Informed Consent and Authorization Form

I understand that my health care provider has ordered the following genetic testing for: ☐ Me ☐ My Child

Signature: _____

What is genetic testing?

Genetic testing is an analysis of a person's genetic makeup. Everyone is born with a distinct set of genes that is unique to them. These genes provide instructions for the body to grow and develop. Sometimes a person's genes may be altered during formation and could lead to a specific syndrome, disease or birth defect. Depending on the type of genetic test ordered, a genetic condition or several conditions could be detected that increase your risk of a syndrome, disease and/or defect. Your provider or a genetic counselor should inform you about these conditions for which you are being offered testing. You may also need to follow up with a genetic counselor or your provider to discuss the results after the testing.

What is the purpose of genetic testing?

The genetic test is considered a predictive test if it is performed to identify whether a patient is at an increased risk of developing a hereditary defect or disease but does not determine for certain that a defect or disease will occur. If a genetic test is being performed after a defect or disease has been diagnosed and the test confirms the cause to be in relation to the gene(s), it is considered a diagnostic or confirmatory test.

How is a genetic test performed?

Genetic tests are usually performed by either blood testing or obtaining tissue or cheek cell samples. These samples contain white blood cells that contain your DNA, RNA and important proteins. When testing during pregnancy, chorionic villus, amniotic fluid or a sample of the mother's blood can be used.

What are the limitations of genetic testing?

A genetic test may provide very important information about your health but there are limitations:

- Performing the correct test: If the provider does not have an accurate personal or family history to determine which genetic test(s) are implicated, the incorrect or incomplete test(s) may be ordered.
- Laboratory Processing: All laboratories must meet the proper requirements to process your sample and strict guidelines may be in place to ensure these requirements; however, in rare cases, problems may occur in handling the sample, which might lead to incorrect results.
- Implications of Results: The genetic test may reveal an alteration in a gene or several genes but there may be limits to what is known about each gene and the significance of the result may be uncertain. A genetic alteration or variation cannot determine whether you will actually develop a suspected condition, the timing of its development or the severity of the condition.

It is important that you discuss your genetic test result with your provider so that you can make an informed decision about your next steps.

What are the benefits of genetic testing?

There are several benefits to performing genetic testing. If a genetic variation is determined,

- There may be preventive measures or identified medical treatments that decrease your chances of developing a related genetic syndrome, disease or defect.
- The knowledge can empower a person to make important choices about life planning, even if a cure is not available at the time of testing.
- A person may qualify to enroll in a related research study, which may lead to new treatments.
- It may provide important health information for a person's family.

What are the risks of genetic testing?

There are possible risks of genetic testing:

- Although low risk, there may be a physical risk involved in obtaining the sample for testing.
- There are potential psychological and social risks of testing because they can change a person's life perspective. It may be stressful and there may be an emotional reaction to learning about risks for yourself or your family. This is why it is important to discuss the testing with your provider or a Genetic Counselor before testing.
- There are possible economic risks of genetic testing that may interfere with a patient's ability to obtain health, life, disability or long-term care insurance.
- The genetic test results will become a part of your medical record. If a genetic test is performed, your insurance company may have access to the result.
- There are both state and federal laws that were developed to help protect a person from genetic discrimination, which is the misuse of genetic information. GINA is the Genetic Information Nondiscrimination Act of 2008 and is a federal law that protects individuals from genetic discrimination in health insurance and employment.

What can I learn from my genetic test result?

Results can be classified as negative or positive.

- A negative or "normal" result means the test did not detect a variation or change in the gene(s) tested. This may have limitations in that all genes related to a particular condition may not have been tested. Therefore, a negative test does not always rule out the development of a problematic genetic condition. Also, technology improves every year and there may be new discoveries that are associated with a particular genetic condition that was unknown at the time of testing.
- A positive or "abnormal" result means that you have a genetic change or variation that is related to the development of a specific genetic condition that may put you at an increased risk. However, not all gene variations lead to symptoms or the development of the genetic condition.
- An inconclusive result means that it may fall between a "normal" or "abnormal" range or be "indeterminate." In such cases, this may be labeled as a VUS or *variant of unknown significance*. Even though a change in the gene may be detected, the laboratory may not have enough information to determine if the gene places a person at an increased risk. Laboratories may learn more about that variant in the future and be able to make a more definitive decision about the significance of the gene variation.
- In rare cases, a genetic test may reveal an important genetic variation that is not directly related to the reason a provider ordered the test. These results are called secondary or incidental findings. Examples may include:
  - Non-paternity: The person designated as the father is not the biological father of the person having testing.
  - Consanguinity: The biological parents are closely related by blood.
  - Identification of a condition unrelated to the reason for testing

Result interpretation is based on current and available information present in medical literature, research and scientific databases. Because these resources are constantly changing, new information that becomes available in the future may replace or add to the information myGenomics used to interpret a person's test results. MyGenomics does not routinely re-analyze test results that have already been issued and has no obligation to do so. A person may monitor publicly available resources such as ClinVar (www.clinvar.com) to learn about current information about the clinical interpretation of a genetic test.

What happens to my sample after testing?

DNA samples are not returned to a person after the test has resulted. De-identified samples and de-identified test results may be stored in a repository and used for internal validation, educational, research purposes including HIPAA-compliant databases or presented in scientific presentations or papers.

Research with de-identified samples and test data that results in medical advances may have potential commercial value and may be developed and owned by myGenomics or the researchers who analyze the data. If any individual or corporation benefits financially from studying a person's de-identified genetic material, no compensation will be provided to the person or person's heirs.

MyGenomics has no obligation to retain a person's sample indefinitely and may destroy it once it no longer has a legal duty to retain it. By consenting to this agreement, I provide authorization for myGenomics and its partners to use my or my child's de-identified sample and test results for such purposes as mentioned above.

Unless opted out on the first page of the requisition, myGenomics may contact me in the future regarding the opportunity to participate in research opportunities, including any available treatment for myself and/or my family.