SaintFrancis Health System Center for Genetic Testing at Saint Francis

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INFORMED CONSENT FOR GENETIC TESTING

411-005 / 03-06

PATIENT NAME IN FULL	☐ M ☐ F	AGE	DATE OF BIRTH

I, the above named patient, hereby request DNA or genetic testing for NAME OF DISEASE ______________________

I understand the specifics of the DNA testing as presented in the accompanying disease-specific information sheet. I understand that samples of blood will be obtained from me and/or members of my family by removing blood from a vein or by collecting buccal cells from the interior of the cheek using several swabs; procedures that carry very little risk. In addition, if prenatal diagnosis is involved, fetal cells obtained by amniocentesis or chorion villus sampling will be used. I understand these samples will be used for the purpose of attempting to determine if I and/or members of my family are carriers of a disease gene, or are at increased or decreased risk of being affected by this genetic disease. In addition I give permission to collect samples from my minor child.

MINOR CHILD - *NAME*	☐ M ☐ F	DATE OF BIRTH

I understand that :

- DNA is a chemical that encodes hereditary information in groupings called genes. Genes come in pairs, one from our mother and one from our father. DNA testing focuses on one or a few selected genes.
- A variety of alterations including symptom causing mutations and polymorphisms can be used to determine the risk of an individual having symptoms of a disease. The efficiency of detecting DNA alterations vary by the type of alteration and by the specific gene being tested. As a result there is a chance I may have this condition but the DNA test will not detect an alteration.
- DNA alterations may also be expressed differently resulting in a range of symptoms from none to severe.
- In some tests biological relationships are very important to the correct interpretation of risk; therefore, incorrectly reported relationships may invalidate the results. Also, in some cases, the testing may detect non-paternity.
- DNA tests are relatively new and are being improved and expanded continuously to provide the best and newest laboratory services available. The testing is often complex and utilizes specialized materials so that there is always a small possibility that the test will not work properly and an error occurs. A low error rate occurs in any laboratory despite the special precautions designed to prevent and detect them.
- My sample will not be stored indefinitely or banked and 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.
- DNA testing is very specific and only the testing requested will be performed on my DNA. My DNA may be destroyed 60 days following the completion and reporting of the results. However, any remaining sample may be used for quality control purposes or research after de-identification.
- DNA testing is designed to improve the accuracy of diagnosis, refine treatment options, contribute to family planning, provide closure or a sense of relief and decreased anxiety. However, in some people the results may increase anxiety or contribute to depression.
- The results are confidential. They will be released only to my referring physician or genetic counselor. They will only be released to other medical professionals or other parties with my written consent. However my insurance carrier may receive information about my DNA testing if it is paying for the testing.
- Participation in DNA testing is completely voluntary.
- I will receive a copy of this consent form.

PATIENT - SIGNATURE	DATE	TIME
WITNESS - SIGNATURE	DATE	
PERSON AUTHORIZED to SIGN FOR PATIENT - SIGNATURE	RELATIONSHIP TO PATIENT	
REASON PATIENT UNABLE TO SIGN		

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

PHYSICIAN / COUNSELOR -*PRINT NAME*	PHYSICIAN / COUNSELOR -*SIGNATURE*	DATE

TRANSLATION - This is to certify that the above Consent has been read to the patient (or representative) in his/her native language; all representations which appear in the Consent were understood and authorized by the patient (or representative).

PATIENT LABEL

INTERPRETER - SIGNATURE