

Community Organization Booklet

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I. Introduction

Over the past decade genetic research on disease susceptibility, drug response, and evolutionary history, has increasingly involved racial and ethnic groups, even as the use of racial and ethnic categories in biomedical research has become more controversial. These developments have led the National Institutes of Health (NIH) and other medical and scientific organizations to call for better communication between investigators and racial and ethnic communities so as to enable them to share each other's understandings of the methods and goals of genetic research, the social risks involved, and the importance of community consultation and informed consent. In its "Points to Consider When Planning a Genetic Study That Involves Members of Named Populations" the NIH recommends that investigators planning research on racial and ethnic populations conduct community consultations prior to initiating their studies.

Community organizations have an important role to play in facilitating communication between investigators and racial and ethnic communities. Community organizations hold in-depth knowledge about the needs, values, and concerns of the communities they represent. Because of this knowledge, community organizations offer genetic researchers a valuable partner in consulting with community members, recruiting participants, and designing genetic studies. Because of their expertise and their respected standing, community organizations are also well positioned to assist the communities they represent to better understand the goals and risks of genetic studies, as well as manage the impact of new genetic knowledge that may result.

This online booklet provides information about the methods, goals, risks, and benefits of genetic research as well as the procedures and information relevant to

participating in studies and managing their outcomes. The information provided in this booklet is informed by interviews with genetic researchers and community organizations as well as supplemental research, all of which were part of a study funded by the Ethical, Legal and Social Implications (ELSI) Research Program at the National Human Genome Research Institute and conducted by the Center for the Study of Society and Medicine at the Columbia University College of Physicians and Surgeons. Each unit in the booklet is accompanied by a list of relevant readings. Where appropriate, further readings are listed as well. In general, the readings are directed toward a lay audience while the further readings are written for those with more than a basic understanding of human genetics.

II. A Brief Overview of Genetics and Genetic Research

Human beings contain tens of thousands of genes, the basic material for cell function including the transmission of hereditary characteristics. Genes play a part in shaping many human characteristics, from the color of our hair and eyes to our level of risk for contracting a variety of diseases and conditions including depression, nearsightedness, allergies, and cancer.

Information about genes is stored in DNA (deoxyribonucleic acid). DNA is composed of four chemical bases: adenine, guanine, cytosine, and thymine, which appear as pairs (adenine with thymine, and guanine with cytosine) in the DNA. In normal conditions, each gene is carried in two copies, one inherited from each parent. Genes occur in particular locations along one of forty-six chromosomes, which, like genes, come half from the mother and half from the father. Each chromosome contains many thousands of genes and many millions of base pairs. The human genome, which encompasses all of the genetic information in the human body, consists of about three billion base pairs. Decoding a particular gene means learning the order of base pairs in that gene. Genes vary in size according to the number of base pairs of which they are comprised.

Genes control the functioning of the human body by producing proteins through processes called transcription and translation. Different proteins perform different functions. For example, some genes produce proteins like hemoglobin, which carries oxygen around the body. Other genes produce collagen, which provides the body with structural support. Still others produce enzymes that facilitate chemical reactions like digestion. Genes called tumor suppressors produce proteins that control or regulate cell

division. If cell division is not properly regulated, cells may divide too much or too rapidly and cancer may result.

Ordinarily, when new cells are produced through cell division, the DNA from the prototypical cell is replicated in the new cells. Sometimes, however, an error in the replication process may result in a change in genetic material, called a mutation. Mutations may also result from the exposure of a cell to radiation or chemical toxins. Mutations may be an alteration in the larger structure of the chromosomes or in specific base pairs, either through the deletion or reordering of one or more base pairs. Some mutations are advantageous to the cell or have little effect. Others, referred to as deleterious mutations, are harmful, causing genes to produce partially or completely non-functional proteins. While mutations in all cells can affect an individual's health, only mutations in sex cells, called germline mutations, will be passed on to one's offspring. Mutations in other cells, called somatic mutations, will not be inherited.

Mutations are actually quite common. It is believed that every individual is born with between five and thirty significant germline mutations in our DNA. Each may affect the risk for any of thousands of disorders, from allergies to depression to diabetes, that have been linked to heredity. Some hereditary disorders are caused by an inherited mutation in a single gene. These disorders, often referred to as Mendelian or single-gene disorders, are characterized as either dominant or recessive. A dominant Mendelian disorder requires a deleterious mutation in only one of the two copies of a gene that an individual carries. An example is Huntington's disease. A recessive Mendelian disorder requires a deleterious mutation in both copies of a gene that an individual carries. Individuals carrying only a single mutation are known as trait carriers, and usually exhibit

no harmful effects. An example is Tay-Sachs disease. Over the past thirty years genetic research has yielded the gene responsible for many of these disorders, including sickle cell disease, Duchenne muscular dystrophy, and Huntington's disease.

Many common diseases, such as cancers, diabetes, and hypertension, also have a genetic basis. However, these diseases are often not inherited in a direct Mendelian fashion. Instead, they develop as the result of complex interactions of genes and environmental stimuli, such as chemical toxins, diet, and lifestyle. In conducting genetic research on such multifactorial diseases, scientists aim to identify and understand the roles of genes in the onset and course of the disease so that diagnostic tests and eventually improved clinical treatments may be developed.

Initial genetic research on a disease often looks to identify genes that increase an individual's risk for the disease. To look for such genes geneticists commonly use association studies. Association studies examine whether variations in certain genetic base pairs correspond to disease symptoms. If this correspondence occurs at a rate above that predicted by chance alone, it is likely that the base pairs are linked to a gene that affects risk for the disease. However, for this to be confirmed, geneticists must conduct additional studies to code the gene and demonstrate that it affects disease risk in large samples of people.

Once a gene is identified additional genetic research is needed to understand its role in the onset and course of the disease. This research includes studies to identify specific mutations in the gene and estimate their distribution and the levels of risk they confer. It also includes studies to understand the function of the gene and how this function affects other genes or environmental factors that may contribute to the onset of

the disease or the types of symptoms it presents. Studies may also be conducted to determine whether the gene has an affect on other diseases. Ultimately, if gene mutations are discovered that confer a significant level of risk for the disease, it may be possible to develop diagnostic tests to identify individuals at elevated risk. Such tests can allow high risk individuals to make dietary or lifestyle changes to decrease their risk or in some cases undergo preventive procedures or drug regiments. Similarly, genetic research that identifies genes that affect the body's response to different drugs can lead to the more efficient prescription of medications. As of yet, genetic therapies that can correct deleterious mutations carried by an individual have not been developed, although some researchers hope that such therapies will become available in the future.

While genes explain much about the way individuals live and function, all too often both physicians and lay people may be guilty of "genetic essentialism," a tendency to view people as solely a creation of their genes. Human beings are more than genetics. To reduce everything to genes and mutations is to minimize other traits of humanity as well as the possibilities for improving the quality of our lives through manipulations of diet, workplace, and environment. We are more than the sum total of our genes.

