Consent for Hereditary Cancer Genetic Testing

Introduction - The purpose of this form is to describe the benefits, risks, and limitations of genetic testing for inherited susceptibility to cancer. Please read this form carefully and discuss any questions or concerns with your team of providers (physician and/or genetic counselor).

Purpose - Genetic testing is performed to determine the presence of mutation(s) in the genome that are associated with an increased risk for hereditary cancer. This test is performed by analyzing specific gene(s) and determining the presence of unusual mutation (variant). If a person has a specific variant that is known to be associated with a significantly increased risk of developing certain tumors, that person is considered predisposed to developing cancer.

Not everyone who has a gene mutation will develop cancer, nor are individuals without a gene mutation immune from cancer. The cancer risk associated with specific mutations varies depending on the tested gene as well as the type of variant (mutation). Furthermore, mutation in a gene known to cause cancer in a specific organ (for example, breast or ovary) may also increase the chance of developing cancer in other organs (for example, pancreas). The risk of having cancer is not always well defined and genetic counseling is always recommended prior to participating in genetic testing as well as after test results are received. Testing is only performed to cover reported relevant genomic areas, and the presence of abnormalities outside these tested areas cannot be ruled out.

Potential Results

- **Positive –** An abnormality is detected that has been reported to be associated with an increased risk for hereditary cancer. This finding may help you and your doctor make more informed choices about your health care and develop a strategy for cancer prevention and monitoring.
- **Negative –** No known pathogenic abnormality is detected. However, you still have at least the same risk of cancer as does a person in the general population or higher if you carry a genetic predisposition that cannot be detected by this test, either in the gene(s) you were tested for or in another gene linked to hereditary cancer. Further, if your negative test is specifically for a mutation known to be in your family, you are considered to have the same risk of developing that specific type of cancer as others in the general population. Since other mutations may exist elsewhere in the genes, persons with a negative result from this test may still be at high risk of cancer due to other changes in the tested genes or another gene not analyzed in this test.
- **Uncertain –** A genetic change (variant) of uncertain significance is detected. This indicates that there is no reliable data or knowledge at this time to indicate if the detected change is linked to an increased cancer risk or not. You have at least the same risk of cancer as the general population, and may still be at greater risk than the general population if the detected variant is proven to be associated with an increased risk of cancer or if you carry another genetic predisposition abnormality that cannot be detected by this test. The genetic counselor and your physician will discuss the results with you and what they mean.

Genetic testing results have implications for blood relatives. This should be discussed with your physician and/or a genetic counselor to help you determine if your rights and notification responsibilities if a mutation is found.

Test Procedure - One vial of blood will be collected and sent to NeoGenomics Laboratories. The laboratory will analyze your specified gene(s) to look for variants (mutations). You are consenting to the specific tests ordered by your physician on the attached requisition form.

Benefits - Genetic testing for inherited susceptibility to cancer may help you and your doctor make informed decisions about your health care, such as screening, risk-reducing surgeries and preventive medication strategies. In the event you already have cancer, knowing that you carry a gene that increases your susceptibility to cancer may help in treating your current cancer as well as devising a strategy for preventing new cancers. The results of this test may identify a gene abnormality (mutation) in your family and enable other blood relatives to determine whether or not they inherited the same cancer risks. If you test positive, you should discuss with your healthcare provider how hereditary cancer is inherited and learn about the chance your children and blood relatives may have inherited the same mutation(s) in the gene(s) tested. If you test negative for a known mutation in your family, you cannot pass on that mutation to your children. If you have had cancer or a pre-cancerous condition and test negative, you still have some increased risk based on your own history. If you have not had cancer, you have the same risk of cancer as the general population.

Risks - Learning that you have a genetic mutation (variant) may be upsetting and may increase feelings of depression, anxiety, and vulnerability. You may feel that you have to make difficult decisions about your medical care. Learning of a positive result may affect relationships with family members. News of an inconclusive result may increase feelings of distress. If more than one family member is tested, there is a possibility of learning sensitive information about your family, such as non-paternity or undisclosed adoption. Negative results may give you false sense of security, and you should be aware that you may still be at high risk of developing

cancer. To address concerns regarding possible health insurance discrimination, most states and the federal government have enacted laws to prohibit genetic discrimination. Furthermore, broad federal legislation (HIPAA) prohibits unauthorized disclosure of confidential personal health information.

However, these laws may not prevent life and disability insurers from using genetic testing information in determining coverage.

Limitations - This test analyzes only the specific gene or portion of gene as stated on the requisition. If no mutation is found, you may still be at risk for hereditary cancer due to a genetic predisposition that cannot be detected by this test, either in the gene you were tested for or in another gene linked to hereditary cancer. Genetic testing clarifies cancer risks for only those cancers related to the genes analyzed.

Financial Responsibility - Genetic testing of appropriate individuals is often reimbursed by health insurance. You are responsible for any cost of the genetic test not reimbursed by insurance, including applicable co-pays or deductibles. For these reasons, it is recommended that you contact your insurance company to determine coverage prior to consenting to genetic testing.

Patient (or Guardian if applicable) Consent

By signing this consent form, I agree to the following:

- I was provided with a copy of the attached requisition form by my physician and/or genetic counselor regarding the specific tests ordered and was given a general description of the disease or condition related to the test.
- I confirm that the possible benefits, risks, limitations and costs of this genetic testing have been explained to me. I further confirm that I have had the opportunity to have all of my questions about the test or possible results answered by the medical practitioner ordering the test, or a genetic counselor provided to me.
- I confirm that prior to giving this consent, I discussed with the medical practitioner ordering the test the reliability of positive or negative test results and the level of certainty that a positive test result for the specific gene mutation tested for serves as a predictor of such disease. I understand that a positive test result may be an indication that I am predisposed to or have the gene mutation tested for. The level of certainty will be reported to me, and utilizing that information, I understand that I may consider further independent testing, consult my physician or pursue genetic counseling.
- I understand that the test results will be communicated to me and my physician and/or genetic counselor privately and will not be released to another party without my consent unless required by law.
- I understand that the blood sample submitted by me, or by the patient for whom I serve as guardian, will only be used in a test that provides results for the gene mutation(s) mentioned above, and that no tests other than those authorized above will be performed on such sample. I further understand that the blood sample provided will be destroyed at the end of the testing process or not more than sixty (60) days after analysis, or permanently stripped of identifying information and used for research purpose. I understand that as a result of the de-identification, such research sample cannot be linked to me or information that I have provided.
- I understand that I that I can seek genetic counseling regarding the genetic testing prior to giving this consent, and was provided with written information identifying a genetic counselor or medical geneticist from whom I may obtain such counseling, as well as opportunity to speak with such individual.
- I understand the confidentiality policy outlined in the consent form. This means that I recognize that genetic information and a copy of the test result will be included in my medical record, and may only be disclosed to individuals who have legal access to this record or to individuals who I designate to receive this information.
- I have read this consent form and will be given a copy for my records.

I, _____, hereby request genetic testing for the gene mutation(s) in the attached requisition for me, or the patient for whom I serve as guardian, _____. .

_____	_____	_____
Signature of Patient or Guardian (if applicable)	Print name	Date

I have explained the possible risks, limitations and costs as well as potential benefits of genetic testing and have answered any questions regarding the test to the best of my ability.

_____	_____	_____
Genetic Counselor/Clinician	Print name	Date