

Privacy Subcommittee hearing of the National Committee on Vital and Health Statistics  
Panel on Consumer Attitudes about Community Health Initiatives  
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Statement of David Kaufman

Director of Research, Genetics and Public Policy Center, Johns Hopkins University.

In many studies about the conduct of research, including work our center has done, people strongly value their privacy as well as the chance to participate in biomedical research. Broad public support for biomedical research is often balanced against concerns about maintaining the confidentiality of individuals, as well as the reputation and well being of communities involved in research. Many studies have observed that, despite ubiquitous concerns about protection of privacy, majorities would be willing to share clinical data and samples for research, provided that either the patients' permission is sought beforehand or data is de-identified to protect their privacy.

In a study we conducted about willingness to participate in a nationwide study of genes and environment, 90% of respondents were concerned about protecting their privacy. Less than half that many said that they feared that the data would be used against them. In addition to worries about discrimination or loss of insurance, concerns about maintaining privacy may be strongly related to issues of control over information about oneself and one's community. Providing individuals and communities with a sense of control over how data and research findings are communicated to the world outside the study may be as important as minimizing the harms that could accrue from studies inadvertently sharing personal information. This does not mean that communities want to or will constrain how research data is used and results are shared. Our observations suggest that if community members are given a seat at the table where decisions about the uses of research data are made, and if communities are told in advance by study leaders about data sharing plans and privacy protections, this transparency will often lead to trust and acceptance of researchers' goals. Participants and communities want to be given the opportunity to understand and assent to the research process. The respect that researchers show communities by communicating their intentions and soliciting input before they act is critical. A proactive, honest approach about the realities of a given research endeavor is critical.

For example, our work has found that large majorities of the public do not believe that researchers can absolutely guarantee the privacy of data collected for research. However, most people are willing to accept this reality and assume that research projects will act in good faith and do their utmost to protect the privacy of participants. If researchers can meet these expectations to do their best, and be explicit and transparent about protections and remaining risks, then communities and individuals are likely to assume the risks associated with participation of mainstream biomedical research.

This sort of transparency must begin, at the very latest, at the time of consent for participation. During the consent process, potential research participants should be told about the different levels of de-identification of data that are possible, the fact that studies including DNA may not be completely de-identifiable, the explicit protections offered by the study protocol, and the privacy risks that remain. In addition to providing research participants with transparent, forthright explanations of the privacy risks that they may face, consent documents should detail what data could be gathered through study protocols, whom the data could be shared with (i.e. academics, industry, government), how the data might be analyzed, and what formats the data are likely to be published in. The desire of research participants to know what risks they face up front will be satisfied, and trust, based on an honest assessment of risks and protections, may be established between researchers and those who choose to participate.

When large longitudinal or community-based studies are being designed that require acceptance from a broad range of participants, or buy-in over a long period of time, researchers may do well to engage communities in advance of recruitment and consent. Transparency about privacy risks and who data and findings are being shared with must also continue throughout the life of the study. If risks, protections, or data sharing practices change, communication in advance of such changes, before they occur is likely to be met with acceptance. When an unexpected situation such as breach of privacy occurs, the researchers should be direct, communicating as quickly as possible to let the community know what is being done.

In addition to clear communications of outlying privacy risks that accompany participation in research, the research enterprise must work to fortify the protections that it offers participants. Policies about the publication of and public access to deidentified data that include genetic sequences should be reviewed by parties that share or publish such data. Researchers should be encouraged to use certificates of confidentiality to protect participants from forced disclosure of their identities for use in civil, criminal, administrative, or legislative proceedings. The NIH should

consider adoption of a different model of certificate of confidentiality, such as the one used by researchers at the U.S. Department of Justice that does not permit the researcher discretion about whether to release study information to law-enforcement officials and instead forbids studies with certificates from all such disclosures. It may also be worthwhile to examine what practices researchers and data-access committees of biobanks and large cohort studies are using to maintain privacy, where they view vulnerabilities, and what problems they have experienced or observed in protecting subjects' privacy, because research practitioners may identify problems and potential solutions long before policy makers become aware that the problems exist.

Finally, people (and research studies) are now using social media to connect and organize themselves into new communities of shared interests, that transcend traditional geographic and socio-demographic boundaries associated with the term "community". These new forms of community have unprecedented ability to both gather and disseminate information about their interests and concerns. Large scale research needs to be increasingly mindful of keeping these new facets of community involved in discussions about privacy and the release of study information that may impact both communities and individuals.