Readings

- Adelman (2006) contains a discussion of "hows" and "whys" of the decoding of the genome.
- Begley, Hayden, Underhill, and Beals (2000) provide a brief introduction to the Human Genome Project.
- Cowley, Underwood, and Check (2000) discuss how genetic science is transforming both medical research and medical practice.
- NIH, National Human Genome Research Institute, Educational Resources [<http://www.genome.gov/Education/>] presents a user friendly guide to human genetics and the Human Genome Project.
- U.S. Dept. of Energy Office of Science, Human Genome Program, Human Genome Project Information [http://www.ornl.gov/sci/techresources/Human_Genome/home.shtml] provides a

concise overview of human genetics and an introduction to the Human Genome Project. It is also linked to “Gene Gateway,” which is a non-technical guide to other genome resources on the web.

U.S. Dept. of Health and Human Services, Centers for Disease Control and Prevention, National Office of Public Health Genomics, Genomics and Disease Prevention [<http://www.cdc.gov/genomics/default.htm>] focuses on the relationship between genetics and health.

World Health Organization, The Genomic Resource Centre [<http://www.who.int/genomics/en/>] contains extensive information on genetics geared toward policymakers and the public, including an international database of documents on the ethical, legal, and social issues raised by genetics.

III. Genetic Research in Racial and Ethnic Groups

Scientists have investigated the connection between genetic disorders genetic and racial and ethnic groups. Even before the discovery of DNA in 1953, geneticists had observed that certain single-gene disorders occurred predominately in specific racial and ethnic groups. For instance, in the early 1900s sickle cell disease was observed to occur predominately in African Americans, while Tay-Sachs disease occurred predominately in Ashkenazi Jews. These early observations meshed with existing scientific views of races as inherent biological divisions in humanity. This led many researchers to conclude that genetic disorders like sickle cell and Tay-Sachs diseases were unique to the groups in which they were most common.

In the years following World War II scientists reexamined the connection between race and genes. Research in the new field of population genetics found that no single genetic alleles were unique to any particular racial or ethnic group and that on a genetic level it was impossible to distinguish between different groups. Instead of racial and ethnic groups, population geneticists advanced the concept of the population as a more accurate representation of how genes vary between human beings. A population is a group of people that share similar variations in their genes. No population has genes that are exclusive to it however, nor do populations correspond well to commonly-defined racial and ethnic groups.

Despite this change, many single-gene disorders have continued to be identified and studied within specific racial and ethnic groups. Medical researchers have also continued to use racial and ethnic categories to study the distribution of common diseases such as cancers and heart disease. Over the past decade, as genetic research on these

common diseases has increased, many geneticists have begun to investigate whether differences in the racial and ethnic distribution of some such diseases is the result of genetic differences between groups. The notion that there exist genetic differences between groups and that these differences affect health is controversial. Some scientists believe that there exist small amounts of genetic variation between different racial and ethnic groups and that this variation may affect a group's risk for certain diseases. Other scientists believe that it is social conditions, such as education, poverty and diet, that best account for a group's risk for disease.

Geneticists look to study racial and ethnic groups for a number of different reasons. Often a group is targeted because a particular disease or disorder occurs at high levels in members of the group. For instance, many studies investigating the genetic basis of diabetes are conducted in Native American and Alaska Native tribes where the incidence of the disease is high. In such cases researchers may target the group in order to best address a pressing health need. They may also target the group to increase the chance that a disease gene will be identified. In an association study, the likelihood of finding a significant correlation between a gene and a disease is increased by the risk level of the study participants. In general, the lower the risk that a disease gene confers the more difficult it is to detect a significant association and thus the greater the risk level or the larger the size a study population must be.

Sometimes geneticists may target a racial or ethnic group even if its members do not have a high risk for a disease. The accuracy and efficiency of some genetic studies can be improved when the study population is genetically similar, or homogenous. Some ethnic groups, particularly those that are small in size or have historically been isolated,

may be more genetically homogenous than the general population. In association studies this homogeneity can make it easier for researchers to locate disease genes. Genetically homogenous groups are also likely to carry a smaller number of mutations in any single gene. For example, while there have found thousands of different mutations in the BRCA1 and BRCA2 breast cancer genes, Ashkenazi Jews have been found to almost exclusively carry just three. This can allow researchers to more easily study characteristics of the mutations, such as the risk they confer, as well as develop simpler and less expensive genetic tests.

To further improve the ability of geneticists to locate and study disease genes, some countries and communities have developed population-wide genetic databases. In such programs DNA samples are linked to a computer database with an individual's health information and family history. Using sophisticated computer programs researchers can then conduct association studies within the group. Recently, a study using a population genetic database in Iceland isolated a gene that contributes to diabetes risk.

Geneticists may also look to conduct research on racial and ethnic groups for non-medical purposes. By comparing specific DNA base pairs from members of one racial or ethnic group with those from members of another, scientists believe they can estimate how closely related the two groups are. Since changes in DNA accumulate slowly over time, the number of base pairs that differ between groups may reveal the amount of time the groups have been separated. Some believe that such research will enable geneticists to identify disease genes more successfully. It may also help inform scientists and historians about the historical migrations of different populations and the genealogy of

families. Some companies now offer services to provide this information to individuals. Such services have been popular, for example, among African Americans, who have used them to determine to which ethnic groups in Africa they may be related.

Readings

- Barrett (2005) presents an argument for the use of racial and ethnic variables in medical research.
- Burchard et al (2003) argue that the benefits of linking racial and ethnic categories to genetics outweigh the risks.
- Hamilton (2005) examines the use of DNA testing to trace ancestry, weighing its pros and cons including the information's emotional effect on people and its dubious accuracy.
- Kalb, Springen, Carmichael, and Macgregor (2006) discuss the use of DNA tests by individuals to trace their ancestry and by geneticists to tell the story of human origins and migration.
- Kingsland (2005) examines the debate around race-specific medicine.
- Lee, Mountain, and Koenig (2001) discuss the consequences of using racial categories in health research.
- Lemonick, Gibson, and Park (2006) provide an overview of the ongoing genetic research in Iceland by deCODE Genetics, including the scientific rationale for studying isolated populations.
- Miranda (2006) discusses the boom in personal DNA tests to trace ancestry, and how the knowledge gained may challenge one's racial or ethnic identity.
- National Human Genome Center at Howard University, Position Paper: State of the Science on Human Genome Variation and "Race"
[<http://www.genomecenter.howard.edu/News%20documents/Position%20Paper%2010-24-04.doc>] is a position paper on the state of scientific knowledge about race and genetic variation.
- NIH, National Human Genome Research Institute, Social, Cultural and Religious Issues in Genetic Research [<http://www.genome.gov/10001848>] contains a discussion and references relating to race and ethnicity and genetic research.
- NIH, Office of Extramural Research, NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research - Amended, October, 2001
[http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm] provides NIH guidelines for the identification of race and ethnicity.
- Nature Genetics, Genetics for the Human Race (Supplemental Issue, November 2004)
[<http://www.nature.com/cgi-taf/dynapage.taf?file=/ng/journal/v36/n11s/index.html>], although a bit more technical than other works in this area, presents interesting "state of the art" discussions of human genetics.
- Nogrady (2006) provides an overview of the social and scientific controversies surrounding the issue of varying racial responses to medication.

