



### Informed Consent for DNA Testing

I, \_\_\_\_\_, hereby agree to participate in testing for (name of disease) \_\_\_\_\_, using a DNA-based test. I understand that samples of blood will be drawn from me and/or members of my family by removing blood from a vein, a procedure which carries very little risk. In addition, if prenatal diagnosis is involved, fetal cells obtained by amniocentesis or chorion villus sampling will be used. I understand that the blood and fetal samples will be used for the purpose of attempting to determine if I and members of my family are carriers of the disease gene, or are affected with, or at increased risk to someday be affected with this genetic disease/condition. In addition, I hereby give permission to collect blood samples from my minor children, named below, to be used for DNA testing for the disease listed above.

Child's Name: \_\_\_\_\_ Date of Birth: \_\_\_\_\_ Sex: \_\_\_\_\_

I have discussed the limitations, benefits and the risks of this testing with a physician/genetic counselor, and I have had my questions answered. I understand the following:

1. While DNA testing is a valuable diagnostic tool, it may not always give a definite answer about the genetic status of an individual. Current testing methods may not detect all gene alterations. Rare variants may be identified with uncertain clinical significance.
2. This DNA test is specific *only for the condition listed above*.
3. While mutation analysis often gives precise information, there are several possible sources of error. These include but are not limited to: clinical misdiagnosis of the condition, sample misidentification, incorrect paternity identification and sample contamination. I understand that the DNA analysis performed at Transgenomic for this disease is specific only with respect to it and in no way guarantees my health, my child's health or the health of my unborn child. Accuracy of DNA analysis is dependent upon clinical diagnosis made by referring physician.
4. The test is complex and is not FDA approved. It uses some reagents produced for research purposes only. There is always a possibility that a diagnostic error may occur. In addition, the laboratory may have difficulties analyzing my sample and a second sample may be requested.
5. DNA testing may involve emotional distress and may result in insurance, employment or social discrimination. The results of this testing will be treated in the standard manner to ensure medical confidentiality. The laboratory is obligated to release test results to my insurance provider if the provider asks for them in order to pay for the test.
6. After the DNA testing of my sample is completed, the DNA may be used anonymously for medical research. **Please check here YES\_\_\_\_\_ NO\_\_\_\_\_** Refusal to permit use of my sample for research will not affect this test procedure. I am free to withdraw this consent at any time without prejudice to future care. I can withdraw my consent by calling the laboratory director. Any results of anonymous research testing will not be individually reported.
7. I understand that my sample is not being banked. The laboratory does not return DNA samples to individuals or physicians. However, in some cases it may be possible for the laboratory to reanalyze my remaining DNA upon request. The request for additional studies must be ordered by my referring physician/counselor and there will be an additional fee.
8. **I understand there will be a fee for this DNA testing in the amount of \_\_\_\_\_ . I will be responsible for the cost of testing.**
9. Because of the complexity of DNA based testing and the important implications of the test results, results will be reported by me only through a physician or genetic counselor that I designate. The result reports are confidential; they will only be released to other medical professionals or other parties with my written consent. All laboratory data is confidential and will not be released within legal limits. Participation in DNA testing is completely voluntary.
10. I can decide not to receive the results of the test, but I will still be responsible for the cost of the test.

Signature of patient, parent or legal guardian: \_\_\_\_\_ Date: \_\_\_\_\_

Physician's/Genetic Counselor's Statement: I have explained DNA testing to this individual. I have addressed the limitations, risks and benefits outlined above, and I have answered this person's questions.

Signature of professional obtaining consent: \_\_\_\_\_ Date: \_\_\_\_\_