GENETICS CENTER

INFORMED CONSENT FOR MOLECULAR TESTING

I, _____, hereby authorize samples of blood or other specimens to be collected from me and/or members of my family in order to participate in testing for (name of disease) _____, using a molecular (such as DNA) test. In addition, if prenatal diagnosis is involved, I authorize fetal cells obtained by amniocentesis, chorionic villus sampling (CVS), cord blood, etc. to be used. I hereby give permission to collect blood samples from my minor children, named below, to be used for molecular testing for the disease listed above.

Child's Name	Date of Birth	Sex
_____	_____	_____
_____	_____	_____

I understand that:

1. The blood and fetal samples will be used for the purpose of attempting to determine if I or 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.
2. In some cases, the DNA test directly detects an abnormality (called a mutation) in the gene, and the test is about 99% accurate for the mutation examined. When a molecular test does not show the most common disease-causing mutations(s), there is still a small possibility that the tested person is carrying the disease gene since not all potential disease-causing changes within the gene are examined in the current test. 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 or diagnosis. Thus, the test is not 100% accurate, and the results will be reported as a probability.
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, nonpaternity means that the father of an individual is not the person stated to be the father. This test may detect nonpaternity, 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 Genetics Center for this disease is specific only with respect to it. It 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, and Genetics Center cannot be responsible for erroneous clinical diagnosis made by others.
5. In order to perform accurate prenatal diagnosis, blood samples may be required from the affected individual in the family, both parents of the fetus, and possibly from other family members. We request the submission of both a direct and a cultured fetal specimen (amniotic fluid or CVS) 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. This is a time consuming process and may take weeks prior to achieving results. Sometimes a definite diagnosis could not be made, and the results could be non-conclusive.
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 one of the newest laboratory services. This testing is often complex and utilizes specialized methods and materials, so there is always some small possibility that the test will not work properly or that an error will occur.
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 (if available) upon request. The request for additional studies must be ordered by my referring physician/counselor, and there will be an additional fee.
8. Once my test result is completed an aliquot of my DNA may be made anonymous (name and all other identifiers removed) and used for diagnosis, quality control, genetic testing, or research purposes. Any results obtained could not be related to the original source, so no results would be reported. Please initial here _____ if you wish to refuse this request. This refusal will in no way affect the present testing(s).

9. Participation in molecular testing is completely voluntary, and the results are confidential. Because of the complexity of DNA based testing and the important implications of the test, upon request, the results will be reported to me only through my physician, genetic counselor, or other health care specialist whom I designated. The results 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 from the laboratory.
10. For Array CGH Testing Only: As a member of the International Standards for Cytogenomic Arrays (ISCA) Consortium, Genetics Center intends to provide de-identified, HIPAA-compliant test results to the National Institute of Health (NIH) database. This is part of the effort to improve diagnostic testing and our understanding of the relationships between genetic changes and clinical symptoms. Even though the confidentiality of each sample is maintained, patients may still opt-out of participation in the NIH database by contacting the Genetics Center by telephone at (714) 288-3500.
11. My signature below acknowledges that my doctor, genetic counselor, or other health care specialist has explained the limitations and benefits of molecular testing to me and that I give my consent for testing.

Signature: _____ Date: _____

Witnessed By: _____

BILLING/INSURANCE INFORMATION

(Attach copy of insurance card front and back)

☐ Hospital/Institution ☐ HMO/PPO ☐ Patient/Insurance ☐ Medicare ☐ Payment Enclosed

Insurance Co. _____

Billing Address _____

City, State, Zip _____

California HMO Medical Group Name _____

Name of Insured _____

Test Preauthorization no. _____

Relationship to Patient: ◯ Self ◯ Spouse ◯ Child ◯ Other

Insured's Employer _____

Policy no. _____ Group no. _____

I hereby authorize Genetics Center to furnish my designated insurance carrier such information concerning my laboratory tests that is necessary for reimbursement. I also authorize benefits to be paid directly to Genetics Center. I understand that my insurance coverage is a contract between me and my insurance carrier, and I am responsible for any amount not paid by my insurance (including co-pays, unmet deductibles, lack of coverage, etc). The charges for these services are ultimately my responsibility. I permit a copy of this authorization to be used in place of the original.

Parent (or Guardian) Signature: _____ Date: _____