

INFORMED CONSENT FOR GENETIC TESTING

**PRESYMPTOMATIC HUNTINGTON DISEASE TESTING** 411-004 / 03-06

PATIENT NAME IN FULL	<input type="checkbox"/> M <input type="checkbox"/> F	AGE	DATE OF BIRTH
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I, the above named patient, hereby request DNA or genetic testing for Huntington Disease (HD). 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 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. For this presymptomatic testing I have undergone extensive genetic counseling discussing the genetics, the presymptomatic protocol, confidentiality risks and insurance risks of undergoing testing. I have also received an examination for depression risks from a psychologist.

I understand that :

- I am at risk for Huntington disease because there is history of this condition in my family.
- 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.
- The variation of CAG repeats can be used to determine the risk of an individual having symptoms of a disease. The testing is highly efficient but there is a 1% chance or less that I may have this condition but the DNA test will not detect an alteration.
- In the affected range (40 CAG repeats and more) the condition may be expressed differently resulting in different ages of onset and different initial presentations.
- 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 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.
- 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.
- 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
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**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 \_\_\_\_\_