the public more
<input type="radio"/>	I don't think they engage the public at all
<input type="radio"/>	I don't know

24. Do you think genetics research contributes to an overall improvement in the public's health?

<input type="radio"/>	I think genetics research greatly improves public health
<input type="radio"/>	I think genetics research improves public health
<input type="radio"/>	I think genetics research has a minimal impact on public health
<input type="radio"/>	I don't think genetics research improves public health at all
<input type="radio"/>	I think genetics research has a negative impact on public health

25. How do you view the risks associated with genetics based research?

<input type="radio"/>	I don't think there are any risks
<input type="radio"/>	I think the risks are minimal
<input type="radio"/>	I think the risks are high
<input type="radio"/>	I don't know

26. How do you view the benefits associated with genetics based research?

<input type="radio"/>	I think the benefits are high
<input type="radio"/>	I think the benefits are minimal
<input type="radio"/>	I don't think there are benefits
<input type="radio"/>	I don't know

27. Overall, would you say the benefits of conducting genetic research outweigh the risks?

<input type="radio"/>	Yes
<input type="radio"/>	No
<input type="radio"/>	I don't know

28. How much do you trust the following people or institutions to use your genetic information responsibly?

	Completely Trust	Somewhat Trust	Do Not Trust	Do Not Know
Your doctor				
Your employer				
University of Minnesota researchers				
Police				
Insurance companies				
Minnesota Department of Health				
National Institutes of Health				

29. Do you feel the existing laws protecting genetic information are sufficient?

<input type="radio"/>	I think the laws protect genetic information
<input type="radio"/>	I think the laws offer some protection but could be better
<input type="radio"/>	I don't think the laws protect genetic information enough
<input type="radio"/>	I don't know

30. Should genetic information be used for the following reasons?

	Yes	No	I don't know
Developing personalized drugs			
Setting the cost of your insurance			
Developing cures for genetic diseases			
Understanding why people develop disease			
Researching biological weapons			
Having a child without a genetic disease			
Investigating your ancestry or ethnicity			
Finding possible criminals using DNA			
Paternity tests			
Choosing characteristics of your children			