

**HUNTINGTON DISEASE (HD) CONSENT FORM**

Patient Last Name \_\_\_\_\_ Patient First Name \_\_\_\_\_ MI \_\_\_\_\_ Date of Birth (MM/DD/YYYY) \_\_\_\_\_

**INDICATION FORM**

CHECK EITHER I or II: Please mark the appropriate indication and complete clinical data.

I **SYMPTOMATIC PATIENT FOR CONFIRMATION OF A CLINICAL DIAGNOSIS OF HD OR CLINICAL SUSPICION OF HD**

Is this individual under 18 years of age?

YES  NO

(If YES, parent/legal guardian MUST sign consent form on page 2)

Is there a confirmed family history of HD?

YES  NO

If YES, what were the DNA results? \_\_\_\_\_

Is there a suspected family history of HD?

YES  NO

Age of onset of movement disorder in this individual? \_\_\_\_\_

Are there any behavioral/psychiatric problems?

YES  NO Age Onset: \_\_\_\_\_

If YES, specify: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Is there cognitive decline or dementia?

YES  NO Age Onset: \_\_\_\_\_

*NOTE: We recommend that genetic and psychological counseling be made available to all patients considering having confirmatory testing for HD, and particularly for those symptomatic individuals who are having difficulty accepting or who are denying their diagnosis, or those who have or have had psychiatric problems. We require that a copy of the HD Informed Consent form signed by the parent (see page 2) be sent along with samples for symptomatic individuals under 18 years of age.*

II **ASYMPTOMATIC PATIENT AT LEAST 18 YEARS OF AGE FOR PRESYMPTOMATIC TESTING FOR HD**

*Available only to individuals at 50% risk and who are 18 years or older.  
NOTE: Asymptomatic patients requesting Presymptomatic Testing for HD MUST sign consent form on page 2.*

Has an affected family member had DNA testing for the HD mutation?

YES  NO

DNA testing result(s) for affected family member(s):  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Relative's Name \_\_\_\_\_

Relationship of Relative to Current Patient \_\_\_\_\_ DOB (MM / DD / YYYY) \_\_\_\_\_

Proband testing location (Select one)

BAYLOR GENETICS Lab # \_\_\_\_\_ Family # \_\_\_\_\_

ANOTHER LABORATORY  
(Attach a copy of the Proband test results, if available)

*NOTE: For individuals who are not symptomatic and have a family history of HD, we strongly recommend referral to a center that has a written protocol for HD predictive testing. We require that a copy of the signed HD Informed Consent form (see page 2) be sent along with the sample. We also recommend testing an affected family member first to confirm the diagnosis.*

*NOTE: Results cannot be released without this completed/signed indications form.*

Physician/Counselor Signature: \_\_\_\_\_ Phone \_\_\_\_\_ Fax \_\_\_\_\_ Date (MM / DD / YYYY) \_\_\_\_\_

CONSENT FORM ON NEXT PAGE

**HUNTINGTON DISEASE (HD) CONSENT FORM**

\_\_\_\_\_  
Patient Last Name    Patient First Name    MI    / / \_\_\_\_\_  
Date of Birth (MM/DD/YYYY)

**INFORMED CONSENT FORM**

I would either like to participate in predictive testing for OR I am the parent/legal guardian of a symptomatic individual under 18 years of age who would like to participate in testing for the presence of the Huntington disease gene. I understand that the gene for HD has been found and is located on chromosome 4. It has been described as being a trinucleotide (CAG) repeat expansion. It is the size of this trinucleotide CAG repeat which determines whether or not HD will be expressed. The blood test will determine the size of this trinucleotide CAG repeat.

I. I understand there can be four outcomes to the test:

- 1. **NEGATIVE:** The CAG repeat size is in the normal range (26 repeats or less). This individual is not at risk for developing HD, and not at risk for passing it on to his/her offspring.
- 2. **INTERMEDIATE:** The CAG repeat size is 27 - 35 repeats. This individual is not at risk for developing HD but his/her children could be at risk.
- 3. **REDUCED PENETRANCE:** The CAG repeat size is 36 - 39 repeats. It is unclear whether this individual will or will not develop HD at some point in his/her life. His/her children could be at risk.
- 4. **POSITIVE (FULL PENETRANCE):** The CAG repeat size is expanded into the HD range (40 repeats and larger). This individual will develop HD at some point in his/her life. Neurological examination is needed to establish the onset of symptoms.

II. I understand that a positive test cannot tell me when I will begin showing signs of HD. I understand that the diagnosis of HD can only be made through a neurological exam.

III. The risks of such testing are primarily of a psychological nature. An inconclusive outcome can be frustrating and intensify the ambiguity of the risk situation or can provide relief. A negative result can produce feelings of guilt as well as of joy. A positive result, i.e. the HD gene is present, could lead to serious psychological consequences including feelings of depression, futility, despair, and severe stress. Test results may also reveal that other family members may be affected or at risk for developing HD, or that familial relationships are not as anticipated. The counselor has discussed with me the possible risks of difficulty with employment, insurance, and confidentiality.

IV. In view of the psychological risks, current standard of care is that HD testing be performed for confirmation of diagnosis in symptomatic patients or for non-symptomatic adults who have undergone appropriate counseling. HD testing is not considered appropriate for non-symptomatic minors.

V. I understand that all information will be held strictly confidential. The results of the testing will be sent from the lab to my provider and disclosed only to me and to no one else without my written consent.

VI. I have been given the opportunity to discuss pertinent aspects of the testing program, to ask questions, and hereby consent to presymptomatic testing for HD, or to HD testing for a symptomatic minor.

VII. I may give consent to allow the sample to be used for test validation, education, and stored indefinitely as long as the patient's privacy is maintained. Refusal to participate in research will not affect the test result. If a response is not checked, consent is implied.

I authorize consent for the use of the above individual's sample for test validation and education:       **YES**     **NO**

VIII. Information obtained from the test may be used in scientific publications, but the identity of all persons in the test will not be revealed in such publications or in any other report.

I have the legal authority to request Baylor Genetics to test this sample for Huntington Disease (HD). I am either the above patient or his/her parent or legal guardian. I have been counseled regarding the risks, benefits, and limitations of knowing the test results and have carefully considered the psychological impact the results may have on the patient and his/her family. My physician or genetic counselor has thoroughly discussed the above information and answered my questions.

\_\_\_\_\_  
Parent/Legal Guardian Name    Parent/Legal Guardian Signature    / / \_\_\_\_\_  
Date (MM / DD / YYYY)

Physician/Counselor: I have explained HD DNA testing and its limitations to the patient or his/her legal guardian.

\_\_\_\_\_  
Physician/Counselor Name    Physician/Counselor Signature    / / \_\_\_\_\_  
Date (MM / DD / YYYY)

\_\_\_\_\_  
Phone    Fax