I authorize my provider at St. Luke’s University Health Network (together with its affiliate hospitals and offices) to order the genetic test identified below for me or my child. I understand that obtaining a genetic test is completely voluntary and that refusing to obtain a genetic test will not impact the care that I receive from St. Luke’s. By signing below, I consent to permit the genetic testing of my or my child’s biospecimen (e.g., blood, tissue, saliva) by the lab identified below.

1. **Description of the Test.** My provider recommends that I or my child receive the following genetic test: _____________________________________________________________. The test will be conducted by the following lab: __________________________________________________________. My provider has explained that the purpose of the test is to identify genetic variants that are associated with the following condition: ___________________________________________________________ OR to determine whether the following treatment would benefit me or my child: ___________________________________________________________. The test will be performed on a __________________________ sample (e.g., blood, tissue, saliva).

2. **Limitations of the Test.** I understand that this test will analyze specific genes and is not comprehensive. Other genes, not included in this test, will not be analyzed and variants in these genes will not be reported. In addition, if I have chronic lymphocytic leukemia (CLL), had an allogeneic bone marrow/peripheral stem cell transplant, or a blood transfusion in the past 4 weeks the test results may not be accurate. Rarely, chemotherapy may affect the quality of my sample and a second sample may be required. I understand that as with every lab test, there is a possibility of error.

3. **Description of Test Result.**

   • Positive: A variant was found in a gene(s) which confirms that I or my child have or are predisposed to have the condition for which the test was done. If the test was ordered for treatment options, it provides guidance to which therapeutic treatments may benefit me or my child more than others.

   • Negative: No variants were found in the gene(s) tested. This does not rule out the possibility that I or my child will develop the condition for which the test was done. I understand that medical conditions whether genetic or not have many causes and not all are known or capable of being tested for. If this test was ordered for treatment options, a negative result may still provide guidance regarding therapeutic treatment options.

   • Variant of unknown significance (VUS)/Inconclusive – A variant was found in a gene(s); however, there is not enough information to determine whether this variant is the cause of my or my child’s condition or whether it predisposes me or my child to certain conditions. The health care provider will make medical recommendations based on relevant personal and/or family history. These results may change over time as more data becomes available and the healthcare provider may contact me to discuss any changes. Of note, not all genetic tests will report variants of unknown significance.

   • Carrier: A variant was found in a gene(s) associated with a recessive genetic condition. This means that the variant does not cause or predispose me or my child to the condition tested for, but there may be reproductive risks (e.g., risks for future children). Further testing of a reproductive partner may be recommended in the future for the purpose of family planning.
4. **Prenatal Testing:** I understand that if I have had prenatal testing or screening and the results are negative, these results do not guarantee that my child will not be born with the specific disease or birth defect for which the test was performed. I understand that a percentage of all pregnancies will have birth defects or genetic conditions that cannot be detected by testing blood, chorionic villi, or amniotic fluid, or by ultrasound. If I am pregnant with twins or other multiple fetuses, the results may only apply to one of the fetuses. It is my sole decision to determine whether to continue or terminate my pregnancy based on the test results or other factors.

5. **Return of Results.** The results of the genetic test will be included in my or my child’s electronic medical record and reported to my or my child’s provider at St. Luke’s. My or my child’s provider may discuss the results with a specialist or a genetic counselor at St. Luke’s if advisable to determine the best course of action for me or my child based on the results. I will also be provided with the results of the genetic test. I can discuss the results with my provider or a genetic counselor or seek any additional follow up care or consultation with any provider at any facility.

6. **Genetic Counseling.** A genetic counselor is a licensed, board-certified specialist who can discuss how genetic test results impact me and my family. I understand that seeking genetic counseling to discuss the results of the test will help me better understand the results and their limitations. I understand that providing an accurate and complete family history to a genetic counselor is important in assessing the impact of the test results on me.

7. **Discussing My Results with Family.** I understand my provider will protect the confidentiality of my test results as required by federal and state law. I further understand that the test results may impact my family. I understand that it is my decision to share or not share the test results with my relatives. If I share the results, I will advise my relatives to contact a genetic counselor if they decide to pursue genetic testing.

8. **Whole Exome Sequencing.** The lab may conduct “whole exome sequencing” to provide the genetic test ordered by my provider. Whole exome sequencing is a technique for sequencing all the protein-coding regions of genes in a genome. Although data will be generated for all protein-coding regions of genes in my genome, only the genes related to this test will be analyzed. Other genes, not related to this test, will not be analyzed and variants in these genes will not be reported. If the lab conducts whole exome sequencing it may retain the information for an indefinite period of time so that if any of my or my child’s providers determine now or in the future that an additional genetic test is clinically indicated, the lab will be able to run the additional genetic test without requesting a new sample from me or my child. The lab will not use my or my child’s exome data for any purpose except to provide the results of an additional genetic test ordered by my provider with my consent or as otherwise expressly permitted by federal and state law.

9. **My Financial Obligations.** I understand that I am responsible for the costs of the genetic test. The lab will be provided with the information needed to submit the cost of the genetic test to my or my child’s insurer. I authorize the lab to submit the claim to the insurer and to appeal any denial of the claim. I assign to the lab all reimbursement received from the insurer for the cost of the genetic test. If the insurer does not reimburse the lab for the cost, or if I am not insured, the lab may bill me for the cost of the genetic test. I understand that payment may be required before the test is done.
10. **Medical Record.** I understand that the results of the test will become part of my or my child’s medical record. St. Luke’s and my provider will protect the confidentiality of my and my child’s medical record as required by federal and state law. A federal law known as The Genetic Information Nondiscrimination Act (GINA) of 2008 (Public Law 110-233) prohibits health insurers and certain employers from requesting, obtaining, or using genetic information to deny coverage, charge higher premiums, or make hiring, firing, or promotion decisions. However, I understand that there are currently no federal laws that prohibit companies who provide life insurance, disability insurance, and/or long-term care insurance from using genetic information to determine coverage and rates.

11. **Retention of Samples and Data.** I understand that it is possible that the lab may not retain my or my child’s sample and that it will not be available for further testing. If I want additional testing, my child or I may have to submit another specimen for testing. The lab may also de-identify my or my child’s sample and data so that it cannot be used to identify me or my child and retain and use the de-identified sample and data along with other de-identified samples and data to assess and improve the lab’s quality of services and tests.

I ACKNOWLEDGE THAT NO GUARANTEE OR ASSURANCE HAS BEEN MADE TO ME AS TO THE RESULT OF THE GENETIC TEST ORDERED FOR ME OR MY CHILD.

I HEREBY CERTIFY THAT I HAVE READ AND UNDERSTAND COMPLETELY THE INFORMATION ON THIS CONSENT FOR GENETIC TESTING, THAT ALL EXPLANATIONS REFERRED TO WERE OFFERED, AND THAT ALL OF MY QUESTIONS HAVE BEEN ANSWERED TO MY SATISFACTION.

___________________________________  ______________________________________  ________
Patient Signature                  Printed Name                  Date                     Time

IF PATIENT IS A MINOR:

ON BEHALF OF MY MINOR CHILD, I HEREBY CERTIFY THAT I HAVE READ AND UNDERSTAND COMPLETELY THE INFORMATION ON THIS CONSENT FOR GENETIC TESTING, THAT ALL EXPLANATIONS REFERRED TO WERE OFFERED, AND THAT ALL OF MY QUESTIONS HAVE BEEN ANSWERED TO MY SATISFACTION.

___________________________________  ______________________________________  ________
Parent/Guardian Signature      Printed Name                  Date                     Time