BAYLOR GENETICS

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INFORMED CONSENT FOR PRENATAL HUNTINGTON DISEASE (HD) GENETIC TESTING

Patient Last Name _____ Patient First Name _____ MI _____ Date of Birth (MM/DD/YYYY) ____ / ____ / ____

TEST INFORMATION

This consent form will provide you with information regarding prenatal genetic testing for Huntington disease (HD). HD is a progressive neurological disease affecting movement, psychiatric, and cognitive abilities. While there are treatments that can help with certain symptoms, there is currently no cure for HD. This testing is recommended to only be performed after a clinical care team specialized in providing care to patients with HD has completed a clinical evaluation and a discussion of the risks, benefits, and limitations of testing. To assist you in understanding the purpose, risks, benefits, and limitations of this testing, we have provided information about the testing process and potential results below.

The purpose of prenatal HD testing is to determine if a patient's pregnancy is at an increased risk to develop symptoms of HD. DNA is the genetic material that we receive from our parents. Genes are made of DNA and are the instructions for maintaining the health of our bodies. Each person has a unique set of DNA and most of the differences in our DNA do not impact our health. Genetic testing for HD involves analyzing the *HTT* gene for a repeating segment of "CAG" nucleotides within the DNA (trinucleotide repeat). The number of these CAG repeats typically determines whether a person might develop HD. The number of CAG repeats can increase when passed from parent to child. The HD testing ordered by your healthcare provider can determine if your pregnancy has a number of CAG repeats that might cause HD to develop. This test does not analyze other types of changes (variants) in the *HTT* gene.

RESULTS

Typically, each person has two copies of the *HTT* gene (one inherited from each parent). Each copy of the gene has a number of CAG repeats. When results are reported for a patient, the CAG repeat number of both copies will be used to determine the result. There are several types of test results that may be reported including:

- **Negative:** Both CAG repeat numbers are not associated with risk for disease (26 repeats or less). The fetus is not expected to be at risk for developing HD. Their children are also not expected to be at risk for developing HD.
- **Intermediate:** At least one CAG repeat has 27 - 35 repeats. The fetus is not expected to be at risk for developing HD. However, as the repeat number can expand with each generation, their children could be at risk to develop HD.
- **Reduced Penetrance:** At least one CAG repeat has 36 - 39 repeats. It is unclear whether the fetus will develop HD at some point in their life. Their children could be at risk to develop HD.
- **Positive (Full Penetrance):** At least one CAG repeat size has expanded into the HD range (40 or more repeats). The fetus is expected to develop HD at some point in their life, and each of their children have a 50% chance to also develop HD.

Samples received from biological parents of the pregnancy will be used as a control to ensure the accuracy and proper interpretation of results obtained by prenatal testing. Information regarding parental HD status is typically included in prenatal reports that are issued. However, parental HD status can be excluded from reports if requested.

CONSIDERATIONS AND LIMITATIONS

- This consent form can only be used for prenatal HD testing. Consent forms for other tests are located at Baylor Genetics' website (https://www.baylorgenetics.com/consent/).
- Given the nature of prenatal HD testing, parental HD status could be determined from the results of this testing if this is not already known.
- A positive genetic test cannot predict when an individual will begin showing signs of HD. The diagnosis of HD can only be made through a neurological exam. There is currently no cure for HD – treatment is aimed at managing symptoms of the disease.
- Due to technical limitations of testing and differences in test methodologies, the number of CAG repeats in the *HTT* gene reported in an individual may vary slightly between laboratories.
- It may not always be possible to complete testing because sometimes the sample does not have enough DNA to perform testing, or for other reasons. In these cases, another sample may need to be sent to the laboratory to perform testing.
- There are several resources available for patients with or at-risk for HD, including the Huntington's Disease Society of America (hdsa.org).