U.S. Department of Energy, Minorities, Race, and Genomics

[http://www.ornl.gov/sci/techresources/Human_Genome/elsi/minorities.shtml]
discusses the role of minority communities in the Human Genome Project and the impact of new genetic knowledge on these communities.

Further Readings

Bamshad et al (2004) and Fausto-Sterling (2004) provide an overview of recent research on whether human genetic diversity is aligned with racial categories.

Byrd and Clayton (1992) and Haller (1970) provide an overview of 19th and early 20th century scientists' views and use of race.

Damon (1969) argues for a continued biological view of race and ethnicity in medical research.

Dobzhansky (1951) and Cavalli-Sforza (1966) provide representative scientific arguments for the replacement of race with population.

Kaufman and Cooper (2001) , Kittles and Weiss (2003) , and Serre and Paabo (2004) argue that human genetic diversity is best represented seen as a continuum.

Krieger and Fee (1996) discuss the ways in which racial and ethnic categories were applied in the efforts to collect health data.

McBride (1991) writes on how early 20th century physicians linked race and disease contagion in order to facilitate segregation.

Montagu (1962) presents an early call for the use of ethnicity instead of race in science.

Oppenheimer (2001) examines current debates surrounding the use of ethnicity versus race in medical research.

Provine (1973) and Sofair and Kaldjian (2000) provide an overview of the effect of early 20th century views of race on the development of eugenics policies.

Reardon (2005) and Marks (2000) provide an overview of the emergence of population genetics and the new discipline's claims about race and human genetic diversity.

Risch et al (2002) , Rosenberg et al (2002) , and Jorde and Wooding (2004) argue that human genetic diversity is organized in genetic clusters that approximate racial categories.

IV. Benefits and Risks of Participating in Genetic Research Involving Racial and Ethnic Groups

Participating in genetic research can offer a range of medical and non-medical benefits to individual participants, their families, and the group as a whole. For individual participants studies may provide therapeutic treatments as well as more general health care services. Some studies may also provide participants with genetic information, such as the presence of a gene mutation. However, this will not always be possible. Some genetic studies require that DNA samples be stripped of all corresponding personal information or that results be kept from participants. Where genetic information is provided, studies often employ personnel to assist participants and their families in understanding the medical and psychological implications of this information.

For a racial or ethnic community more broadly, participation in genetic research can lead to improved health for all of its members. Research that identifies a disease gene or a disease-susceptibility gene or produces findings about the characteristics of such genes may provide the basis for future diagnostic and therapeutic advancements. Genetic tests for recessive single-gene disorders, such as sickle cell disease, can be used either prenatally or postnatally to identify individuals with the disorder and help prospective parents make informed decisions about childbearing. For adult onset diseases, such as breast cancer, genetic tests can be used to identify high risk individuals within a population so that those individuals can make appropriate lifestyle and medical changes to lower their risk. In some cases, knowledge of genetic risk may also enable individuals to undergo preventative treatments, such as surgery and drug therapy. For

instance, both mastectomy and the use of the drug Tamoxifen have been shown in studies to reduce the risk of breast cancer in women who carry a genetic mutation. In cases where a racial or ethnic group is found to carry only certain specific mutations in a disease-susceptibility gene, diagnostic tests may be developed that are more effective and less expensive than those available for the general population. For instance, because the majority of Ashkenazi Jewish women with a BRCA1 or BRCA2 gene mutation carry one of three mutations common in the group, researchers have been able to develop a diagnostic test specifically for those three mutations which is significantly less expensive than other BRCA1/2 tests. Some genetic studies may also offer communities more general medical benefits. For instance, as part of a long-term genetic project on diabetes in the Pima Indians of Arizona the National Institutes of Health has established a series of comprehensive health clinics on the Pima reservation. Opportunities for local employment and education may also accompany genetic studies. In fact, some Native American tribes have begun to require that researchers, when feasible, hire tribe members for supporting positions.

Genetic research does not always lead to timely benefits, however. Many studies yield basic knowledge that cannot be directly translated into therapeutic advancements. Such advancements often require the alignment of new knowledge and technology from a number of different scientific fields. Furthermore, it often takes multiple studies to confirm the accuracy of a genetic finding. It is not uncommon for genes linked to a disease in one study to be found in subsequent studies to have a lesser effect or none at all. A recent review of past association studies found that a low percentage (33%) of

genes initially linked to a disease were subsequently confirmed to affect risk for the disease.

Participation in genetic research can also pose certain risks to both individual participants and to racial and ethnic groups as a whole. In rare instances, there may be a risk of physical harm to participants. In addition, some genetic studies can pose psychological or psychosocial risks to participants. Research may yield personal information regarding disease and disability risks, susceptibility to toxins, paternity, and ancestry. Especially given the familial nature of this information, it may create anxiety, depression, and guilt, as well as disrupt family and community relationships. This genetic information also may be of interest to a wide range of individuals and organizations, including family members, employers, insurers, courts, and the government. If the information is disseminated, discrimination or other harm to research participants might result. While reported cases of genetic discrimination have been limited, they evince a willingness on the part of some employers and insurers to act upon genetic information, often attributing to particular alleles a higher level of risk of disease than might a scientist. Some commentators have stated that the perceived risk of genetic discrimination among the public is significantly greater than the actual risk. Nevertheless, the perceived risk of discrimination has its own effects and has been shown to discourage individuals from seeking predictive genetic testing, as well as from participating in genetic research. Several studies have found that members of racial and ethnic groups with a history of exploitation by medical researchers are particularly concerned about the risk of genetic discrimination.

Because both race/ethnicity and genetics are often imbued with exaggerated degrees of absolutism by the public, genetic findings that link a racial or ethnic population to a disease or disorder may stigmatize the group involved. Oversimplified presentations of genetic findings by the media can lead to incorrect understandings about a group's overall fitness, intelligence, or behavior. Stigmatization can be particularly powerful when the presentation of genetic findings aligns with traditional stereotypes about a group. Research linking racial or ethnic groups to a disease or disorder may also result in discrimination against the group. Where genetic findings communicate the notion that a particular racial or ethnic group is at higher risk for a disease, an occupational injury, or a mental or behavioral disorder, there exists the possibility that insurers, employers or health care providers may decide it is in their best interests to implement policies pertaining to the group generally. Genetic research that offers conclusions about a group's origins, ancestral composition, or genetic relation to other groups may also lead to cultural harm if those conclusions differ from those held by the group.

Federal regulations exist to help protect research participants. Researchers collecting genetic information may be subject to the confidentiality requirements of the Common Rule, which applies to federally funded research and to research under the auspices of institutions that have adopted the rule more broadly. In addition, some research projects are covered by privacy regulations issued under the Health Insurance Portability and Accountability Act (HIPAA). However, the Common Rule provides only a loose framework for regulation of confidentiality: "When appropriate, there are [to be] adequate provisions to protect the privacy of subjects and to maintain the confidentiality

of data.” In addition, the HIPAA regulations only cover researchers when they are seeking information from a health care provider or plan or when they themselves are providing health care. Most states have taken steps to provide enhanced protections for genetic information. However, states differ greatly in the amount of protection they provide. As a result, a number of racial and ethnic groups have expressed concern about the confidentiality of genetic information, advocating the implementation of additional protections including prohibiting the secondary use of genetic information and destroying samples at the conclusion of a study. Stored DNA samples present particular problems in that they are often attached to personal information, such as race and ethnicity. As a result, even if samples are stripped of personal identifiers, their use may still enable researchers to link findings to particular racial or ethnic groups.

