Informed Consent for Hereditary Cancer Genetic Testing

This Informed Consent Form is to be filled out and signed by the patient. This form reviews the benefits, risks and limitations of genetic testing that is ordered by your healthcare provider to assess your risk for developing certain types of inherited cancers. **Genetic testing is confidential and voluntary and you are not required to have the test. You may wish to obtain genetic counseling prior to signing this consent form. If so, a request should be made to your healthcare provider.** Please read carefully and discuss any questions you may have with your healthcare provider before signing the consent below.

Purpose of Testing: Genetic changes or mutations can occur in certain gene(s) that are associated with specific hereditary cancer risks. This test analyses these particular gene(s) to determine if there are genetic changes present in your test sample that significantly increase your risk for developing inherited cancer. Genetic testing provides a more precise estimate of a person's risk for hereditary cancers than using your personal and family history alone. In some cases, the results of this test may also provide information about risks for medical conditions that are not related to cancer.

Test Procedure: Your healthcare provider typically obtains a tube of blood or a saliva sample and sends it to Otogenetics Corporation (Otogenetics) for analysis. Otogenetics will analyze the DNA of the specific gene(s) to check for genetic changes related to an increased risk for specific hereditary cancers. Additional information about testing and about the genes that are analyzed can be found on Otogenetics Patient Portal at www.otogenetics.com

Test Results and Interpretation: Your test results should be explained in support with your personal and family health history, results of your physical examination, other laboratory and hospital tests, and the clinical expertise of your healthcare provider. There are three possible results from this test: - positive, negative, or uncertain.

A Positive Result: A mutation(s) was identified in your DNA that is associated with an increased risk for hereditary cancer. This means you are at increased risk for developing cancer. Knowing that you have a mutation in one or more of the genes analyzed may help you make more informed choices with your doctor about your medical care. You and your healthcare provider can use this information to make a personalized screening and prevention plan. Following your plan may lower your chance of developing cancer or may increase the chance that any cancer detected will be diagnosed when it is at an earlier and more treatable stage. Screening for family members may be recommended. A positive result does not mean that you have cancer or that you will definitely develop cancer in your lifetime.

A Negative Result: No mutations were identified in any of the genes that were tested using the test method specified. This result greatly reduces the likelihood that you have a mutation in the genes that were tested and known cancer risk associated with these genes. If you are the first person in your family being tested, a negative result means that you still have at least the same risk for cancer as a person in the general population. You may still be at a greater than average risk for hereditary cancers due to a genetic predisposition that cannot be detected by this test. If you test negative for a mutation that is known to be in your family, then you may be considered to have the same risk for cancer as a person in the general population.

A Result with Unknown Clinical Significance: A genetic change was identified, however it is not known if this mutation is associated with developing cancer based on current knowledge and currently available clinical data. You may be considered as having the same risk for cancer as a person in the general population. You may also still be at a greater than average risk for hereditary cancers due to this mutation or a genetic predisposition that cannot be detected by this test.

If you are found to carry a mutation in any of the genes analyzed, this may be informative for your blood relatives.

The results of your Hereditary Cancer Test will be sent to your ordering physician and will become part of your medical record. All other parties can only obtain results by submitting an Authorization for Release of Information Form.

Benefits of the Test: Your genetic test results may help you make more informed decisions with your healthcare provider about your health such as screening, risk-reducing surgeries, and prevention medication therapies. If a gene mutation is identified, blood relatives may choose to be tested to determine whether or not they share the same risks for hereditary cancer. If you get a positive result, you should discuss with your healthcare provider how hereditary cancer is inherited and learn about the likelihood that your children or blood relatives may have to inherit the same mutation(s) in the gene(s) tested. If you test negative for a known mutation in your family, then you cannot pass that mutation onto your children and you may be considered as having the same risk as a person in the general population.

