



530 North Lafayette Boulevard
South Bend, IN 46601-1098

South Bend Medical Foundation Informed Consent Form for Genetic Testing

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

UPIN# _____

Name _____

Address _____

City _____ State _____ ZIP _____

Telephone _____

Fax _____

Test(s) Requested: Huntington Disease

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

Symptoms _____

Racial/Ethnic Background (required for interpretation):

African American American Indian Ashkenazi Jewish Asian/Pacific Islander
 Caucasian Hispanic Middle Eastern Other

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 **relationship to patient whether they are affected or a carrier** _____

Is patient pregnant? yes no

If yes, estimated gestational age: _____ weeks on _____ date

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 child's or my fetus, or my 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 such test(s).

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

1. DNA test results may:
 - a. Diagnose whether or not I have a condition or am at risk for developing this condition;
 - b. Indicate whether or not I am a carrier for this condition;
 - c. Predict another family member has or is at risk for developing this condition;
 - d. Predict another family member is a carrier of this condition;
 - e. Be indeterminate due to technical limitations or familial genetic patterns; or
 - f. Reveal non paternity.
2. This DNA test will only test for the specific disease(s) or condition(s) listed above. It will not detect ALL possible mutations possible within this 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 the disease or condition for which the sample was tested, and further independent testing and 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. DNA tests are relatively new, and are being improved and expanded continuously. SBMF is an authorized laboratory under the Clinical Laboratory Improvement Amendments of 1998, and is competent to perform DNA tests. The results of the tests are not intended to be used as the sole means for clinical diagnosis or patient management decisions.
6. That there is a statistical possibility for false and aberrant results, and as such 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 testing 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 child's, fetus' or my 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 my 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: _____