BAYLOR DNA DIAGNOSTIC LABORATORY

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.. 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 understand that:

1 In some cases the DNA test directly detects an abnormality, called a mutation, in the gene, and the test is >99% accurate. In other cases, an indirect method called linkage analysis is used. If linkage analysis is being used, naturally occurring rearrangements in the DNA (recombination) may produce an uncertainty in predicting carrier status of diagnosis. Rare variations in the DNA of individuals can also cause uncertainty in predicting carrier status of diagnosis. Thus, the test is not 100% accurate, and the results will be reported as a probability.

2 In some families, the markers may not be informative. If this is the case, this DNA test can not provide results for that family, or for some members of that family.

3 An error in the diagnosis may occur if the true biological relationships of the family members involved in this study are not as I have stated. For example, non-paternity means that the father of an individual is not the person stated to be the father. This test may detect non-paternity, and it may be necessary to report this finding to the individual who requested testing.

4 Any erroneous diagnosis in a family member can lead to an incorrect diagnosis for other related individuals in question. I understand that the DNA analysis performed at Baylor College of Medicine for this disease is specific only with respect to it and in no way guarantees my health or the health of my unborn child. The accuracy of DNA analysis is entirely dependent on the clinical diagnosis made elsewhere, and Baylor College of Medicine cannot be responsible for erroneous clinical diagnosis made at other centers.

5 In order to perform accurate prenatal diagnosis, blood samples are required from the affected individual in the family, both parents of the fetus and possibly from other members. We request the submission of both a direct and a cultured fetal specimen (amniotic fluid or CVS) or two sets of primary cultures for each prenatal study. All fetal studies will be performed twice, ideally on direct first and then on culture to confirm. The final report for a fetal analysis will be sent only after the confirmation study is complete.

6 Generally, these tests are relatively new and are being improved and expanded continuously. The tests are not considered research, but are considered to be the best and newest laboratory service which can be offered. This testing is often complex and utilizes specialized materials so that there is always some small possibility that the test will not work properly or that an error will occur. There is a low error rate (perhaps 1 in 1000 samples) even in the laboratories. My signature below acknowledges my voluntary participation in this test, but in no way releases the laboratory and staff from their professional and ethical responsibility to me.

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.

8a Once my test result is completed, an aliquot of my DNA may be made anonymous (name and all other identifiers removed) and used for research purposes. Any results obtained could not be related to the original source, so no results would be reported.

8b I indicate my desire to opt out of participation in anonymized research studies using my DNA sample by checking this box. ☐

9 Because of the complexity of DNA based testing and the important implications of the test results, results will be reported to me only through a physician or genetic counselor whom 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 limit. Participation in DNA testing is completely voluntary.

10 I will receive a copy of this consent form.

Signature: _____

Witnessed by: _____

Date: _____

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

Signature _____ Date_____