

Genetic Testing for Cancer Risk Consent Form



Procedure Description: Genetic testing requires taking a blood sample from your body. If your healthcare provider orders a cancer screening genetic test for you, the DNA in your blood will be tested to help determine your future risk of some types of cancer, including those of prostate, colorectal, ovarian, breast or pancreatic origin. DNA can be extracted from blood and is the carrier of your genetic information. You may wish to obtain professional genetic counseling prior to giving your consent for this test, and after receiving your results.

The genetic test that will be ordered for you looks for mutations of genes that are associated with future risk of cancer. The results of this test will then be reported to your physician and will be entered into your medical record at The Urology Group (“TUG”). Any mutations found may, depending on the specific mutation and the available information regarding the clinical impact of that mutation, be an indication that you may be predisposed to diagnosis with form(s) of cancer in the future. If that is the case, you may want to consider further independent testing, pursue genetic counseling, and consult with your physician, who will use these results to guide treatment decisions or help you make decisions about cancer screening. In addition, your test results can provide information that may be relevant to your family members’ health. Your family members may wish to consult with a physician or genetic counselor if you choose to share your test results with them. A potential risk of genetic testing may include learning that you and your family members have a disease gene that might affect your or their insurability for life or disability insurance.

All results provided from this test are based on available information that is current as of the date of the test report. It is possible that in the future, a new variant or mutation may be identified or the interpretation of an existing variant or mutation would change based on information not available at the time of the report. It is possible that such information could change your overall risk profile. Your test result will not be automatically updated to reflect any such future changes. You should contact your healthcare professional to discuss the possibility of follow-up testing if you are concerned about future developments.

No genetic tests, other than those authorized by this consent or as part of a research protocol (discussed below), will be performed on your sample.

Retention, Use, and Sharing of Genetic Information and Sample:

By signing this consent form, you also agree that your de-identified and/or anonymized genetic information may be disclosed for quality, operational, educational, research, or other commercial purposes. This means that to the extent required by applicable law, we will either anonymize your information (which means stripping it of all information that could reasonably be used to identify you including any key code) or de-identify your information (which means removing your name and certain other identifiers required to be excluded by applicable law, but potentially assigning the information a key code in accordance with an institutional review board approved coding system).

In addition, by signing this consent form, you consent to the storage of your sample indefinitely after the end of the genetic testing process for use for operational, educational, research, or other commercial purposes. Any genetic testing performed on your retained de-identified sample for research will be conducted under an institutional review board approved research protocol and coding system.

There is no guarantee that this research conducted using your samples or genetic information will help you, but it is possible that the research could help you or other patients in the future. TUG takes the confidentiality of your personal information seriously and confidentiality will be maintained in accordance with applicable federal privacy law and applicable state law. For more information about TUG's privacy practices, please refer to TUG's Privacy Policy (<https://www.urologygroup.com/privacy-policy/>) and Notice of Privacy Practices (<https://www.urologygroup.com/all-forms/notice-of-privacy-practices/>).

The use of samples and genetic information such as yours may have commercial applications in the future. If commercial applications are derived from the original testing or future research you will not be compensated or receive any rights or interests in those products.

In addition, by signing this consent form, you agree that we may contact you in the future to obtain additional information or consents. The purposes of our contacting you include for research purposes, to provide you with general information about research findings, and to provide you with information that may be relevant to you or your family in relation to you or their choices about preventative or clinical care. The potential benefits of such contact may include learning about a condition for which early screening or preventative care may be beneficial to you or your family members' health. The potential risks of such contact may include learning that you and your family members have a disease gene that might affect your or their life, insurability or employability. Note that with regard to insurability and employability, federal law (the Genetic Information Discrimination Act) provides some protection from discrimination based on genetic information. There are currently no federal laws that prohibit life insurance, long term care, or disability insurance companies from discriminating based on genetic information. Your state may have more comprehensive laws in this area.

You may contact TUG at any time to revoke your consent to the retention of your sample, the sharing of your genetic information, and to be contacted in the future. However, your revocation will not have any effect on the following: (i) any genetic information or sample that has been anonymized, because it cannot be traced back to you; or (ii) any use or sharing of genetic information or sample that has already happened. You will not lose any benefits or medical care to which you are entitled should you revoke your consent.

Consent:

I have been given sufficient opportunity to ask about the genetic testing, including the information that may be learned through the genetic testing. All my questions have been answered to my satisfaction, and I have sufficient information to give informed consent to the genetic testing.

Patient's name: _____ Signature: _____

Witness' name: _____ Signature: _____

Date: _____