***Informed Consent for Genetic Testing***

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| **Patient name: ………………………………………………………………..**  **DOB: ………………………………………………………..**  **MRN: …………………………………………………………..**  **Gender : 🢬 Female 🢬 Male**  **I request Genetics test for:** A multigene panel test that includes specific genes known to increase the risk of breast cancer susceptibility includes BRCA1, BRCA2, CDH1, PALB2, PTEN, and TP53 |

**For patient use only:**

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| It has been explained to me through the decision aid system (DAS) and I understand the following: | | | |
| **1.** | I agree to have genetic (DNA) testing for: …… A multigene panel ……. | | |
| **2.** | I understand the purpose of this genetic test | | |
| **3.** | I have been informed about the benefit, risks, and limitations of the genetic testing:  **Benefits of the genetic testing:** Genetic test results help you and your doctor make more informed choices about your health care, such as screening, risk-reducing surgeries, and preventive medication strategies. Identifying gene mutation(s) in a family enables other blood relatives to determine whether or not they share the same hereditary cancer risks.  If you are positive, you should discuss with your Physician / Counselor 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.  Understanding your risk for hereditary conditions empowers you to make informed decisions about preventive measures and personalized healthcare. This newfound awareness provides psychological relief, easing anxieties or presenting early detection opportunities for proactive health management. Genetic testing enhances your understanding of your genetic makeup, offering profound insights into potential health outcomes. It supports healthcare professionals in tailoring treatment plans to your unique genetic profile.  Suppose you test negative for a known mutation in your family. In that case, you cannot pass on that mutation to your children, and you may be considered to have the same genetic risks for cancer as others in the general population.  **Risks of the genetic testing:** Genetic testing requires DNA, most often provided from a sample of blood from a saliva sample or a tumor sample.  Side effects of having blood drawn are uncommon but may include dizziness, fainting, soreness, bleeding, bruising, and rarely, infection.  You may experience heightened anxiety or emotional distress, particularly if results indicate an increased risk. Challenges may arise due to the complexity of genetic information, emphasizing the importance of clear communication between healthcare providers and individuals. Ethical considerations around privacy, genetic discrimination, and familial dynamics may come into play. Genetic testing unveils predispositions that can influence lifestyle choices and preventive measures, contributing to a holistic approach to health and well-being. It's crucial to carefully weigh these facets and engage in genetic counseling to make choices aligned with your values and preferences.  **Limitations of the genetic testing:** This test analyzes only certain important gene(s) associated with specific hereditary cancer risks. Genetic testing clarifies cancer risks for only those cancers related to the genes analyzed. If you are found to be a carrier of a gene that predisposes you to cancer, there may be differing opinions among physicians about the best steps to take. You best determine your medical care in consultation with your Physician / Counselor. Analysis for a specific genetic variant of uncertain significance may be considered investigational and may not provide additional cancer risk information to blood relatives. | | |
| **4.** | I understand that the possible result outcomes include positive, negative, Uncertain, and Incidental Findings:  • Positive – A mutation that is associated with an increased risk for hereditary cancer was identified. Knowing this information may help you and your doctor make more informed choices about your health care, such as screening, risk-reducing surgeries and preventive medication strategies.    • Negative – A mutation was not identified in any of the genes included as part of your testing.  ▫ If you are the first person tested in your family, you still have at least the same risk of cancer as does a person in the general population. You may still be at greater than average risk for hereditary cancer due to a genetic predisposition that cannot be detected by this test, either in the gene(s) for which you were tested or in another gene linked to hereditary cancer.  ▫ If you test negative for a mutation known to be in your family, you may be considered to have the same genetic risks as others in the general population.  • Uncertain – A genetic change was detected but it is not known if this change is linked to cancer risk. You still have at least the same risk of cancer as the general population. In addition, you may still be at greater than average risk due to this change or a genetic predisposition that cannot be detected by this test, either in the gene(s) for which you were tested or in another gene linked to hereditary cancer.  • Incidental Findings: Additional findings not specifically related to the assessed cancer risk may emerge during the analysis. These incidental findings could have health implications and require further investigation or medical follow-up. | | |
| **5.** | I agree that all information I gave about my family history and their clinical diagnosis are correct as far as I know | | |
| **6.** | I understand that the genetic testing is often complex and need specialized material, however, a small chance of errors may occur | | |
| **7.** | I agree to storage of my sample after analysis | | |
| 8. | I understand that stored sample may be used anonymously for development of new tests and quality assurance | | |
| 9. | I understand that my information may be used for clinical audit to improve our service | | |
| 10. | It has been explained to me that some genetic tests can occasionally reveal information that is unexpected | | |
| 11. | I understand that my results may be discussed in the multi-disciplinary committee (MDC) meeting for the breast | | |
| 12. | If new tests for the condition become available: | | |
| OR | I want to be contacted before further tests are carried out | Yes | No |
| I agree for further tests to be undertaken without being contacted beforehand | Yes | No |

**Patient Consent Statement:**

By signing below, I, the patient having the test performed, acknowledge that:

• I've been given the chance to explore the decision aid support system and also have the option to inquire through the chatbot. I'm ready to:

Complete and sign the consent form without needing further discussion with my healthcare provider during the pre-genetic counseling phase.

I need to have more discussion with my healthcare before I can decide on signing the consent form. Please arrange a meeting for this.

• I have read this document in its entirety.

• I consent to being tested for predisposition to hereditary cancer and I will discuss the results and appropriate medical management with my Physician / Counselor.

• I am the owner of my medical history and test results. My Physician / Counselor may discuss or disclose my test results and associated medical history to a third party, without my express written authorization.

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| Name of patient having testing : …………………………………….  Date of Birth of patient (or legal guardian\*): ………………………………………  Date & Time of Signature: ………………………………………………………..  Email of patient: …………………………………………………………  Signature of patient:……………………………………………………………… |

**- If applicable, in the event of my death I would like the following person to be consulted or given results:**

Name: ………………………. Tel: …………………….. Email: ………………………….

**For Office use only**:

**I confirm that I have explained that purpose, nature and implications of the test**

Signature of Physician / Counselor: ……………………………… Date: …………………….