Risks of the Test: Genetic testing is done on DNA most often obtained from a blood or saliva sample. Side effects from having blood drawn are uncommon, but may include dizziness, fainting, soreness, bleeding, bruising and rarely, infection. Saliva collection is not invasive. Genetic screening test may cause you to discover sensitive information about your health or disease risks, including disease risks other than the one you are testing for, or for diseases that have currently have no treatment.

The US Genetic Information Discrimination Act-GINA of 2008 prohibits discrimination on the basis of genetic information in regard to health insurance and employment. Some states have enacted laws that limit the use of this information by life insurers. Federal legislation prohibits unauthorized disclosure of confidential personal information.

Limitations of the Test: This test only analyzes for certain specific genetic changes that are associated with an increased risk for developing specific hereditary cancers. Genetic testing provides a risk assessment only for those cancers associated with the gene(s) being analyzed. If your test results are positive, there may be differing opinions amongst physicians as to which treatment option is best to take. Your course of treatment and medical care is best determined by you in consultation with your doctor or healthcare provider. Identification and analysis for Variants of Uncertain Significance or VUS may be considered investigational and may not provide additional information on cancer risks of blood relatives.

Financial Responsibility: Genetic testing of appropriate persons is generally reimbursed by health insurance. You are responsible for any cost of the genetic test that is not reimbursed by your health insurance.

Sample Retention: After testing is complete, your 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 health care providers unless specific prior arrangements have been made. Samples from residents of New York State will not be included in the de-identified research studies described in this authorization and will not be retained for more than 60 days after test completion, unless specifically authorized by your selection below. The authorization is optional, and testing will be unaffected if you do not check the box for the New York authorization language.

Participation in Research: You have the option of consenting to the use of your anonymized sample, genetic information and results in research to develop new tests for all patients. Participation in research is voluntary. If you consent to participating in research and later change your decision, Otogenetics will destroy any remaining portion of your test sample that was stored and remove your information from the research database.

Patient Consent Statement

By signing below, I, the patient acknowledge that

- Hereditary cancer testing is done to determine a person's predisposition to developing inherited cancer.
- This test is not done to diagnose whether I have or will get a certain disease in the future. This test is intended to tell me about my hereditary risk related to certain types of cancer as discussed with my healthcare provider and selected on my test order form.
- I have been offered the opportunity to ask questions and discuss with my healthcare provider the benefits and limitations of the genetics test(s) to be performed as indicated on the test requisition form or on the follow-on tests ordered by my healthcare provider.
- I have discussed with the healthcare provider ordering this test the reliability of positive and negative test results and the level of accuracy that a positive result has for a specific disease or condition and serves as a predictor of such a disease.
- I understand that I should not make any medical decisions based on my results without speaking with my healthcare provider first. I understand that I should discuss my results and appropriate medical management with my healthcare provider.
- I have been informed about the availability and importance of genetic counseling and was provided with written information on access to genetic counseling.
- I understand that I am the owner of my medical history and test results. My healthcare provider cannot discuss nor disclose my test results and associated medical history to a third party unless related to treatment or payment for treatment, without my written authorization.
- I understand it is entirely my decision to have or not to have any genetic testing.
- I have read this document in its entirety and understand that I can keep a copy of the signed document for my records.

I have read and fully understand the above. **Please initial** _____

☐ I **consent** to being tested for predisposition to hereditary cancer and I will discuss my test results and appropriate medical management with my healthcare provider.

☐ I **decline** to being tested for predisposition to hereditary cancer at this time.

I understand the following information regarding use of my test sample for research:

Otogenetics is committed to improving genetic testing for all patients and contributing to scientific research. For more information on research please visit www.otogenetics.com **Please NOTE: If left blank, the consent for research is interpreted as "NO".**

☐ **Optional**: I consent to use of my de-identified test samples for research.

☐ **Optional**: In addition to the above, I consent to be contacting by Otogenetics regarding research opportunities.

☐ **Optional**: I am a New York State resident and I consent to storing my test samples at Otogenetics beyond 60 days for future use or testing.

Signature of Patient or Legal Guardian _____Date: _____/_____/_____

Name of Patient: _____ Name and Relationship of Legal Guardian _____