530 North Lafayette Boulevard
South Bend, IN 46601-1098

South Bend Medical Foundation
Informed Consent for Huntington Disease Genetic Testing

Minors below the age of consent (<18 years of age) will not be tested for Huntington disease.

Patient Information

Patient's Name________________________________

Birth Date:________________________________

Social Security Number:________________________

Daytime Telephone Number:______________________

Sex: ☐ Male ☐ Female

Patient's Address________________________________

City__________________ State_____ ZIP________

Required Ordering Physician Information

NPI____

Name____

Address______________________________________

____

City__________________ State_____ ZIP________

Telephone_____________________

Fax__________________________

Test(s) Requested: ☐ Huntington Disease

Reason for Ordering Test(s): ☐ Diagnostic ☐ Predictive ☐ Clinical Study ☐ Other

Patient Symptoms:____

Is there a history of this condition in the patient's family? ☐ yes ☐ no

Has the patient or a family member had this test before? ☐ yes ☐ no

If yes to either question, please indicate the ***biologic relationship of the individual with a positive Huntington disease test or a clinical diagnosis of Huntington disease with the patient whose sample will be tested:*** ______________________________

____

Specimen Type: ☐ Whole Blood EDTA
☐ Whole Blood ACD

Date Collected:________________________________

Facility Where Specimen Obtained:____

Facility Reference Number:______________________

IMPORTANT: Reverse side of form must be completed.

I request and authorize South Bend Medical Foundation, Inc., (“SBMF”) to test my **(or my adult ward’s)** sample for the above-listed genetic condition(s).

My signature below constitutes my acknowledgment that the benefits, risks, and limitations of this testing have been explained to my satisfaction by a qualified medical professional before coming to SBMF for this test.

More specifically, a qualified medical professional has explained the applicable and important information including but not limited to the following:

1. This DNA test result may:
   a. Diagnose whether or not I am at risk for developing Huntington disease or confirm that I have this condition;
   c. Predict if another family member is at risk for developing this condition;
   e. Be indeterminate due to technical limitations or familial genetic patterns; or
   f. Reveal non-paternity.
2. This DNA test will only detect Huntington disease. It will not detect ALL possible mutations within the Huntington disease gene, nor will it detect mutations in other genes.
3. The significance of a positive and a negative test result based on my reported family history has been explained to me by a qualified medical professional. A positive test result indicates either a predisposition to or a case of Huntington disease, and further consultation with a physician and/or genetic counselor should be considered.
4. Several sources of error may yield imprecise information, including: clinical misdiagnosis of the condition, sample misidentification, sample contamination, and inaccurate information regarding family relationships.
5. SBMF is an authorized laboratory under the Clinical Laboratory Improvement Amendments of 1998, and is competent to perform DNA tests.
6. There is a statistical possibility for false and aberrant results, and as such this test result should not be used as the sole means for clinical diagnosis or patient management decisions.
7. DNA analysis is a fee-for-service test. As such, I am responsible for payment after the testing process begins, even if I decide not to receive the results.
8. Participation in DNA testing is completely voluntary. Because of the complexity of DNA-based testing and the implications of the test results, results will be reported to me only through the physician or genetic counselor that I designate. The result reports are strictly confidential, and will only be released to other medical professionals or other parties with my written consent. All laboratory data is confidential.
9. My **(or my adult ward’s)** sample may be used for medical research, test validation, or education after personal identifiers are removed. Refusal to permit the use of my sample for research will not affect the test results. I can withdraw my consent to use my sample for medical research, validation, or education at any time by contacting SBMF in writing.
10. My questions about DNA testing have been answered by a qualified health professional prior to coming to SBMF for this test, and I have received a copy of this informed consent form.

Patient/**Guardian** Signature:______________________________

Witness:______________________________

Date:______________________________

Physician/Genetic Counselor:

I have explained DNA testing and its limitations to the patient **or legal guardian.** I have addressed the limitations of DNA testing including but not limited to the matters outlined above, and I have answered all of this person’s questions to their stated satisfaction.

Printed Name of Physician/Genetic Counselor:______________________________

Signature of Physician/Genetic Counselor:______________________________

Date:______________________________