



Sharing Your Genetic and Health Information

A Decision-Making Guide



Why is data sharing important?



Imagine a world in which doctors could use information about your environment, history, and genetics to tailor treatment just for you. Every day we get closer to making this a reality, but to do this, doctors and researchers need to understand more about how changes in your genes affect your health.



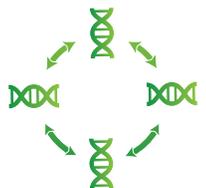
Each person's genetic code has thousands of changes from person to person - these are part of what makes us unique. We still have a lot to learn about which genetic changes cause health and developmental problems and which do not.



When a laboratory performs genetic testing and finds a change for the first time, they often know little about it. Knowing more about each person with that change provides the lab with helpful clues - do all those people have the same health problems? Or all they all totally different?



By sharing information about your general health and which genetic changes you have, you can provide doctors, laboratories, and researchers with this valuable information. This may help future patients by improving our understanding of genes and health.



Currently, laboratories share group summary-level information about genetic changes.

They can do this because this information is very general.

GENE	PARTICIPANTS	SEX	RACE/ETHNICITY	HEALTH DETAILS
BRCA1 <small>Variant R1495M</small>	5 	4 Female	2 Caucasian	4 Breast cancer
		1 Male	1 African American 2 Not specified	1 Ovarian cancer 1 Developmental Delay

In the example above, a laboratory has seen the genetic change in 5 individuals they have tested.

This summary-level information is helpful, but it would be even MORE helpful if doctors and researchers knew more specific information about each of those individuals.

As you can see, we cannot tell which of the 5 people had each of these health problems.

With your permission, the lab will also share individual-level information.

The extra level of detail provides valuable information about potential effects of the genetic change.



Now, if the same 5 individuals from the example above had given their permission to share individual details, it might look something like what is shown below. Organizing the information in this way makes it more useful.

GENE	PARTICIPANTS	SEX	AGE	RACE/ETHNICITY	HEALTH DETAILS	OTHER GENETIC CHANGES
BRCA1 <small>Variant R1495M</small>	 343Ds2	Female	50	African American	Breast cancer	No
	 574GC1	Female	35	Caucasian	Breast cancer	No
	 854GE1	Female	34	Unknown	Ovarian cancer	No
	 CF234H	Female	23	Caucasian	Breast cancer Developmental delay	Yes chr8: 103066066 -104430435 x 1 (GRCh37/hg19)
	 917HB1	Male	45	Unknown	Breast cancer	No

The characteristics of each person are now easily seen. No one is easily identifiable. It is possible to understand the ways they are similar, and the ways they are different.

Each person has similar diagnoses, but organizing the information in this way allows you to see that one person has an additional genetic change.

What are we asking your permission to share?

Do you need a consent form?
Go to www.clinicalgenome.org/share

Your privacy is important.



You may have received a one-page consent form, asking if you would like to give your lab permission to share your individual genetic and health information.



By choosing **YES**, you are giving your lab permission to share more specific, deidentified, information about your individual genetic and health information, including:

- ✓ All the information about your genes from your individual test results.
- ✓ Information about your health that your doctor provides on the test order form.



By choosing **NO**, and/or not signing, your laboratory will **NOT** share your individual information.

Laboratories will continue to share general summary information about the changes they find. They can do this because it is very generalized and contains no protected health information.

Regardless of your decision, laboratories will take all appropriate measures to protect your privacy. All personal identifying information is replaced with a unique code. They will not share:

- ⊘ Your name
- ⊘ Your date of birth
- ⊘ Your medical record number
- ⊘ Your address
- ⊘ Your doctor's name
- ⊘ Your laboratory ID numbers

Where will this information be shared?



The laboratory might share your information with two types of databases, and there are benefits to being able to share with both types.



Open-access databases

These are publicly available and display limited amounts of your information, such as reason your doctor ordered your genetic test.



Controlled-access databases:

These are not open to the general public and the information is only available to approved users. Since access is controlled, these databases may display more detailed information, such as a list of all changes found in your genes during testing.



By choosing **YES** and signing the consent form, you are giving your lab permission to share information in **BOTH** types of databases.



If you are uncomfortable or have questions, you should consider choosing **NO** and contacting your health care provider for additional information.

What are the risks and benefits?



Understanding The Risks

- The main risk associated with data sharing is that someone could identify you based on the information shared, and use this to discriminate against you in some way.
- This risk is likely very low. However, the chance that someone could identify you from your shared information can never be eliminated.
- For someone to identify you, they would already need to have access to your genetic information AND be able to associate it with your name.
- The more widely you share your genetic information, the greater the possibility of identification.
- If for any reason someone were to identify you, a Federal law, called the Genetic Information Nondiscrimination Act (GINA), has been put in place to protect you against discrimination by health insurance companies, group health plans, and most (but not all) employers.



Understanding The Benefits

- Sharing may help you, members of your family, and others with the same genetic change or disease in the future by improving understanding of genetics and health.
- If you choose, you can also benefit by having other patients and families with similar genetic changes or health issues reach out and connect with you!
- For those interested in connecting with other, consider signing up for a patient registry, such as GenomeConnect, at www.genomeconnect.org.



Want to Learn More?

Visit www.clinicalgenome.org/share to watch a short video explaining this information.

Call toll-free: 1-800-555-5555

Email: share@clinicalgenome.org

Don't forget to talk to your doctor or genetic counselor about any questions you may have.

Name of Healthcare Provider

Telephone Number



The Clinical Genome Resource (ClinGen) is a not-for-profit, National Institutes of Health (NIH)-funded resource dedicated to sharing genetic data, building knowledge and improving patient care.

www.clinicalgenome.org