Readings

- Begley, Hayden, Underhill, and Beals (2000) provide a brief introduction to the Human Genome Project, including an overview of its perceived social benefits and risks.
- Cowley, Underwood, and Check (2000) discuss the limits of genetic knowledge when genetic therapies are still years away, as well as new ways in which researchers are harnessing the power of DNA to inform medical care.
- Cowley, Underwood, Springen, and Hager (1996) discuss the benefits and risks of genetic testing, focusing on the prospect of insurance discrimination and resulting privacy policies.
- Kalb (2006) presents personal stories attesting to the benefits of BRCA testing for breast cancer.
- Murray (2004) and Szalavitz (2001) present the risks and benefits of participation in genetic research in connection with the opening of National Human Genome Center.
- National Newborn Screening & Genetics Resource Center, Resources [<http://genes-r-us.uthscsa.edu/resources.htm>] encompasses a collection of links to genetic information, including websites that relate to underserved populations.
- NIH, National Human Genome Research Institute, Genetic Discrimination [<http://www.genome.gov/10002077>] explores the implications of using genetics in public health.
- Power (2001) reports on the search for disease genes in isolated communities in Gioi, Italy and Talana, Sardinia, focusing on the relationship between researchers and community residents.

The New Atlantis editorial (2003) discusses the promises and controversies of the Human Genome Project's new "HapMap" endeavor, including its implications for the scientific validity of race.

The New Atlantis editorial (2005) looks at the use of DNA databases in law enforcement in terms of privacy, civil liberties, and racial profiling.

UNESCO (1995) provides an overview and recommendations for involving different racial and ethnic groups in genetic research.

U.S. Dept. of Energy, Human Genome Project Black Bag
[http://www.ornl.gov/sci/techresources/Human_Genome/publicat/jmmbbag.pdf] discusses the future of genetics, with particular attention to its risks and benefits for minority communities.

U.S. Dept. of Health and Human Services, Centers for Disease Control and Prevention, National Office of Public Health Genomics, Genomics and Public Health: Ethical, Legal and Social Issues

[<http://www.cdc.gov/genomics/activities/ogdp/2003/chap08.htm>] provides an overview on public health ethics and genomics.

Zeta Phi Beta Sorority, The Challenges and Impact of Human Genome Research for Minority Communities

[http://www.ornl.gov/sci/techresources/Human_Genome/publicat/zetaphibeta/index.shtml] presents the proceedings of a conference on risks and benefits of genetics for communities.

Further Readings

Brunger (2003) and Nicholas (2001) discuss the ethical considerations of class and gender inequalities in community-researcher collaborations.

Davis (2000) compares efforts to involve different racial and ethnic groups in genetic research.

Galarneau (2002) examines how the characteristics of different groups affect their health care priorities.

Kone et al (2000) review different community-research collaborations in the Seattle area.

Sude and Hager (2003) discuss how community structure affected community involvement in the International HapMap Study.

V. Partnering with Genetic Researchers

There are many ways in which community organizations can partner with genetic researchers to both facilitate more effective studies in racial and ethnic groups and ensure that the community they represent is adequately protected from the risks present in such studies. Much depends on the specific expertise of an organization as well as the type and size of the genetic study in question. In general, however, an organization will be more effective if it has members who are fluent in both the science used by researchers and the cultural values of the community. Where an organization envisions extensive collaboration with genetic researchers it may be worthwhile to provide members with basic training in genetics. In some cases, training may be available through the institution funding the research or through the researchers themselves.

Readings

Genetic Alliance [<http://www.geneticalliance.org/>] contains a considerable amount of resource material on community/research partnerships, some of which deals specifically with racial or ethnic communities.

National Human Genome Center at Howard University, Community Partnership Program [http://www.genomecenter.howard.edu/units/genethics/cpp_default.htm] provides information and resources on community engagement around genetics.

NIH, National Human Genome Research Institute, Collaborative Research for Minority and Special Populations [<http://www.genome.gov/10001281>] presents materials relating to community/researcher partnerships for genetic research.

NIH, National Human Genome Research Institute, Community Outreach and Public Education for Minority and Special Populations [<http://www.genome.gov/10001279>] discusses available educational materials for communities with respect to genetic research.

Power (2001) reports on the search for disease genes in isolated communities in Gioi, Italy and Talana, Sardinia, focusing on the relationship between researchers and community residents.

Further Readings

Baty, Kinney, and Ellis (2003) provide a guide for culturally sensitive genetic research and education in African Americans.

Burhansstipanov, Bemis, and Dignan (2002) provides a guide for culturally sensitive genetic research and education in Native Americans.

Campbell (1998) and Palmer and Tano (2004) discuss cultural views of the body and their effect on research participation.

Kaback (2001) reviews the development and success of Tay-Sachs screening programs in the Jewish community.

Lin-Fu (1998) discusses the views of Asian Americans and Pacific Islanders on genetics.

Phan, Doukas, and Fetters (1995) examine views of genetics within different religious denominations in the US.

Richards and Ponder (1996) , Catz et al (2005) , and Furr (2002) examine how different racial and ethnic groups in the US understand genetics and genetic research.

Romero et al (2001) discuss the views of Native Americans on genetics.

Rothenberg and Rutkin (1998) and Dorff (1997) discuss the response of the Jewish community to being the focus of BRCA1/2 research.

Terry and Boyd (2001) report on the partnering between a disease organization and scientists in research on PXE.

VI. Shaping the Research Agenda

A. Community Consultation and Consent

Community organizations can play important roles in shaping the objectives and design of genetic research that occurs within the groups they represent. Community organizations can work directly with geneticists seeking to conduct research in their communities. Contact with individual genetic researchers can take a number of forms. Frequently researchers contact community organizations directly for consultation or for assistance with recruiting study participants. Many research universities and hospitals also maintain contacts with various community organizations in their locales in order to gain input on community research needs and connect affiliated researchers with community members. The NIH, as well as many academic institutions and biotechnology companies, also organize a diverse array of conferences and forums aimed at establishing contacts between genetic researchers and community organizations. Some past conferences have focused on facilitating genetic research in specific racial and ethnic communities.

Community organizations can also initiate contact with genetic researchers themselves. The NIH, as well as many universities and hospitals, will often provide organizations with information about ongoing studies in a certain field and area. In some cases, community organizations have approached genetic researchers regarding specific health concerns in their community and requested research to investigate the possible genetic basis of those concerns.

