



**Referring Physician Consent Form for
GENETIC TESTING FOR HUNTINGTON DISEASE**

The Huntington Disease Society of America (HDSA) and the American Academy of Neurology (AAN) have developed recommendations and guidelines regarding pretest genetic counseling for any patient considering genetic testing for Huntington disease.

Topics that are recommended to be discussed and considered prior to electing this testing, and are not limited to:

- Coping strategies and support network when results are reported.
- Reliability of test results.
- The effects a positive or negative result would have on the patient and/or their family members.
- Life and health insurance coverage.

I am familiar with the practice guidelines of the Huntington Disease Society of America (HDSA) and the American Academy of Neurology (AAN) and have discussed the benefits, limitations and ramifications of Huntington disease testing with my patient and have received patient consent to order this testing.

Patient Name: _____ DOB: _____

PURPOSE OF TESTING (please choose only one):

Patient is symptomatic Patient has no symptoms, has a positive family history.

I also confirm this patient is 18 years or older.

Physician Name: _____ Date: _____

Physician Signature _____

Physician Telephone: _____ Physician Fax: _____

***Please fax this document back to 714-288-3510.
Test results will not be released without this documentation.***

INFORMED CONSENT FOR HUNTINGTON DISEASE MOLECULAR TESTING

I, _____, hereby authorize samples of blood or other specimen types to be collected from me for diagnostic genetic testing for Huntington disease, using a molecular (DNA) test.

Purpose of Testing (please choose only one):

- I am symptomatic and would like to confirm a diagnosis of Huntington disease.
- I have no current symptoms, but have a positive family history and would like predictive genetic testing for Huntington disease.

I confirm that I am 18 years or older _____ (initials).

I understand that:

1. The blood and/or saliva sample I am providing will be used for the purpose of attempting to determine if I am affected with, or at increased risk to someday become affected with, Huntington disease.
2. Huntington disease is a progressive neurological condition, and I am aware that there are available support networks for me if my test result is positive.
3. Knowledge of a positive or negative Huntington disease test result may have clinical or reproductive implications for myself and/or my family members.
4. As Huntington disease is considered a progressive condition, knowledge of this diagnosis may have an impact on my life and health insurance coverage.
5. I am aware that the US Genetic Information Nondiscrimination Act (GINA) of 2008 (Public Law 110-233) prohibits discrimination on the basis of genetic information with respect to health insurance and employment. However, GINA does not apply to life insurance, disability insurance, or long-term care insurance, which may be governed by state law. (For information on GINA, visit <http://www.genome.gov/10002328>).
6. 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 mutation(s), there is still a small possibility that the tested person is carrying an abnormality in the gene tested, as not all potential disease-causing changes within the gene are examined in this specific test. Only final test results will be provided.
7. 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.
8. 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 Huntington disease is specific only with respect to it. A negative result in no way guarantees my health. 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.
9. Generally, genetic testing is complex and are being improved and expanded on continuously. This test is not considered research, but is considered to be diagnostic. Genetic 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.
10. 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.

11. 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, 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).
12. 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 in person. The results will only be released to other medical professionals or other parties with my written consent. Genetics Center is fully in compliance with all Health Insurance Portability and Accountability Act (HIPAA) and other relevant regulations.
13. My signature below acknowledges that my doctor or genetic counselor has explained the limitations and benefits of Huntington disease molecular testing to me. I also understand the clinical and medical implications of a diagnosis of Huntington disease, as well as my personal risk to have the condition and the potential test results. I voluntarily give my consent for Huntington disease testing.

Patient Signature: _____
Witnessed by: _____
Date: _____

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 my insurance carrier and me, 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.

Patient (or Guardian) Signature X _____ **Date** _____