Cleveland Clinic
Laboratories

CLEVELAND CLINIC LABORATORIES
REFERENCE LABORATORY
INFORMED CONSENT FOR GENETIC TESTING

Patient Last Name:_____ **Patient First Name:**_____

Date of Birth: ____/____/____ **Gender:** ☐ **Male** ☐ **Female**

I request genetic testing for the following condition(s) or clinical indications:_____

_____

The intended purpose is: ☐ **Carrier** ☐ **Prenatal** ☐ **Diagnostic** ☐ **Predictive** ☐ **Prognostic/Therapeutic**

Sample type: ☐ **Blood** ☐ **Skin** ☐ **Cheek swab** ☐ **Tissue block**

☐ **Amniotic Fluid** ☐ **Chorionic villi (placenta sample)** **Other**_____

I request the following test(s) be performed: _____

_____

1. I understand that the biological specimen identified above as the "sample type" will be obtained from me/my child (the "Specimen"). I request and authorize Cleveland Clinic Laboratories ("CCL") to test the Specimen for the genetic condition(s) stated above. By signing below, I acknowledge that the benefits, risks, limitations, and alternatives of this testing have been explained to me by a qualified health professional.

2. I understand that the purpose of this genetic testing is to attempt to determine if I/my child is affected with, is a carrier of, or is at risk of developing the genetic disease or condition listed above. I understand that genetic test results may confirm my/my child's clinical diagnosis, carrier status or future risks of developing this disease or condition. The results may also identify a condition not suspected clinically. The genetic test results may also predict whether another member of my family has, is a carrier of, or is at risk of developing this disease or condition.

3. In many cases, a genetic test detects an inherited abnormality. An inherited abnormality is one that is passed from parent to child. One type of genetic testing called molecular testing may detect a change in the DNA. DNA acts as the building blocks for genes and genes carry the blueprints for inherited traits. Another form of testing called cytogenetic testing may identify extra, missing or rearranged genetic material.

4. I understand that it is possible for genetic testing to reveal unexpected information, such as a genetic disease or condition that I/my child might have that was unknown to me prior to the genetic testing. Genetic test results may also detect unknown information about family relationships such as adoption or parentage**.** It may be necessary to share this kind of unexpected information with me if the results could directly affect my/my child's medical care.

5. The meaning of a positive and a negative test result has been explained to me. A positive result usually means that I/my child has or may be at risk for the disease or condition; however further testing may be required to confirm the diagnosis. I understand that it is possible for test results to be negative even if I/my child has this genetic disease or condition. The chance of this happening depends on the medical and family history, the gene(s) being tested and the type of genetic test.

6. I also understand that the genetic test results may be unclear or difficult to interpret. This may be due to current understanding of the genetic disorder or condition and/or technical limitations of the test.

7. I understand that there is a chance of error, even though the genetic test is considered to be the most clinically appropriate at this time. Causes of error may include clinical misdiagnosis of the condition or inaccurate

information regarding medical and family history, among others. An error in diagnosis may occur if I do not accurately disclose biological relationships of my family.

8. I understand that genetic counseling is recommended before and after genetic testing. My health care provider can provide genetic counseling or refer me to another provider for genetic counseling.

9. Because genetic testing is complex and the test results are important for my medical care, my results will be reported directly to my doctor or genetic counselor so that he or she can explain them to me. Genetic test results are confidential. They will only be released with my written consent or as permitted or required by law.

10. I understand that genetic test results may impact my ability to obtain disability, long term care or life insurance for myself/my child. These results may also impact health insurance rates and/or the ability to find employment if not otherwise protected by law. It is my responsibility to consider the potential impact of the genetic test results *before* having genetic testing. There is a federal law that addresses genetic information, called the Genetic Information Nondiscrimination Act of 2008. More information about this law is available at http://www.genome.gov/10002328.

11. I will be responsible for payment for genetic testing if I/my child does not have insurance coverage for the test. It is my responsibility to confirm that my/my child's insurance plan covers the genetic testing *before* having the test performed.

12. CCL cannot guarantee that my/my child's Specimen will be available for future clinical testing. After personal information is removed, the Specimen may be stored indefinitely to be used for quality assurance or medical education, or research if a special review process required by medical research and privacy laws is completed..

13. My participation in this genetic testing is completely voluntary.

14. I understand that the alternative to having this genetic testing performed is not having the genetic testing performed and to be treated without the added knowledge of the genetic test results.

My signature below acknowledges my voluntary participation in this genetic testing. I understand that the genetic testing performed by CCL is not intended to identify all genetic conditions that I/my child may have. This genetic testing in no way guarantees my/my child's health, the health of an unborn child, or the health of other family members.

Patient Signature or Patient's Personal Representative Signature	Printed Patient Name	Signature Date	Time

Witness Signature	Printed Witness Name	Signature Date	Time

Physician or Genetic Counselor Statement: I have explained the risks, benefits, limitations, and alternatives of genetic testing to this individual. I have addressed the limitations outlined above, and I have answered this person's questions to the best of my ability.

Physician/Counselor Signature	Printed Name	Signature Date	Time