In working with genetic researchers, the degree to which community organizations can affect the objectives and design of a study depends both on the level

and the quality of the contact between the researchers and the organization. In most cases, community organizations are best placed to affect research through a community consultation process. Community organizations can play either of two roles in this process. They can represent members of the community and offer feedback and collaborate with researchers on its behalf or they can facilitate public forums where researchers consult directly with community members. In community consultation researchers present a proposed study to the community, explaining the goals and methods of the study, as well as the potential benefits and risks that it poses both to individual participants and the community as a whole. Researchers then elicit feedback from the community. Depending on whether the proposed study is still in a planning stage or is finalized, feedback can provide the community the opportunity to suggest changes in the objectives and design of the study, as well as to voice concerns about potential physical or social risks. In cases where feedback is appropriate, researchers and representatives of the community may agree to collaborate in designing or conducting the study. In designing a genetic study, community organizations can often offer researchers important insights into the demographics and cultural values of a community, as well as strategies to increase the health benefits that participants and the community as a whole derive from the study. In consulting with genetic researchers community organizations ultimately cannot force researchers to address certain community concerns or make specific changes to a study. However, they can make it clear that their cooperation is dependent on such concerns and changes being adequately attended to.

Readings

Foster (1999) and Royal (1999) discuss culturally specific risks in participating in genetic research and the need for community consultation.

Indigenous Peoples Council on Biocolonialism [<http://www.ipcb.org/>] provides a document on requirements and assurances for community consultation and consent aimed at American Indians and Alaska Natives.

Little People of America, Position Statement on Genetic Discoveries in Dwarfism [http://www.lpaonline.org/resources_faq.html] discusses the concerns of little people about genetic research on dwarfism.

National Institutes of Health, Points to Consider When Planning a Genetic Study That Involves Members of Named Populations [http://bioethics.od.nih.gov/named_populations.html#consultation] provides an overview of community consultation, including how to conduct it as a researcher.

Wong et al (2004) examine community concerns over participating in genetic research.

Zmuda (2000) provides an overview of Jewish community concerns about genetic research and the need for consultation at different levels of the community.

Further Readings

Andrews (2004) and Dalton (2004) discuss the conflict between the Havasupai Tribe and the genetic researchers at Arizona State University.

Burhansstipanov et al (2005) and Anonymous (2003) provide examples of community IRBs in Native American tribes.

Chadwick (2003) discusses group consent in the context of DNA banks.

Davis (2000) provides an overview of the debate over group consent for genetic research.

Foster, Bernsten, and Carter (1998) provide examples of community consultation on genetic research in Native American tribes.

Greely (2001) and Juengst (1998) argue against the feasibility of group consent and propose the development of community consultation protocols in its place.

Knoppers, Hirtle, and Lormeau (1996) , Weijer and Emanuel (2000) , and Piquemal (2001) support the idea of group consent protocols.

Pfeferbaum (1997), Brugge and Missaghian (2002), and McDonald, Peterson, and Betts (2005) discuss the organization of tribal IRBs and health committees and their actions concerning genetic research.

Quinn (2004) discusses the functioning of community advisory boards.

B. Community-Based Participatory Research

A more involved level of community-researcher collaboration is provided by Community-Based Participatory Research (CBPR). In CBPR researchers involve community organizations from the onset in establishing research objectives and methods. Often researchers and partnering organizations survey community members regarding their health needs and design research studies that both address those needs and take

advantage of the capacities and skills of the community. Usually members of partnering organizations are trained to assist in conducting the research and providing related services to the community. While some CBPR projects incorporate genetics, they usually take a comprehensive and interdisciplinary approach towards researching a community's health. While CBPR offers community organizations a significant role in shaping research, it also requires the commitment of substantial time and resources on the part of organizations, as well as extensive cooperation between researchers, community leaders, and funding agencies. The NIH offers funding specifically for CBPR projects in defined communities, including racial and ethnic communities.

Readings

- Community-Campus Partnerships for Health, [<http://www.ccpd.info/>] presents extensive information about successful researcher-community collaborations and available opportunities for future collaborations.
- National Human Genome Center at Howard University, Community Partnership Program [http://www.genomecenter.howard.edu/units/genethics/cpp_default.htm] provides information and resources on community engagement around genetics.
- NIH, National Human Genome Research Institute, Education and Community Involvement Branch [<http://genome.gov/11008538>] provides information on education and community involvement programs.
- Ritas (2003) offers a guide to policy work for community-based participatory research practitioners.
- U.S. Dept. of Health and Human Services, Agency for Healthcare Research and Quality, Creating Partnerships, Improving Health: The Role of Community-Based Participatory Research [<http://www.ahrq.gov/research/cbprrole.htm#resources>] explores the benefits of CBPR.

Further Readings

- Brodwin (2005) reviews community involvement in population genetics research.
- Burhansstipanov et al (2005) provide examples of CBPR in Native American tribes.
- Burhansstipanov, Christopher, and Schumacher (2005) suggests a number of successful strategies for using CBPR that derive from experience with Indians.
- Cornwall and Jewkes (1995) and Fong, Braun, and Tsark (2003) provide examples of CBPR.
- Dukepoo (1998) and Foster et al (1999) provide examples of community involvement among Native American tribes.

Jackson (1997) suggests the need for increased community involvement in genetic research on African Americans.

Knottnerus (2003), Gaudet, Hudson, and Larberge (2000), and Jackson (1999) discuss different strategies for involving communities in setting research objectives.

Macaulay and Nutting (2006) strongly urge the incorporation of CBPR in practice-based research networks.

NIDDK (2002) and Wheelwright (2005) review the research collaboration between the NIDDK and the Pima Indians.

NIH, Community Participation in Research [<http://grants.nih.gov/grants/guide/pa-files/PAR-05-026.html>] provides information about program announcements and funding for CBPR.

Stidley et al (2003) , Boyer et al (2005) , and Herbert (1996) provide examples of research collaborations between tribes and geneticists.

Viswanathan et al (2004) provide an overview of the experience with CBPR.

C. Community-Funded Research

Community organizations can take an even larger role in shaping research objectives by deciding to fund research initiatives themselves. Funding research can allow organizations to tailor research directly to the needs of the community they represent, as well as ensure that studies pose the least possible risk to community members. It can be particularly helpful for organizations that represent small ethnic groups or work with rare diseases that have attracted little research funding from government or private research agencies. In funding research, organizations may choose either to directly hire a researcher with who they have an existing relationship or to publicly solicit grant proposals. However, funding research requires that an organization dedicate significant time and effort to raising money, from members or from outside sources, as well as to administering the funding it distributes. As with any funding agency, it is important that community organizations actively oversee the studies they fund to ensure that their money is being used efficiently and that research conforms to the organization's expectation. Community organizations also must determine how best to

allocate control over intellectual property rights and financial benefits deriving from the research. In the past, some organizations have been angered when researchers have patented discoveries resulting from research they supported. As a result, some community organizations have established formal protocols regarding their control over intellectual property rights deriving from research they fund. An example is PXE International, an organization that funds and advocates for research on Pseudoxanthoma elasticum (PXE), a genetic disorder that affects the body's connective tissue. PXE International mandates that it retain authorship over any papers and ownership over any patents produced by research that it funds. When researchers funded by PXE International discovered the gene causing PXE in 2000 the organization's director was listed as a co-author on the resulting article and when the gene was subsequently patented in 2004 the patent rights were assigned to the organization.

