NATIONWIDE CHILDREN'S
When your child needs a hospital, everything matters.℠

Institute for Genomic Medicine Clinical Laboratory

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Patient Name_____ **Date of Birth** _____

Testing to be performed_____

Purpose of Testing
I understand that blood/tumor/bone marrow samples from me/my child will be tested to determine the presence or absence of certain genetic characteristics associated with a particular genetic disorder or diagnosis (germline), or associated with my (my child's) cancer. It is the responsibility of the referring physician to ensure that I understand the implications of this testing. I understand that participation in this testing is voluntary.

Accuracy of Testing
I understand that the accuracy of the testing is limited to the techniques used. I understand that, as with all complex testing, there is always a chance of error or test failure. It is the responsibility of the referring physician to explain the limitations of the testing.

☐ **Germline (Constitutional) Testing**
The tests that will be performed on the samples aims to identify genetic features I (my child) was born with and are present in all of my (my child's) cells. I understand that the accuracy of the testing is influenced by the information that I provide regarding myself (my child), the medical history of family members, and biological relationships in my family. Testing may also reveal that my (my child's) parents are related by blood. In addition, non-paternity may be detected in some family-based studies, and this result may be reported to the referring health care provider.

☐ **Cancer (Tumor) Testing**
The primary aim of testing is to identify genetic changes in the cancer cells. The tests that will be performed on the samples can, in rare cases, identify genetic changes I (my child) was born with and are present in all of my (my child's) cells (not just the cancer cells). This could include a genetic disorder caused by gene mutation, gain or loss of DNA, or determination that my (my child's) parents are related by blood. If changes in the non-cancer cells are found that are thought by the testing laboratory to have significant clinical importance, the results may be communicated to the referring physician for consideration of follow-up testing.

Reporting of Results
I understand that the results of this testing will be reported only to the referring healthcare provider, or to a designated professional. All results are confidential and will be reported to other individuals only with my written consent, unless otherwise required by law.

Disposition of Samples
I understand that a portion (an aliquot) of my (my child's) sample will be kept with identifiers intact, and it may be available for additional testing as ordered by my (my child's) healthcare provider. I will not consider this as a banking procedure, and the laboratory will not be responsible for ensuring that the sample is available in the future. The remainder of the sample can be used for research-based testing with the option that I have checked below.

I give the following permission regarding research use of the unused portion of my (my child's) sample.
(Please Choose ONE):

- ☐ Can be used for research purposes including studies designed to investigate the cause of my (child's) condition without removing the identifying information on the sample. Results, at the discretion of the laboratory, may be communicated through the referring physician.
- ☐ Can be used for research purposes only after the identifying information is removed from the sample. I understand that I will not be given any results from the testing, because the sample will be anonymous.
- ☐ Cannot be used for research purposes.

Signature of Signature of Patient/Parent/Guardian: Signature of Patient/Parent/Guardian: I consent to participate (or have my child participate) in genetic testing for the above mentioned scenario. The testing has been explained to me, including its limitations and implications, and I have been given the opportunity to ask questions which have been answered in a satisfactory manner.

_____ Date/Time_____

Signature of Ordering Clinician: I have explained the testing, limitations, consent, and implications to the patient/parent and accept responsibility for ensuring genetic counseling is provided.

_____ Date/Time_____

A signed copy should be provided to the Patient/Parent/Guardian.