



Public Consultation Project on Genes, Environment, and Your Health

Would you volunteer to help solve medical mysteries?

Are you and a half-million of your fellow citizens ready and willing to volunteer for a study in which health agencies would collect your DNA and other biological samples and record what you do; where you live and work; what you eat, drink, and breathe; how often you exercise; and various other life choices – to try to advance our understanding of how genes and environment contribute to disease?

That question, as well as what incentives would encourage study participation and what concerns people might have, is at the heart of the Genetics & Public Policy Center's Public Consultation Project. The two-year project aims to find out what Americans think about a proposed U.S. population-based cohort study that would be funded by the National Institutes of Health (NIH) and other federal healthcare agencies.

NIH is the federal government's premier medical research organization and was a key player in the Human Genome Project, a decade-long multinational effort that successfully deciphered the entire human DNA code. Data from the Human Genome Project was used to pinpoint places where the genetic code differs from one person to another, and has already helped researchers identify genetic risk factors for many diseases. However, many common conditions – such as heart disease, cancer, and diabetes – are believed to involve multiple genes that may interact with one another, and with the environment. One way to study these complex diseases is to set up large "biobanks" of samples and health information from volunteers that researchers can use to study the causes of diseases by following people over a long period of time. Scientists could use the information in the biobank to conduct research on how a person's genes, environment, and lifestyle interact to cause disease, which may then result in better risk predictors, treatments, and prevention.

A number of biobanks are now being set up to collect samples and data from defined populations, such as patients being treated in a particular healthcare system. However, charting the important gene-environment interactions that lead to disease in a broader range of Americans would require unprecedented amounts of data and a large number of participants that would represent the extensive diversity in our country. NIH has begun to consider just such a study, which would enroll approximately 500,000 volunteers, representing U.S. residents of all shapes, ages, sizes, and colors. Researchers would give volunteers a physical exam, record their medical histories, monitor their lifestyles and environmental exposures, take biological samples (including DNA), and track their health for a period of years or decades. The data collected would be made available to scientists for use in research of virtually every common human malady from heart disease to cancer. It would be an enormous project from every

standpoint – size, cost, technology, management, and its potential contribution to medical science.

Some countries are already setting up large national biobanks. Determining whether the United States should do the same is a complicated task. One consideration is how receptive the public would be. The Center's experience exploring similar issues with the public is one reason it was selected to manage the Public Consultation Project. The Center's previous projects, such as the genetic town hall series "Making Every Voice Count," collected public opinions on sensitive issues surrounding reproductive genetic testing. Continuing in this vein, the Center consulted citizens about the proposed large cohort study through focus groups of members of the public, community leader interviews, and a national survey. The final activity to collect public opinion and to gauge the efficacy of different methods of disseminating study information, is the set of town hall forums held in five U.S. cities. These cities represent a diverse range of Americans in terms of region, ethnicity, culture, income, urban vs. rural, age, and environmental exposures: Portland, OR; Phoenix, AZ; Kansas City, MO; Philadelphia, PA; and Jackson, MS.

Questions addressed during the Public Consultation Project include: How acceptable would a large cohort study be to the general public, and what community-specific concerns would need to be considered? What would the public expect in exchange for participation – monetary compensation, information about their own health? What are the best recruitment strategies and how might they differ between communities? What concerns exist regarding who might have access to the data in the biobank, and what level of confidentiality would volunteers require? What kind of oversight would be needed, and who should be included on an oversight committee to ensure the well-being of participants?

Before posing these questions to people, however, the Center knew it needed to be able to explain the study and supporting science in a clear and consistent way, since pre-conceived notions about genetics and its complexity make the acquisition of meaningful public opinion data a challenge. One aim of the Public Consultation Project, therefore, is to develop and evaluate educational materials. The Center prepared three videos that explain basic scientific principles and the proposed cohort study. Steps were taken to ensure a balanced presentation of the study that reveals both potential benefits and risks. A portion of one video was presented to the focus groups and will be shown at the town hall meetings to inform participants about details of the proposed project and facilitate group exploration of the issues it raises. The Center is evaluating the effectiveness of the videos, and its findings will guide development of future recruitment materials by NIH if the proposed study or similar large-cohort studies are funded.

The Center is working with a couple of partners on the project. A citizens' advisory panel, comprising a diverse group of leaders from citizens' advocacy organizations, was assembled to help identify broad issues to address during the project. The Public Forum Institute (PFI) identified community coordinators in the five locations where consultation activities are taking place. These coordinators shared the perspectives of their

communities, helped select community leaders for the Center to interview, and are recruiting participants for the town hall meetings.

Sixteen focus groups were held in the spring of 2007. In addition to a pilot focus group held in Hagerstown, MD, three focus groups were conducted in each of the five cities. The focus group format is an excellent way to elicit personal views, beliefs, and values; the informal group atmosphere encourages spontaneity and can reveal issues with greater texture than can one-on-one interviews or surveys. The focus groups revealed general and community-specific issues and concerns that a potential large-cohort study might raise. Collectively, the focus groups were diverse. However, within any particular group, attendees shared a common characteristic, such as ethnicity, age, or environmental exposure. This encouraged the exploration of issues that may be of significance to particular individuals or of local interest or concern. Focus groups featured moderators who were matched to participants' common demographic characteristic and were held in neutral locations to create an environment conducive to open, thoughtful dialogue. Center staff observed, recorded, and analyzed the focus groups for themes in order to gauge different issues' significance and determine which to revisit in future project activities.

Community leaders are one of the best sources of knowledge on the areas they serve. The Center, with assistance from PFI, identified community leaders to interview in each region. Interviews highlighted community-specific issues that otherwise might have been overlooked.

A nationwide Web-based survey evaluated themes highlighted by the focus groups and community leader interviews. The survey was administered by Knowledge Networks to a randomly-selected panel of over 4,000 U.S. residents adjusted to approximate U.S. Census demographics. Over-samples of African-Americans, Hispanics, and rural residents allowed for the collection of sufficient data to generate meaningful statistics about the views of these groups. Analysis of survey data will assess general support for the proposed large cohort study and identify issues of concern broadly and among specific communities.

Views on complex issues often are dynamic, and they can be shaped by reflection and discussion among fellow citizens and leaders. An individual's level of understanding of an issue also affects his or her views. To determine how these factors affect public opinion on the proposed large cohort study, the public town hall meetings will serve as the capstone for this project. Each town hall will engage a diverse group of approximately 200 citizens alongside scientific experts, policy decision-makers, and community leaders. With the assistance of an experienced moderator and a video generated by the Center, town hall attendees will learn about the proposed large cohort study and explore study-related issues in small groups and all together. Demographically, town halls will reflect regional U.S. census data. Polls, onsite survey data, participants' demographics, and analysis of the town hall transcripts will generate quantitative and qualitative data that could inform the design and limitations of a large-

cohort study, and reveal the effectiveness of town hall meetings as a means of public engagement on the issue.

Results from the Public Consultation Project have been delivered periodically to NIH throughout the two-year grant, and a full summary, including results of the town hall meetings, will be submitted at the Project's conclusion. The Center also will seek to publish results in peer-reviewed journals and to make results available on its Web site.

The Public Consultation Project will gauge Americans' readiness for a large-cohort study on genes, environment, and lifestyle interactions, and will provide important input into the design and conduct of such a study if and when it is launched. It also will open communication channels between NIH, other federal healthcare agencies, and the public.