Readings

For examples of community organizations that fund medical research, see the following:

American Diabetes Association [<http://www.diabetes.org/home.jsp>]

American Heart Association [<http://www.americanheart.org/>]

Cystic Fibrosis Foundation [<http://www.cff.org/>]

Muscular Dystrophy Association [<http://www.mdausa.org/>]

National Tay-Sachs and Allied Diseases Association [<http://www.ntsad.org/>]

Susan G. Komen Breast Cancer Foundation [<http://www.komen.org/>]

Bryant and Beals (2000) present arguments for and against gene patenting, and one community organization's response to it.

Terry (2003) describes intellectual property law and biotechnology application in light of PXE International's experience.

Further Readings

Davis (2004a) overviews concerns held by racial and ethnic groups regarding gene patenting.

Dickenson (2004) , Weijer (2000) , and Knoppers (2000) review different community implemented benefit-sharing arrangements.

Greely (1996) , Friedlaender (1996) , Bhat (1996) discuss past examples where groups believed genetic material was improperly patented.

Stephenson (2001) and Zion (2001) provide examples of alternative mechanisms used by groups to retain intellectual property rights. Zion (2003) and Marks (2005) summarize concerns held by racial and ethnic groups regarding financial exploitation.

D. Community-Established Genetic Databases

Along with funding research, some community organizations have sought to shape genetic research by establishing genetic databases for specific diseases or specific racial or ethnic populations. Genetic databases consist of blood or tissue samples and corresponding personal and health information. Most organizations that have established genetic databases have collected samples from members and their families. By allowing researchers to easily analyze a large number of DNA samples in conjunction with relevant personal and health information, genetic databases can facilitate both studies searching for disease genes and studies investigating the properties of those genes. The establishment of a genetic database can allow organizations to either sell or provide free use of the database to researchers. This can provide organizations the ability to tailor research to the needs of the community. However, like funding research, the establishment of a genetic database requires organizations to oversee the studies they support, as well as come to agreements with researchers over patent rights.

Organizations must also make sure that they implement a comprehensive informed consent process that includes information about the full range of research for which the samples might be provided. In establishing a genetic database organizations also need to determine what personal and health information to collect. This may include deciding whether or not samples should list the race or ethnicity of the donor, and if so, how this label is to be determined. As the use of some types of personal information,

including race and ethnicity, may present risks to the community, organizations may want to consult with community members regarding these decisions.

Readings

Lemonick, Gibson, and Park (2006) provide an overview of the Icelandic genetic database compiled by deCODE Genetics.

PXE International [<http://www.pxe.org/>] provides an example of a blood and tissue bank created by a community organization.

The New Atlantis editorial (2005) looks at the use of DNA databases in law enforcement in terms of privacy, civil liberties, and racial profiling.

Further Readings

Eiseman (2003) overviews the policies, including those related to racial and ethnic labeling, of human tissue repositories in the US.

Fuchs (2002) and Hahn (1992) discuss potential shortcomings with self-identification.

Hahn, Truman, and Barker (1996) , Moscou et al (2003) , Hammerschmidt (1999) , and Boehmer et al (2002) summarize the different methods employed by researchers to identify race and ethnicity.

Kaufman (1999) argues that self-identification is the only acceptable method of identification.

National Bioethics Advisory Commission (1999) provides recommendations for the use of stored samples in medical research, including that on racial and ethnic groups.

National Bioethics Advisory Commission (1999) , Kaiser (2003) , and

Meslin and Quaid (2004) discuss groups concerns over the use of stored samples. Schwartz et al (2001) discuss the response of the Jewish community to the use of stored samples.

Shields et al (2005) argue for the development of genetic methods of participant identification.

E. Community-Driven National Policy on Genetics

Community organizations can also play a role in shaping the research agenda at a national level. Many organizations have joined with the NIH to shape research policies and funding on a national level. Some NIH programs that fund genetic research have advisory committees or consultative forums that include representatives of organizations from affected communities. These bodies are designed to provide organizations a voice in setting research priorities and protective guidelines. An example is the Sickle Cell

Disease Advisory Committee held by the National Heart, Lung, and Blood Institute (NHLBI) which helps set funding priorities for federally funded sickle cell disease research and includes representatives of community and patient organizations among its members. Similarly, the National Human Genome Research Institute (NHGRI) commonly invites representatives from community organizations to the meetings of its advisory committees. The NHGRI's Education and Community Involvement Branch works with the institute's various programs to organize forums through which community organizations can provide input regarding research needs and concerns. Some NIH programs also host consumer groups, which may include representatives of community organizations. An example is the National Cancer Institute (NCI)'s CARRA program, which works with representatives of cancer organizations to provide patient-level input in the development of NCI-funded studies.

A number of non-governmental advocacy coalitions also operate to affect genetic research agendas and policies on a national level. These coalitions are composed of representatives of diverse community and patient organizations involved with genetics, as well as sometimes representatives of research institutions and biotechnology companies. They work to shape federal research spending and regulations through involvement with the NIH and other government research bodies, as well as by lobbying legislators. Some coalitions, such as the Genetic Alliance, work to affect broad research objectives and policies, while others such as the National Organization of Rare Diseases (NORD) and the Sickle Cell Disease Association of America (SCDAA), target research related to specific diseases.

Readings

For examples of groups that either develop or influence genetic policy, see the following:

Communities of Color and Genetics Policy Project

[<http://www.sph.umich.edu/genpolicy/>]

Genetic Alliance [<http://www.geneticalliance.org/>]

National Organization for Rare Diseases [<http://www.rarediseases.org/>]

NIH, NCI, CARRA Program [<http://carra.cancer.gov/>]

NIH, NHLBI, Sickle Cell Disease Advisory Committee

[<http://www.nhlbi.nih.gov/meetings/scd/index.htm>]

SCDAA [<http://www.sicklecelldisease.org/>]

Cowley, Underwood, Springen, and Hager (1996) discuss the benefits and risks of genetic testing, focusing on the prospect of insurance discrimination and resulting privacy policies.

Further Readings

Garland (1999) discusses the need for partnering between experts and the general public in developing genetic policy.

Gollust et al (2005) report on community involvement in developing policies for genetic testing.

Lehrman (1997) reports on the call by Jewish leaders to establish genetic guidelines in their communities.

Schibeci et al (1999) examine the interaction between experts and communities in genetic medicine.

Terry and Boyd (2001) report on the partnering between a disease organization and scientists in research and policy on PXE.

VII. Recruitment

In working with genetic researchers, community organizations can play an important role in recruiting participants for a study. The work of community organizations can be particularly important for studies that target racial or ethnic groups where distrust of medical research is significant or for studies involving a rare disease or with highly specific eligibility criteria. How organizations can best facilitate recruitment depends on both the nature of the organization and the design of the study. In cases where an organization has members or clients that match the eligibility requirements of a study the organization may be able to simply provide those individuals with a description of the study and contact information for the researchers. In such cases an organization can also work to ensure necessary follow-up contact for both participants seeking research results and researchers seeking additional samples. Many organizations also post descriptions of ongoing studies on their websites, allowing interested users to compare studies and contact researchers on their own. Alternately, organizations can provide a link to the NIH's Clinical Trials website, which provides a searchable list of ongoing genetic studies, along with other non-genetic studies.

