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CONNECT

HUNTINGTON DISEASE TESTING CONSENT

Patient Last Name	Patient First Name	MI	Date of Birth (MM / DD / YYYY)	Genetic Sex
			/ /	

HUNTINGTON DISEASE TESTING CONSENT

This consent form can only be used for Huntington disease testing. Consent forms for other tests are located at Baylor Genetics' website (https://www.baylorgenetics.com/consent/).

For the purposes of this consent, "I", "my", "you", and "your" can refer to you, your child, your unborn child, or other individual you are the legal representative of.

TEST INFORMATION

Your healthcare provider (doctor, genetic counselor, or other person with medical training) wants to order genetic testing for Huntington disease (HD). HD affects movement, psychiatric, and cognitive abilities. These health issues get worse over time. While treatments may help with some health issues, there is currently no cure for HD. Genetic testing for HD can determine if your current health issues are caused by HD or if you might be at increased risk to have HD later in life.

This test looks at the gene (specific part of DNA needed for our health) that causes HD. DNA is our genetic material. The gene that causes HD is HTT. Certain changes, called variants, in this gene cause HD. These variants can be passed along from parent to child. They can also change from parent to child. These changes might cause health issues at an earlier age or that are more serious than other affected family members.

Before you sign this consent form, you should speak with your healthcare provider. They can help you understand this testing and what it means for your health.

TEST RESULTS

There are several types of test results that may be reported including:

- **Negative:** Both gene copies have 26 or less CAG repeats. You are not expected to be at risk for HD.
- **Intermediate:** At least one gene copy has 27-35 CAG repeats. You are not expected to be at risk for HD. However, this repeat number can get larger from you to your child. Your children could be at risk for HD.
- **Reduced Penetrance:** At least one gene copy has 36-39 CAG repeats. You may be at risk for HD. Your children could also be at risk for HD.
- **Positive (Full Penetrance):** At least one gene copy has 40 or more CAG repeats. You are expected to have or develop HD. Each of your children are expected to have a 50% (1 in 2) chance for HD.

CONSIDERATIONS AND LIMITATIONS

- You should speak with your provider before signing this consent form to understand the risks, benefits, and alternatives to testing.
- Minors without health issues related to HD usually do not have HD testing.
- This testing cannot predict when health issues may start. This is checked through a clinical exam.
- A Reduced Penetrance and Positive (Full Penetrance) result cannot determine how health issues might progress. Family members with the same findings might not have the same issues or progression as you.
- Depending on the results of testing, more testing may be needed to understand these results.
- A negative result does not rule out the chance for health issues. Our knowledge of variants and how they cause disease may change over time as we learn more about genetics. Testing has limitations to what it can find as well.
- Certain factors may lead to incorrect results. These include mislabeled samples, incorrect information in the test order, and rare technical errors.
- More sample may be needed if the first sample is not sufficient to complete testing.
- The Huntington's Disease Society of America (hdsa.org) and other groups have patient resources about HD.

PATIENT CONFIDENTIALITY AND SAMPLE RETENTION

- If several family members are tested, knowing the correct biological relationships among them is important. In rare cases, testing can show that family members are not related as expected. If this is found, we may contact the provider who ordered your testing.
- If this testing is requested to be cancelled after the order and sample are sent to the laboratory, please see our Test Cancellation Policy at www.baylorgenetics.com/cancel-test/.
- Only Baylor Genetics and its contracted partners will have access to your sample for the ordered testing. Results from testing will only be released to: (i) a licensed healthcare provider, (ii) those authorized in writing, (iii) the patient or their personal representative, and (iv) those allowed access to test results by law. You have the right to access your test results from Baylor Genetics by providing a written request. You also have the right to request raw data obtained from your sample by providing a written request or HIPAA Authorization Form.
- In rare cases, people with genetic diseases may have problems with health insurance and employment. The U.S. Federal Government has several laws that prohibit discrimination based on test results by health insurance companies and employers. These laws also prohibit unauthorized disclosure of this information. For more information, please visit www.genome.gov/10002077.
- Samples will be kept in the laboratory based on our retention policy. Once testing is completed, the de-identified sample may be used for test development, quality assurance, and training purposes. Samples are not returned to patients or providers unless requested prior to testing. You and your heirs will not receive payments, benefits, or rights to any resulting products or discoveries.
- The information from your testing may be used in scientific research, publications or presentations, but your specific identity will not be revealed. We may contact your provider to obtain more clinical information about you. Baylor Genetics also performs other types of scientific research and may contact you to see if you would like to be involved.
- Variants found may be submitted to databases. The medical community uses these databases to collect information about how variants might cause disease to improve testing and treatment for patients. An example is ClinVar, a free, public archive of reports on human genetics. Limited clinical information may need to be shared with these databases. In rare cases, this information may be enough to allow you or your family members to be identified.
- For more information on privacy practices at Baylor Genetics, please visit www.baylorgenetics.com/privacy-practices/.

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FOR SAMPLES FROM NEW YORK STATE RESIDENTS

Samples from New York State residents shall not be included in research without written consent. Samples will not be retained for more than sixty (60) days after receipt by Baylor Genetics, unless authorized by marking below. No tests other than those authorized shall be performed on the samples.

☐ I authorize Baylor Genetics to retain sample(s) longer based on our retention policy for test development, quality assurance, and training purposes.

FINANCIAL AGREEMENT

By signing below, I hereby authorize Baylor Genetics to provide my insurance carrier any information necessary, including test results, for processing my insurance claim. I understand that I am responsible for any co-pay, co-insurance, and unmet deductible that the insurance policy dictates. I designate Baylor Genetics as my designated representative for purposes of appealing any denial of benefits by my insurance carrier. I irrevocably assign associated payment to Baylor Genetics, and direct that payment be made directly to Baylor Genetics. Please note, some payers may not cover certain screening tests.

If my health insurer does not cover the test or I do not have health insurance, I have received a good faith estimate of the cost for the genetic testing ordered by my provider and agree to pay for the cost of the genetic testing billed to me by Baylor Genetics based on that good faith estimate. More information is available in Baylor Genetics' No Surprises Act and Good Faith Estimate Notice located at https://www.baylorgenetics.com/no-surprises-act/.

A Medicare Advance Beneficiary Notice (ABN) is required for services Medicare identifies as not medically necessary.

PATIENT AUTHORIZATION

By signing this statement of consent, I acknowledge that I have read, understand, and hereby grant my informed consent for genetic testing. I have received appropriate explanations from my healthcare provider about the planned genetic test(s) and possible results. I have been informed by my healthcare provider about the availability and importance of genetic counseling and have been provided with written information identifying a genetic counselor or medical geneticist who can provide such counseling services. All my questions have been answered, and I have had the necessary time to make an informed decision about the genetic test(s).

I hereby give permission to Baylor Genetics to conduct genetic testing as recommended by my physician*.

Patient Name	Patient's Signature	Date Signed (MM / DD / YYYY)
		____ / ____ / ____

Patient's Parent / Personal Representative* Name	Patient's Parent / Personal Representative Signature	Date Signed (MM / DD / YYYY)
		____ / ____ / ____

*If you are signing on behalf of the patient as the parent(s) and/or person with legal authority to act on behalf of the patient or parent, you may be required to provide evidence of your authority.