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


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


Further Readings

Anderlik and Rothstein (2001) and Fuller et al (1999) provide reviews of recent writing and research on genetic privacy.


Davis (2004b) and Elliot and Brodwin (2002) review the issues that arise for groups when genetic research reflects on identity.


Freeman (1998), Grounds (1996), and Tallbear (2000) discuss varying views held by Native American tribes on genetics and genetic research.


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


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.


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