In cases where recruitment is required from outside of an organization's membership, an organization can organize public forums where information on the study can be presented to interested community members. Organizations can also assist researchers in designing culturally sensitive presentations or advertisements for the study as well as in reaching out to influential local political or religious institutions. In situations where community members are reluctant to participate in a study, either due to mistrust or cultural barriers, community organizations can be vital in effectively

communicating accurate information about the study and the benefits and risks it poses. For instance, in recruitment for the African American Hereditary Prostate Cancer (AAHPC) Study a variety of local African American community organizations worked with researchers to both distribute information about the study and identify eligible families. Often the simple affiliation of a respected community organization with a genetic study can significantly allay community reservations. However, organizations must be cognizant that in actively endorsing a study they may communicate to the community a belief in the likelihood of a positive outcome.

In some cases community organizations may also play important roles in conducting a genetic study. Many types of genetic research rely on ascertaining both DNA samples and personal health information from participants. Community organizations with experience providing health or patient services may be able to assist researchers in collecting samples and health information. Based on their experience with the community, they may also be able to inform researchers of the most culturally appropriate way to collect samples or request personal and health information. Where a study requires travel or a significant time commitment community organizations can also provide participants with assistance either in reaching the location of the study or in alleviating work or childcare responsibilities. This may be particularly important for studies conducted in poor or rural communities where participants may not be able to easily take time off from work or access to transportation. In communities where members speak a different language than do researchers, community organizations can also be essential in translating between participants and researchers. Translation may be necessary for both informing participants about the study and ascertaining their consent

and in terms of collecting personal and health information from participants. Effectively translating for a genetic study usually requires translators to be adequately familiar with the science related to the study as well as the specific details of the study itself.

Readings

The following are examples of community organizations that are involved in recruitment:

- FORCE [<http://www.facingourrisk.org/>]
 - Foundation Fighting Blindness [<http://www.fightblindness.org/>]
 - Genetic Alliance [<http://www.geneticalliance.org/>]
 - National Organization for Rare Disorders [<http://www.fightblindness.org/>]
 - National Tay-Sachs and Allied Diseases Association [<http://www.ntsad.org/>]
 - NCI's CARRA Program [<http://carra.cancer.gov/>]
- NIH, Clinical Trials [<http://www.clinicaltrials.gov/>] provides a searchable list of ongoing genetic studies, along with other non-genetic studies.
- NIH, National Human Genome Research Institute and Howard University, National Cooperative Study of Hereditary Prostate Cancer in African-Americans [<http://www.genome.gov/10002040>] provides information on the AAHPC Study, including who is being recruited and how.
- Royal (1999) explores the implications of racial congruence between researchers and subjects for recruitment in genetic research.

Further Readings

- Baker (1999) examines levels of distrust for medical research among different minority groups.
- Blumenthal et al (1995) and Swanson and Ward (1995) summarize strategies for recruiting members of minority groups into medical research generally.
- Duran (1998) discusses obstacles to the recruitment of Hispanics into medical research.
- Fouad et al (2000a) discuss the importance of racial/ethnic concordance for the recruitment of African Americans into medical research.
- Gamble (1997) , Fouad et al (2000b) , and Shavers, Lynch, and Burmeister (2000) examine the legacy of Tuskegee among African Americans and its effect on research participation.
- Hughes et al (2004) discuss the significance of racial/ethnic concordance in recruitment for hereditary breast cancer research.
- Kaback (2001) reviews the development and success of Tay-Sachs screening programs in the Jewish community.
- Marcer (2003) and International HapMap Consortium (2004) discuss the recruitment strategies used in the International HapMap Study.
- Powell et al (2001) and Ahaghotu et al (2004) describe and present data from the AAPHC study.

Royal et al (2000) , Hughes et al (2004) , and Patterson et al (2005) provide examples of recruitment strategies used in cancer genetics studies.

Shavers, Lynch, and Burmeister (2002) and Roberson (1994) summarize the effect of past medical experience on minority recruitment within medical research in general.

Stevens, Shi, and Cooper (2003) , Cooper-Patrick et al (1999) and Brach and Fraser (2000) examine the effect of racial/ethnic concordance in health care generally.

Williams et al (2000) provide an example of recruitment strategies used in a hypertension genetics study.

VIII. Protecting Participants

One of the most important roles that a community organization can play in genetic research is in ensuring that study participants, as well as the community as a whole, are sufficiently protected from the risks posed by such research. Community organizations can work to protect their members and the communities they represent on a number of different levels. Prior to becoming involved in a genetic study, organizations can draft guidelines to screen proposed studies to ensure that they are led by responsible researchers and provide both clear benefits and appropriate safeguards. For instance, some of the Jewish organizations that have been contacted by researchers recruiting for studies on the BRCA1/2 genes in the group have mandated strict qualifications for distributing lists of their members. Alternately, some organizations have established advisory committees made up of health care professionals and community leaders to review and select proposed studies. Screening studies is especially important for organizations that are considering making lists of members or clients available to researchers.

Once involved in a genetic study, community organizations can work to transmit community concerns to researchers. In communities with diverse views and values this may require organizations to formally sample members of the community regarding their views on genetic research. In response to these concerns, organizations can assist researchers in designing informed consent forms that sufficiently address the risks of the study. In particular, community organizations should work to ensure that informed consent includes specific descriptions of the risks of discrimination and group stigmatization. In comparison to the risks of physical harm, these risks may be

downplayed on consent forms for genetic research. In genetic studies where researchers plan to store DNA samples or use them for other studies, organizations should press to have such secondary uses clearly stated on consent forms. If community members are concerned about the misuse of genetic information gathered from DNA samples, organizations can press researchers to develop necessary protocols to maintain the confidentiality of DNA samples and associated genetic information. This may entail removing personal information, including race and ethnicity from samples. Alternately, it may mean limiting the secondary uses of samples.

Ensuring that consent is adequately obtained may also require organizations to assist researchers in drafting forms that correspond to the community's language and cultural values. This may be particularly important in communities where a majority of individuals do not speak the same language as researchers or have little exposure to science education. In working with researchers to design and implement informed consent, it is also important for community organizations to work to communicate accurate views of benefits and risks to community members.

Finally, to ensure that genetic information is protected in society at large and is not used in discriminating or stigmatizing ways, community organizations can advocate for genetic privacy legislation at national and state levels. While many states currently have some form of legal protection for genetic information, the uses that such protections extend to vary widely. Currently there exist no comprehensive federal genetic privacy regulations, although a bill entitled the Genetic Information Nondiscrimination Act has been repeatedly introduced in both the Senate and the House of Representatives. As of the end of 2006, it has yet to become law.

