Gulf grows between research practice and participant preferences in genetic studies

January 20 2011

Obtaining consent can be an opportunity for researchers to foster respectful engagement with study participants, not just mitigate legal risk. Credit: Clare McLean/University of Washington

Obtaining consent for genetic studies can be an opportunity for researchers to foster respectful engagement with participants, not merely to mitigate legal risk. This shift is proposed in a policy forum appearing tomorrow, Jan. 21, in *Science,* the journal of the American Academy for the Advancement of Science.

The authors of the article, "Research Practices and Participant Preferences: The Growing Gulf" recommend new approaches that treat participants as true stakeholders in research, who willingly take on risks

because they believe the potential benefits to society outweigh potential harms. Current practices presume that study participants don't want to hear from researchers, or that participants find general, one-time consent acceptable. However, these practices may be contrary to participants' preferences, according to their report.

The commentators are ethicists and medical researchers from the University of Washington (UW) and Group Health Research Institute in Seattle. They are: Susan Brown Trinidad and Stephanie M. Fullerton from the UW Department of Bioethics and Humanities, Evette J. Ludman and Eric B. Larson from Group Health Research Institute, Gail Jarvik, division head, UW Medical Genetics, and Wylie Burke, department chair, UW Bioethics and Humanities.

The authors point to recent national events that have increased attention on the use of biological samples in research: The Immortal Life of Henrietta Lacks, a best-selling book on the origins of the HeLa cell line; a lawsuit over the Texas Department of Health Services supplying newborn screening blood samples for research; and the settlement of the Havasupai tribe's lawsuit against the Arizona Board of Regents for unauthorized use of biospecimens. Claims of harm in these and other cases have included breach of privacy, stigmatization, and attacks against cultural beliefs.

Settlements have included financial payments, research restrictions, and sample destruction. In some cases, plaintiffs simply wanted to be asked permission.

Increased scrutiny of research practices is coming at a time when advances in genomic science depend on collecting massive amounts of data for analysis, the authors observed. To obtain large numbers of samples, improve the reliability of findings, and achieve greater efficiency, genome scientists around the world have begun pooling

biospecimens and data from previous studies. The Science commentary notes that current U.S. federal policies or laws regarding human subjects' protection or privacy of health information do not apply to studies using only coded samples and data. At the same time, other federal policies mandate data sharing and strongly encourage researchers to deposit their study data in public repositories such as the database of Genotypes and Phenotypes (dbGaP), a public access resource maintained by the National Institutes of Health.

The authors added that many disease-specific and general-purpose biorepositories have attracted many participants who have signed blanket informed consents for a broad range of potential purposes. Although a U.S. survey showed that more than 90 percent of respondents would be willing to have their samples and health data placed in a research biobank, their views on blanket consents were divided: 48 percent preferred one-time blanket consent, and 42 percent wanted the chance to re-consent for each new use of their data. Policy disagreement continues, the authors said. Some policy advisors want stronger regulations, but other s believe an opt-out model is better. In an opt-out, consent for research use of clinical samples (with personal identifiers removed) is presumed unless denied.

What's missing from research policy and practice, in many cases, is knowledge and consideration of participants' viewpoints and values, and participants' desire to be notified and to give permission for sharing of their data for other studies. Recent research at Group Health Cooperative, a non-profit Seattle health system, has offered insight into study participant views. Group Health patients enrolled in the Adult Changes in Thought (ACT) study, a long running joint UW and Group Health project on brain aging, were asked if their ACT data could be submitted to the database of Genotypes and Phenotypes (dbGaP). Telephone interviews with a sample of those who granted such permission showed that while they were willing to have their information

used in this way, this didn't mean that they had no interest in learning how and by whom the data might be used.

"What was really important to participants in the cases we mention," said Susan Brown Trinidad, research scientist in the UW Department of Bioethics and Humanities, "wasn't solely driven by the desire for control, or the chance to say no to certain kinds of studies. Rather, participants viewed being asked as an important demonstration of the researchers' respect and appreciation."

When contact with research volunteers is feasible and practical, then the extra work to re-engage them for re-use of data can be a valuable investment in science.

"Our experience with the ACT study," said Dr. Eric B. Larson, executive director of Group Health Research Institute, "showed informing subjects and seeking additional consent was worthwhile. Every time we share information and involve research subjects, we build on the trusting relationship that ultimately improves our research — and the value our research has for participants, the scientific community, and the public. Through trusting relationships, research can inform patient care, while patient participation keeps informing research."

UW bioethicist, physician, and genetic researcher Wylie Burke has served for many years as a national advisor on the legal, ethical and social implications of genomic research.

"The good news here," she said, "is that participants are interested in research and feel themselves to have an investment in the studies in which they are involved. It's up to the research establishment – scientists, policy makers and institutional review boards – to respond appropriately."

Provided by University of Washington