MICHIGAN MEDICINE Pathology Request and Consent to Germline Genetic Testing	MRN: NAME: BIRTHDATE: CSN:

Your healthcare provider has ordered genetic testing for _____.
(Name of condition)

This testing will be completed through:

☐ The Division of Genetics and Genomics (CAP#7123231 / CLIA#23D1088637)

☐ _____

What is the purpose of this testing?
The purpose of this testing is to evaluate for the presence of a specific chromosomal abnormality, genetic variant, or other genetic disease process that may pose risk to your health, or the health of your family members. For this consent, the term "you" may refer to you, your child, or your fetus.

Your healthcare provider has determined that genetic testing may be helpful in identifying a plan for your medical care. This may include changes in treatment, surveillance, or options for reproductive management. This document outlines the details you should consider before deciding to proceed with this testing.

How will this testing be performed?
Testing will be performed on a blood, saliva, or other tissue sample that you provide. Testing will evaluate for changes, called variants, in the genetic instructional code of the body.

What are the possible results from this testing?
Positive – A variant in a gene or chromosome was identified. This may provide you and your healthcare providers with a specific diagnosis for your health condition or may reveal an increased risk for you to develop a specific health condition in the future. This result could also indicate health risks unrelated to the purpose of testing. Health risks for other relatives, including children, siblings, or parents, may also be identified.

Negative – A variant in a gene or chromosome was NOT identified or only benign gene variants were identified that do not cause health complications or risk for disease. This result may not eliminate the chance that your health condition is due to a genetic cause and may not eliminate future risk to develop a specific disease.

Inconclusive (Variant of Uncertain Significance) – A variant in a gene was identified but there is not enough information to determine whether the variant is positive (disease-causing) or negative (benign). More testing may be recommended to help clarify the result. More research or time may be required before the significance can be clarified. We encourage you to contact our clinic periodically for any updates.

What are the limitations of this testing?
Clinical, certified laboratories follow necessary procedures and precautions to ensure that your results are accurate and valid. However, there may be limitations in current medical knowledge or testing technology that may prevent certain gene variants from being identified. Genetic testing cannot detect all possible health risks. A negative/normal test result does not guarantee your health.

The accuracy of results may also be limited by poor sample quality, sample damage during shipment, sample contamination, mosaicism, or laboratory processing error. In some situations, the laboratory may request a second sample.
Accuracy is also dependent on the information that you provide to your healthcare team about yourself and your family members including medical history and biological relationships.

What are the risks of this testing?
The physical risks of genetic testing are minimal. For blood draws, they include bruising, pain, and infection at the site where the blood was taken. Physical risks for other sample type (e.g., saliva collection, buccal swab, skin biopsy, chorionic villus sampling, amniocentesis, etc.) may vary. Your healthcare team has explained any other physical risks.

Additional possible risks from genetic testing may include adverse psychological or emotion reactions (e.g., stress, anxiety, depression, anger, grief), loss of social support, impacts on family relationships, and financial risk. It is possible that genetic testing reveals differences in biological relationships (e.g., it may identify that your mother and father are not your biological parents or that your parents are related by blood).

It is your responsibility to consider your desired insurance coverage prior to proceeding with genetic testing. The United States has a federal law called the Genetic Information Non-Discrimination Act (GINA) that prohibits health insurance companies and employers from making decisions based on your genetic information. These protections, however, do not

apply to life insurance, disability insurance, or long-term care insurance. For more information on this law and existing limitations, please visit www.ginahelp.org.

How will I be informed of the results of my testing?
The results from this testing will be forwarded back to your healthcare provider and saved securely in your electronic medical record at Michigan Medicine. Your results may become available to you in your patient portal before you are contacted by your healthcare provider/team.

Your healthcare provider will review the results of the testing with you and will discuss any available management recommendations based on the results.

Genetic counseling can help you and your family members understand, adapt to, and make decisions surrounding your genetic test results. Your healthcare providers may recommend genetic counseling before, during, or after genetic testing. You can also request that your doctor place a referral for you to meet with a genetics specialist at Michigan Medicine.

Can my sample or the information (data) from my testing be shared?
This testing is being ordered as a clinical test and results are kept confidential in accordance with the Health Insurance Portability and Accountability Act (HIPAA) of 1996. The results of your testing will become part of your electronic medical record at Michigan Medicine and may be viewed by other members of your healthcare team.

Commercial genetic testing laboratories may have specific policies regarding data protection, data sharing, sample storage and retention, and use of deidentified samples for research. Your healthcare provider can provide you with online or printed resources available reviewing the policies for the laboratory used to complete your testing.

If you sign the consent document, below, it confirms your agreement to pursue germline genetic testing that may be of help to your healthcare providers in managing your healthcare. This consent specifically gives us your permission to either internally test your tissue sample(s) or send them and any required clinical data to our external molecular testing laboratory partner identified above.

Financial Responsibility. I understand that I may be responsible for any testing-related fees not covered by my health plan, including non-authorized or non-covered testing.

In the case of newborn screening, obtaining a Children's Special Health Care Services (CSHCS) diagnostic evaluation may help to cover costs of testing not covered by primary insurance. Family understands if they do not complete a CSHCS diagnostic evaluation for testing, they may be financially responsible for test related fees, based on insurance.

I HAVE READ AND UNDERSTOOD THE INFORMATION ON THIS FORM BEFORE I SIGNED IT. I ACCEPT THE RISKS LISTED ABOVE OR AS DISCUSSED WITH MY DOCTOR, GENETIC COUNSELOR, OR OTHER HEALTH PROFESSIONAL.

_____ **Date:** _____
Signature of Patient or Legally Authorized Representative (if patient is unable to sign) (mm/dd/yyyy)

_____
Printed Name of Legally Authorized Representative (if patient is unable to sign)
Relationship: ☐ Spouse ☐ Parent ☐ Next-of-Kin ☐ Legal Guardian ☐ DPOA for Healthcare ☐ Other (specify): _____

_____ _____ _____
Obtained and Explained by (Printed Name and Signature) Title Pager/Provider No.

Date: _____ **Time:** _____ **A.M. / P.M.**
(mm/dd/yyyy)