



Advancing Research and Privacy Protections: Core Principles

The public is a vital partner in genetics research studies, and research participants deserve clear informed consent and strong protections to ensure their rights and welfare. In establishing broad data privacy protections, it is critical to avoid imposing undue restrictions on the conduct of genetics research, which is already subject to regulations that protect the rights of research participants.

ASHG Values and Aims to Protect Research Participant Privacy

Lifesaving advances in health and medicine, driven by large-scale genomic datasets and biobanks, depend on broad public research participation. Given the centrality of data to genetics and genomics, the research community is proactive in addressing privacy risks or breaches, assessing how new technological advances could identify individuals from genomic information, and helping to lead the development or revision of professional practices to protect confidentiality.

In Federally Funded Research, Genetic Data is Already Well-Protected

- The U.S. Federal Policy for the Protection of Human Subjects (45 CFR 46, also known as the Common Rule) requires informed consent and a description of how participant results are shared.
- The National Institutes of Health’s Genomic Data Sharing Policy, Certificates of Confidentiality, and Freedom of Information Act provisions in the 21st Century Cures Act protect research participant data from disclosure for non-research purposes.
- The Health Information Portability and Accountability Act (HIPAA) protects individuals against unauthorized access to clinical genetic information such as test results.
- The federal Genetic Information Nondiscrimination Act (GINA) and a variety of state privacy laws restrict access to genetic data by employers, health insurers, and others.

Consent and Privacy Are Important for Participation in Genetic Research

Which of the following factors would be included in your own decision to participate in genetic research? (Choose all that apply)

Confidentiality: knowing that your information will not be shared without your consent	66%
Privacy: knowing that your information will not be shared publicly	66%
Potential for your information to lead to an important cure or treatment for yourself or a family member	60%
Potential for your information to lead to an important cure or treatment for others	55%
Potential payment or reimbursement	48%
Confidence that your genetic information will be protected by current laws and policies	47%
Convenience of participating in the study	33%

Source: An ASHG and Research! America poll of U.S. adults conducted in partnership with Zogby Analytics in December 2019

Emerging Broader Privacy Policies Must Consider Research Needs

ASHG believes that essential privacy principles should govern genetic information acquired for publicly or privately funded research:

- Individuals should have a right to maintain the confidentiality of their own genetic information and should not be compelled to disclose it.
- Entities holding human genomic data must take robust measures to protect the confidentiality of individuals' medical and genetic information.
- The users of research participants' genetic and genomic information should assess the risks and benefits for both the participants and for society. The nature of those analyses should determine which privacy protections and data-sharing practices are appropriate.
- When establishing privacy policies and practices, it is important to consider context—when it is desirable and appropriate for genetic information to be treated the same way as other biological, health, or personal information and when there are factors that require genetic information to be treated differently from other forms of health data.
- Research policies should both facilitate data sharing and protect the confidentiality of research participants' medical and genetic data in a way that both advances research and respects participants' preferences.



ASHG is the primary professional scientific membership organization for human genetics specialists worldwide. The Society's 8,000 members include researchers, clinicians, laboratory practice professionals, genetic counselors, nurses, and others who have a special interest in the field of human genetics.