

Informed Consent for Hereditary Cancer Testing

Patient Name: _____

Date of Birth: _____

MRN: _____

Hereditary cancer syndrome: _____

Specific genes to be analyzed: _____

Why: Genetic testing looks for changes in genes, called mutations, that cause the gene to not work properly. Mutations in some genes can increase the risk for cancer(s) or tumor(s). This test helps find out if you have a greater than average risk of certain cancers or tumors due to mutation(s) in a cancer-related gene. Genetic testing may give you and family members a better estimate of your lifetime risks for cancer. This estimate is better than personal and family history alone.

How:

- Your blood, saliva, or other sample (e.g., skin biopsy) is sent to a laboratory which looks for mutations in specific genes within your DNA.
- Genetic testing takes about 2 to 4 weeks to complete. The results are shared with you over the phone or during a return visit to the Genetics Clinic when they are available.
- Genetic testing for hereditary cancer genes is not typically done on anyone under the age of 18.

Limits:

- This test only looks at certain gene(s) associated with hereditary cancer, tumors, or applicable conditions. Risk factors other than genes can increase a person's risk for cancer.
- This test may not find all possible mutations that could be found in the specific gene(s).
- It is possible that your family may have a different inherited mutation related to cancer that will not be found by these tests.

Payment:

- There may be a laboratory fee for this testing.
- There may be other charges for the office visits related to this testing.
- Some insurance companies may pay some or all of these fees. You are responsible to pay deductibles, co-pays, or co-insurance if your insurance does not.

Test Results: Your results are reviewed along with your personal and family medical history. Possible test results include:

- **Positive:** A mutation was found. This means that you may have an increased risk for certain cancer(s) or tumors (depending on the gene). If you have a mutation in this gene(s), other family members may also be at risk of having this mutation.
- **Negative:** A mutation was not found. You or your family may still be at greater than average risk for cancer. This may be due to a genetic factor that cannot be detected by this test or due to shared environment or lifestyles factors.
 - Genetic testing may be recommended in the future as more genes and technologies are discovered.
 - If you test negative for a known mutation in your family, you typically have the same cancer risks as an average person.
- **Variant of Uncertain Significance (VUS):** A genetic change was detected. It is not known if this change is linked to an increased cancer risk.

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Place patient label here or fill out information below:

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Possible Risks:

- Genetic testing requires a blood or saliva sample. Side effects of having blood drawn may include dizziness, fainting, soreness, bleeding, bruising, and infection. Potential side effects of other sample methods (e.g., skin biopsy) are listed in that procedure consent form.
- Learning the results of your genetic testing has mental and emotional risks. It may create feelings of depression, anxiety, anger, or fear. It may affect relationships with other family members.

Benefits: The test results may give a better estimate of your risk to develop cancer, or your children and your relatives risk to develop cancer. This may help you and your doctor make health care decisions around cancer screening or prevention.

Keep In Touch:

- Keep in contact with the Division of Medical Genetics every 2 to 3 years by phone, MyChart message, or follow-up appointment so that you can:
 - Learn of changes in the field of cancer genetics.
 - Receive potential updates regarding current classifications of VUS results.
- Let the clinic know of changes in your personal or family history which may alter your cancer risk assessment.

Confidentiality:

- Your genetic counseling notes and the results of your genetic testing are put in your medical record. A copy is sent to your doctor.
- Your medical record is not released outside Henry Ford Health or to family members without your written permission.
- Your insurance company may get information about this test if it is paying for the test or treatment, or if you agree to provide your medical records to them for other reasons.
- Your blood or saliva sample may be sent to a lab outside of Henry Ford Health. The person collecting your sample and employees in the lab handle your sample. Any leftover sample may be kept, stored, or used by the lab in accordance with regulatory requirements.

Genetic Information Nondiscrimination Act (GINA): (GINA) provides federal protection from genetic discrimination in health insurance and employment. GINA's protections do not apply to life, disability, or long-term care insurance. Employers with 15 or more employees must comply with GINA regulations. More information can be found through the U.S. Equal Employment Opportunity Commission (eoc.gov).

I understand and agree to the following:

- I agree to have a sample taken to find out if I and possibly my family members have an increased chance to develop certain cancer(s) or tumors associated with a gene mutation.
- I was given the time to ask questions and understood the answers to my questions.
- I have read all parts of this consent.

Signature of patient, parent, or legal guardian

Time

Date

Print name of signer if not patient

Signature of healthcare provider

Time

Date