BAYLOR GENETICS

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INFORMED CONSENT FOR GENETIC TESTING

I, _____, understand that my physician has recommended genetic testing for myself and/or my child or children for (insert name of test) _____, hereby voluntarily agree to submit my and/or my child's or children's sample(s) for testing as recommended by my physician. I understand that biological samples will be collected using generally accepted techniques, the risk(s) of which I have been separately informed. I understand that testing of my and/or my child's or my children's sample(s) will be limited to the test ordered by my physician. I understand that the sample(s) will be used for the purpose of attempting to determine if I and/or my family members have a pathogenic variant in this disease gene(s). Results may indicate affected status, increased risk to someday be affected with and/or reproductive risk for this disease. The minor child or children for which I hereby give permission to collect biological sample(s) for this test is/are named below*:

Child's Name (Last, First, MI) _____ Date of Birth (MM/DD/YYYY) _____ Biological Sex: ◯ M ◯ F ◯ Unknown

Gender identity (if different from the left): _____

☐ *If additional children are being tested, please check this box AND list their name, date of birth, and gender on the back of this consent

1. There are several categories of test results that may be reported including:
    a. A clinically significant abnormality IS detected, known to be associated with a genetic disease.
    b. A clinically significant abnormality IS NOT detected, however my clinical diagnosis may still be correct. This event may be due to medical science's current lack of knowledge of all the gene(s) involved with the disease or the inability of the current technology to identify certain types of mutations in the gene(s) which cause the disease.
    c. A result of uncertain clinical significance is detected. Additional testing of the patient and/or other family members may be recommended to help determine the significance of the result.
    d. Unexpected test results may be detected. These results may occur with screening tests that evaluate many different genetic regions. From these tests, information may be learned about you, your child/children or your family that is not directly related to the clinical reason for ordering the test. This information may provide data about the risk for a different genetic disease with symptoms that may or may not be currently evident.
2. An error in the test interpretation may occur if the true biological relationships of the family members being tested are not as I have stated. For example, a sequence change or deletion or duplication detected in an affected individual but not detected in the parents may be interpreted as a clinically significant change, but this interpretation is wholly dependent on testing of the biological parents. If the stated parents of an individual are not the biological parents, the interpretation may be incorrect. On rare occasions, the laboratory may obtain results that suggest misattributed parentage and it may be necessary to report this to the physician who ordered the testing.
3. This consent cannot be used for prenatal studies, Huntington disease studies or whole exome studies. Huntington disease studies and/or whole exome studies have specific consents that may be located on our website. Prenatal cases involving molecular studies should be reviewed with our laboratory genetic counselor to confirm specimen and paperwork requirements.
4. Genetic tests are relatively new and are being improved and expanded continuously. The tests are not considered research, but are considered to be an appropriate means of evaluation at the time of testing. This testing is complex and utilizes specialized materials so that there is always a very small possibility that the test will not work properly or that an error will occur.
5. The laboratory does not return or bank the remaining sample to individuals or physicians; however, in some cases, it may be possible to perform additional studies on the remaining sample or send for banking elsewhere. These requests must be made by my referring physician or other authorized healthcare professional and there may be an additional charge. Samples will be retained in the laboratory in accordance with the laboratory retention policy. I do understand that I have the right to withdraw this consent at any time, and the entity storing the sample shall promptly destroy the sample or portions thereof that have not already been used.
6. Because of the complexity of genetic testing and the implications of the test results, results will only be reported to me through the ordering healthcare professional. The results are confidential and will only be released to other medical professionals or other parties with my written consent. All laboratory raw data are confidential and will not be released unless a valid court order is received.
7. Results may have clinical or reproductive implications for my family members. In rare cases, persons with genetic diagnoses have experienced problems with insurance coverage, employment and other entities. Participation in genetic testing is completely voluntary. I understand that I may wish to obtain professional genetic counseling prior to signing this consent form.
8. I understand that a positive test result is an indication that I or the individual(s) being tested may be predisposed to or have the specific disease or condition tested for and may wish to consider further independent testing, consult my or his/her/their physician or pursue genetic counseling.
9. My signature below acknowledges my voluntary participation in this test, but in no way releases the laboratory and staff from their professional and ethical responsibility to me.
10. I will receive a copy of this consent form.

Signature _____ Printed Name _____ Date (DD/MM/YYYY) _____

Relationship to Patient _____ Witnessed by _____

PHYSICIAN'S STATEMENT: I have explained the genetic testing specified to this individual. I have addressed the limitations outlined above, and I have answered this person's questions. I have obtained consent from the patient or the legal guardian for this testing.

Physician Signature _____ Physician Name _____ Phone _____ Date (MM/DD/YYYY) _____