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.

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.


Further Readings


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.


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.ccph.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


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.
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


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.
Lehrman (1997) reports on the call by Jewish leaders to establish genetic guidelines in their communities.
Terry and Boyd (2001) report on the partnering between a disease organization and scientists in research and policy on PXE.