# **Guide to Informed Consent Genetic Testing Language**

***For studies involving genetic testing, the language below is a guide and may be customized as needed. Please use, or provide your own language, for all applicable situations.***

For this study, your [***identify samples:*** blood, urine, tissue, etc.] will be tested for genetic changes that may relate to [insert condition]**.** The information obtained from these tests will include genetic information about you.

Genes are made up of DNA, and have the information needed to build and operate the human body. Genetic factors are inherited and run in families. Since genetic information is shared by family members, the information from these tests may apply to your family members, as well.

***If returning results to participants(verified in CLIA laboratory)***

The results will be shared with you and may/will be placed in your medical record. ***Include who will communicate the results and to whom, and/or plan for referral to a genetic counselor.***

***If returning only primary target result to participants***

Only genetic results related to [insert condition] will be reported. We will not share results that are related to other diseases or conditions, even if the result may be related to cancer, or other serious conditions.

***If returning medically relevant results to participants***

If the laboratory should identify a genetic variation that impacts your medical care, we will share the results with you.

***If not a CLIA lab:*** We will ask your physician to have the result verified in a certified laboratory. This additional testing will usually require a new sample and will be charged to your insurance.

***If returning variants of uncertain clinic significance to participants***

The results we share may or may not have clinical meaning at this time. However, the results may have meaning in the future that are not anticipated at this time.

***If returning incidental findings to participants***

The testing in some cases may reveal information not expected. ***Include information about potential incidental findings e.g.*** The DNA test may reveal private information about blood relationships.

***If returning future results to participants***

Researchers must study some samples from many people over many years before they know if the results have meaning. In the rare event that we discover something that may help you prevent or treat a serious illness, we may try to locate you and offer you the information.

***If not returning results to participants***

Most tests done on samples in research studies are only for research and have no clear meaning for health care. We will not contact you or share your individual test results with you.

***If returning only aggregate data and not individual results to participants***

Only results of a group of study participants will be returned to you. When reviewing the results for the entire group of study participants, you will not be able to easily identify yourself or any other study participant. Results for the group may not provide results that are relevant to you as an individual. You will not receive individual information even if a medically significant result is found.

***If whole genome sequencing may be done***

These tests could look at all of your genetic material. This is called whole genome sequencing. It allows researchers to see your entire genetic code.

Nearly every cell in the human body (from your skin to your blood to your saliva) contains a complete set of your DNA. This set of DNA, or operating instructions for everything from your hair color to your risk to disease, is known as your genome. Researchers will be mapping out your genome and then searching that genome for mutations (changes) or additions. These changes and additions can be inherited from your parents or can occur randomly.

You will/will not ***[Select appropriate one]*** receive a complete dataset of your genomic data***. If results are provided to participant, include information related to any costs related to interpretation, evaluation and treatment.***

***Use if, genetic data may be shared in a public database e.g. per the NIH Genomic Data Sharing Policy [modify as applicable]:***

Your genetic information may be shared in a public online database for future research. The database will not contain any information that directly identifies you, such as your name, address, or birth date, so it is unlikely that someone would know the genetic information came from you. In the future, people may develop ways to identify you or your blood relatives from this information. Currently, there is not a way to identify you without having additional information to compare to it, such as information from your DNA sample.

***The following section is required if the study is funded by the NIH and is subject to the 2014 Final NIH Genomic Data Sharing Policy. The language in this section should agree with your genomic data sharing plan and Extramural Institutional Certification submitted to NIH as per*** [***NIH Data Sharing Policy***](https://osp.od.nih.gov/wp-content/uploads/NIH_GDS_Policy.pdf).

**Why will my data be shared with the National Institutes of Health (NIH)?**

The NIH is funding this study. The NIH’s goal is to maximize the benefits that come from the research.

The hope is that sharing research data broadly will speed up the process of turning study data into knowledge, products and procedures that improve health. For example, data may be used to find out:

Who is more likely to develop a certain illness, such as asthma, cancer, or diabetes, or a condition like high blood pressure or obesity;

What genes affect the progress of a certain disease or condition; and

What genes may affect treatments which now may or may not work in certain people.

***Revise this paragraph if participants select whether their data is shared.***

By joining this study, we will share your study data, ***if applicable*:** genetic data, with the NIH. If you change your mind, tell us in writing to stop using and sharing your information. However, data that the NIH has already shared with other researchers cannot be retrieved.

The data shared will not identify you directly. The NIH will store this data for other researchers to use on any topic. These researchers could be from government, companies or academic institutions. ***Add if data will be stored in an unrestricted database:*** The study data will also be stored in a public data bank that anyone can use.

The researchers who access data must promise to keep the data confidential and to use it only for the purpose(s) approved by NIH. They must also promise to not try to re-identify anyone.

***If applicable:*** If future research is done using your data, we will not share the results with you.

***The following information must be added to the What are the Risks? Section.***

There is a risk that others could trace your data back to you or your blood relatives. The current risk of this happening is very small. The risk may grow in the future as new technologies are developed.

If this happens, someone might use this data to learn about your health or genetic heritage. This could affect your ability to get or keep some kinds of insurance. It could affect family members because certain conditions and traits run in families. Your information could become known to the public, employers, or law enforcement agencies.

The Genetic Information Nondiscrimination Act of 2008 (GINA), makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This protection does not apply to life insurance, disability insurance, or long-term care insurance.