Readings

- Citrin (2001) suggests ways to balance benefits and risks of genetic research to protect individuals and communities, particularly communities of color.
- Common Rule, 46 C.F.R. Sec 101ff
[<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>] codifies the federal rules dealing with human experimentation.
- Lee (1999) discusses the benefits and risks of maintaining medical privacy from a clinician's perspective.
- Lemonick, Gibson, and Park (2006) provide an overview of the ongoing genetic research in Iceland by deCODE Genetics, including some of the privacy issues that have arisen.
- National Human Genome Research Institute, Informed Consent
[<http://www.genome.gov/10002332>] includes a list of websites dealing with protection for human subjects in research.
- Standards for Privacy of Identifiable Health Information, 45 C.F.R. Secs. 160 and 164
[<http://www.hhs.gov/ocr/combinedregtext.pdf>] contains the HIPPA privacy regulations.
- U.S. Dept. of Health and Human Services, Centers for Disease Control and Prevention, National Office of Public Health Genomics, Informed Consent: A Public Health Perspective [<http://www.cdc.gov/genomics/training/perspectives/infmcnst.htm>] links to further information on informed consent for population-based research involving genetics.
- U.S. Department of Health and Human Services, Office for Human Research Protections, Regulations and Policy Guidance [<http://www.hhs.gov/ohrp/>] lays out the legal protections for participants in federally funded human subjects research.

Further Readings

- Anderlik and Rothstein (2001) and Fuller et al (1999) provide reviews of recent writing and research on genetic privacy.
- Bowman (2000) discusses the specific concerns of African Americans about genetic-based discrimination.
- Davis (2004b) and Elliot and Brodwin (2002) review the issues that arise for groups when genetic research reflects on identity.
- Deschenes et al (2001) and Anderlik (2003) examine genetic privacy in regard to DNA banks.
- Freeman (1998), Grounds (1996), and Tallbear (2000) discuss varying views held by Native American tribes on genetics and genetic research.
- Hall and Rich (2000) and Peterson et al (2002) discuss the effects of this perceived risk on the use of diagnostic genetic tests.
- Hudson et al (1995) and Miller (1998) discuss the potential for genetic-based employment discrimination.
- Lapham, Kozma, and Weiss (1996) present data on the public's perceived risk of genetic-based discrimination.

Merz (2003) discusses the implications of privacy, consent, and commerce for communities in genetic research.

National Conference of State Legislatures (2006) presents a study of the ways different states treat genetic privacy.

Nelkin (2002) examines past cases of genetic stigmatization.

Richards (2003), Black (2003), Charafeddine (2003), Wertz (2003), and Leach Scully, Rippberger, and Rehmann-Sutter (2003) discuss the implications of genetic information and discrimination.

Rothstein and Anderlik (2001) review research and statements on genetic discrimination.

Strauss et al (2001) discuss the role of community advisory boards in the informed consent process.

Wang et al (2001) and Wong et al (2004) describe the concerns of specific racial and ethnic groups regarding genetic privacy.

Weijer, Goldsand, and Emanuel (1999) discuss the challenges to protecting communities in research.

Wolf (1995) and Parrott et al (2005) review the risk of group discrimination and stigmatization from genetic research.

IX. Managing New Genetic Knowledge

Findings from genetic research may present both foreseen and unforeseen challenges to racial and ethnic groups. As is discussed above, findings that link a racial or ethnic group to a disease or disorder can result in discrimination and stigmatization. However, new genetic knowledge can create more immediate challenges as well. The discovery of a gene affecting disease-susceptibility or drug-response can lead to significant uncertainty among both individuals with a gene-mutation and individuals unsure of their status. Often important information about the gene, such as the level of risk it poses or its distribution within the group, may not be immediately available or may be highly variable between studies. Furthermore, even once diagnostic tests become available for a gene there may remain only limited or controversial preventative measures available for individuals found to carry a mutated gene. Without clear information or clear preventative measures, new genetic knowledge can lead to confusion about whether individuals should get tested for or undertake certain preventive measures as well as to psychological conditions, such as anxiety, guilt, and depression. Because of the hereditary nature of most gene mutations these conditions often spread to family members.

Community organizations can play an important role in helping individuals manage new genetic knowledge. Once results from a genetic study are announced, community organizations can work to disseminate the findings among members of the community. This may take the form of public forums or distributing informational publications or advertisements. Especially as media accounts of genetic discoveries often exaggerate the conclusiveness of genetic findings, community organizations should take

care to present a comprehensive description of findings which clearly states what scientists know and what they are still unsure about. However organizations undertake educating the community, they should make an effort to continually update the community as new information about a gene or genetic condition becomes available. Often subsequent research on a gene not only expands knowledge about it, but also alters previous estimates regarding such information as the risk it conveys, its distribution within a specific group.

To help members of the community decipher and act upon genetic information some community organizations have also implemented or established relationships with genetic counseling programs. In such programs, trained genetic counselors provide individuals with information about a gene or genetic condition so that they can make informed decisions about genetic testing, potential preventative treatments, or reproduction. Most genetic counselors follow strict non-directive protocols, whereby they provide individuals with information about available diagnostic or therapeutic options but do not attempt to influence an individual's decision. Community organizations may also choose to run support groups for individuals or family members affected with a gene or genetic disorder. Support groups can be effective in both educating individuals about a gene or genetic condition and alleviating associated psychological difficulties. Some organizations have established support groups specifically for carriers of disease-susceptibility genes in recognition of the different sets of challenges faced by these individuals from individuals with a genetic disease or condition.

Readings

Begley (1998) examines how genetic knowledge, particularly about disease, changes the way we think, our perceptions of the world, and how we act as individuals and as a society.

Brandt-Rauf (2000) provides a guide to genetic testing for Ashkenazi Jewish women and discusses the social implications of new knowledge about breast cancer genetics.

Cowley, Underwood, and Check (2000) discuss the limits of genetic knowledge when genetic therapies are still years away.

Cowley, Underwood, Springen, and Hager (1996) discuss the benefits and risks of genetic testing, including the implications of their ambiguous predictive potential for individuals and their families.

Kalb (2006) presents personal stories attesting to the benefits of BRCA testing for breast cancer.

Miranda (2006) discusses the boom in personal DNA tests to trace ethnic ancestry, and how the knowledge gained may challenge one's identity.

Sapolsky (2000) discusses the social implications of genetic knowledge in light of the complex interaction between genes and environment.

The New Atlantis (2005) discusses the way genetic information can be used and abused.

Underwood (2000) examines the promises and pitfalls of genetic testing.

Further Readings

Baker (2006) explores the dilemmas raised by new genetic knowledge.

Brandt-Rauf et al (2006) provide an overview of BRCA1/2 research on Ashkenazi Jews.

Condit et al (2004) and Nelkin (2001) examine how the media communicates genetic findings about race and ethnicity to the public.

Severo (1980) and Markel (1998) discuss the cases of discrimination that occurred as a result of misinformation about sickle cell, and how these cases were viewed by the African-American community.

X. Conclusion

As scientific research uncovers the genetic basis of human disease and health, it has become increasingly important to insure that all individuals benefit equally from genetic advancements. Towards this end there is a vital need for community organizations within racial and ethnic communities to work with genetic researchers to develop genetic studies that address both the methodological needs of researchers and the health needs of the community. It is hoped that this booklet provides a framework for potential collaborations between community organizations and researchers to achieve this

goal. The information provide here is meant to provide a general survey of the different ways in which community organizations can become involved with genetic research. Ultimately, in determining when and how to become involved in genetic research, organizations must evaluate their own capabilities and expertise, as well as the needs and concerns of both the community they serve and the researchers with whom they seek to collaborate.

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