



**Patient Name:** \_\_\_\_\_ **MRN/DOB:** \_\_\_\_\_

***HUNTINGTIN (HTT) CAG REPEAT TEST INFORMED CONSENT:***

In accordance with New York State Law, the following has been discussed with the patient/legal guardian and informed consent obtained. The following was signed in my presence.

Please read the following carefully and discuss with your ordering physician/person obtaining consent before signing consent.

1. This is a test for expansion of a CAG repeat in the HTT (Huntingtin) gene, by PCR.
2. The purpose of this analysis is to confirm a diagnosis of Huntington's Disease (HD), or to evaluate risk for development of HD.
  - 2a. Genetic counseling is strongly recommended before you sign the consent.
3. This is a test for genetic susceptibility ("genetic predisposition"), the risk of having the disorder may be altered by family history and/or other factors. If the test is positive for the disorder or for an increased risk of the disorder, the patient may wish to have further independent testing, consult your physician or have further genetic counseling.
4. The condition being tested is Huntington's disease, a progressive, fatal, neurological disorder.
5. If the result is "normal", then the patient will not be at increased risk for having HD. If the test shows an "HD allele" the patient will develop HD at some point in his/her life; if the result shows a "mutable normal allele" then the patient will not be at increased risk for HD, but his/her descendants may be at increased risk for developing HD. If the result of the test is "HD allele with reduced penetrance", then the patient may or may not develop HD during your lifetime, although the risk will be higher than the general population.
6. The results of the above test become a part of the patient's medical record, and may be made available to individuals/organizations with legal access to the patient's medical record, on a strict "need-to-know" basis, including, but not limited to the physicians and nursing staff directly involved in the patient's care, the patient's current and future insurance carriers, and others specifically authorized by the patient/authorized representative to gain access to the patient's medical records. Columbia University, NewYork-Presbyterian and Weill Cornell Medicine and their related entities participate in an Organized Health Care Arrangement (OHCA). This allows us to share health information to carry out treatment, payment and our joint health care operations, including integrated information system management, health information exchange, financial and billing services, insurance services, insurance, quality improvement, and risk management activities. Organizations that will follow this Notice include Columbia University, NewYork-Presbyterian sites, Weill Cornell Medicine and their related entities.
7. No additional tests will be performed on this sample, without specific, signed authorization by the patient/authorized representative. After 60 days, unless consent is given the sample will be destroyed, or will be de-linked from all patient information and used for standard laboratory quality assurance purposes.
8. Medicare/Insurance Carriers may not pay for the test, in which case, the patient/responsible party will be billed for the test.



**HUNTINGTIN (HTT) CAG REPEAT TEST INFORMED CONSENT:**

Name of Person Obtaining Consent:

Title: \_\_\_\_\_

\_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

I have read and fully understood the above, and give my consent for this testing.

Patient signature: \_\_\_\_\_

Date: \_\_\_\_\_

If consent is given by parent or legal guardian:

Name: \_\_\_\_\_

Date: \_\_\_\_\_

Signature: \_\_\_\_\_

**Consent for sample retention:**

**I consent to the retention of my/the patient's DNA for: (check and sign on appropriate line)**

I do not consent to research. DNA may be used for routine laboratory quality assurance only. \_\_\_\_\_

You may store my DNA indefinitely, if you remove all identifying information and use anonymously for research purposes. \_\_\_\_\_

Please save the DNA with demographic information, indefinitely, for future testing, or to allow me to participate in Research on Huntington's Disease. \_\_\_\_\_