PATIENT CONFIDENTIALITY AND SPECIMEN RETENTION

- If several family members are tested, the correct interpretation of the results depends on the information provided about the relationships amongst family members. In rare cases, genetic testing can reveal that the true biological relationships in a family are not as they were reported. If a difference is identified, it may be necessary to share this information with the healthcare provider who ordered the testing.
- Genetic testing is highly accurate, however in rare cases, inaccurate results may occur. Reasons for this include, but are not limited to, mislabeled samples, inaccurate reporting of clinical/medical information, or rare technical errors.
- If you sign this consent form, but you no longer wish to have your/your child's sample(s) tested, you can contact the healthcare provider who ordered the test to cancel the test. If you wish to cancel testing, the laboratory must be notified of the cancellation request before 5 PM CST the business day after the sample has been received by Baylor Genetics. If the laboratory is not notified of your cancellation request until after this time, you will be charged for the full cost of the test.
- Only Baylor Genetics and Baylor Genetics contracted partners will have access to the sample(s) provided to conduct the requested testing. Results will only be released to the following person(s): (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. I understand that I have the right to access my test results directly from Baylor Genetics by providing a written request. I also understand that laboratory raw data can be requested by providing a written request or HIPAA Authorization Form.
- In rare cases, persons with genetic diagnoses have experienced problems with insurance coverage and employment. The U.S. Federal Government has enacted several laws that prohibit discrimination based on genetic test results by health insurance companies and employers. In addition, these laws prohibit unauthorized disclosure of this information. For more information, you can visit www.genome.gov/10002077.
- Samples will be retained in the laboratory in accordance with the laboratory retention policy.
- After testing is complete, the de-identified submitted specimen may be used for test development and improvement, internal validation, quality assurance, and training purposes. DNA specimens are not returned to individuals or to referring heath care providers unless specific prior arrangements have been made.
- Samples from residents of New York State will not be included in general research studies without your written consent and will not be retained for more than 60 days after receipt of the sample, unless specifically authorized by your selection below. No tests other than those authorized shall be performed on the biological sample.

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FOR SAMPLES SUBMITTED FROM NEW YORK STATE

_____ Initial

I understand that no genetic test other than those I have authorized shall be performed on my biological sample, and the sample will be destroyed at the end of testing or not more than 60 days after the sample was taken. However, by initialing here, I hereby authorize the lab to retain my sample(s) for longer retention in accordance with the laboratory retention policy for internal laboratory quality assurance studies and possible research testing.

- By signing this Consent form, I understand and agree that information identified may also be submitted to public databases, such as ClinVar. Such submission serves to contribute knowledge to the medical community. I understand that limited clinical information is also required for the submission of information to ClinVar's database and further that the contents of this limited clinical information may, although unlikely, include information that may identify me or members of my family.

PARENTAL HD STATUS REPORTING

Parental samples are highly recommended when prenatal HD testing is performed. They are used as control samples to ensure accurate prenatal results are issued. As part of this testing, parents that do not already know their HD status may not want to have their own HD status reported. Please mark below how HD status information for each parent's sample should be included in the report. If no selection is made, this will default to "Include the results from this parent's HD testing in any reports issued."

Given the nature of prenatal HD testing, please note that parental HD status may be inferred from the results of this testing if not already known.

MATERNAL

☐ Include the results from this parent's HD testing in any reports issued.

☐ DO NOT include this parent's HD results in any reports issued.

PATERNAL

☐ Include the results from this parent's HD testing in any reports issued.

☐ DO NOT include this parent's HD results in any reports issued.

☐ A sample for control testing will not be available.

FINANCIAL AGREEMENT AND GUARANTEE

By signing this consent form, I accept full and complete financial responsibility for all genetic testing ordered by my healthcare provider. For insurance billing, I hereby authorize Baylor Genetics to bill my health insurance plan on my behalf, and further authorize Baylor Genetics to release any information to my insurance carrier which is reasonably required for billing. I additionally 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. I understand that my out-of-pocket costs may be different than the estimated amount indicated to me by Baylor Genetics as part of a verification of benefits investigation. I agree to be financially responsible for all amounts as indicated on the explanation of benefits issued by my health insurance plan. If my insurance provider sends a payment directly to me for unpaid services performed by Baylor Genetics on my behalf, I agree to endorse the insurance check as appropriate and forward such check to Baylor Genetics within thirty (30) days of receipt thereof, as payment towards Baylor Genetics' claim for services rendered. If I do not have health insurance, I agree to pay for the full cost of the genetic testing that was ordered by my healthcare provider and billed to me by Baylor Genetics.

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/.

I understand that a completed Advance Beneficiary Notice (ABN) is required for Medicare fee for service patients if the service is not payable by Medicare as not medically necessary or reasonable.

RECONTACT FOR RESEARCH CONSENT

Baylor Genetics participates in research relating to health, disease prevention, drug development, and other scientific purposes. Baylor Genetics may contact patients directly as part of this research. I agree to allow Baylor Genetics to contact me about possible research involving the sample(s) and/or information associated with this testing. I understand that patients generally receive no compensation for this participation in research. For more information on research at Baylor Genetics, please visit baylorgenetics.com.

If I wish to opt out of being recontacted for research purposes by Baylor Genetics, I understand that I may check the box below:

☐ Please do not contact me regarding any research that uses information obtained from this testing.

For any research I may be contacted about, I prefer contact through the following methods (please check all that apply – if no choices are selected, contact via secure email will be made if an email address is provided):

☐ Email ☐ Phone ☐ Mail

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

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

Relationship of Personal Representative to the Patient

Paternal Name | Paternal Signature | Date Signed (MM / DD / YYYY)

Paternal Personal Representative* Name | Paternal Personal Representative Signature | Date Signed (MM / DD / YYYY)

Relationship of Paternal Personal Representative

Ordering Provider's 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, you may be required to provide evidence of your authority.