NATIONWIDE CHILDREN'S
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Laboratory Client Services
Tel: (614) 722-5477 / (800) 934-6575
NationwideChildrens.org/Lab

Pediatric Oncology
Genetic Test Requisition Form

Institute for Genomic Medicine (IGM) Clinical Laboratory
Tel: (614) 722-2866 / Fax: (614) 722-2887

Ship Samples to: Nationwide Children's Laboratory Services
700 Children's Drive, Room C1955
Columbus, OH 43205 U.S.A.

PATIENT INFORMATION (Please Print or Place ID Label)

Last Name	First Name	MI

Date of Birth (DOB)	Sex ☐ Male ☐ Female	SSN	Patient ID #/ MRN

Street Address	City	State	Zip

ORDERING PHYSICIAN INFORMATION (Please Print)

Ordering Physician Name (REQUIRED)	**Phone (REQUIRED)**	**Fax (REQUIRED)**	NPI #

Attending Physician Information - **REQUIRED** if Ordering Physician is a Trainee (e.g. Resident, Fellow)

Attending Physician Name	Phone	Fax	NPI#

Institution / Practice / Facility Name

Street Address	City	State	Zip

Physician Email **(REQUIRED if sending from outside U.S.A.)**

Ordering Physican Signature **X**	Date

ADDITIONAL REPORT TO (Please Print)

Name ☐ Physician ☐ Lab ☐ Other	Phone	Fax

DIAGNOSIS / ICD-10 / CLINICAL INFORMATION

Diagnosis / ICD-10

Other Clinical Information / Special Instructions

SAMPLE INFORMATION (List each sample submitted with this form) - REQUIRED

SAMPLE 1 **Type:** _____ ☐ Tumor sample with _____ % tumor/blasts ☐ Normal sample ❑ This sample may be depleted for testing if necessary	Time Point (diagnosis, relapse, day 28, etc)	Collection Date:	☐ This is a banked COG sample COG #: _____
SAMPLE 2 **Type:** _____ ☐ Tumor sample with _____ % tumor/blasts ☐ Normal sample ❑ This sample may be depleted for testing if necessary	Time Point (diagnosis, relapse, day 28, etc)	Collection Date:	☐ This is a banked COG sample COG #: _____
SAMPLE 3 **Type:** _____ ☐ Tumor sample with _____ % tumor/blasts ☐ Normal sample ❑ This sample may be depleted for testing if necessary	Time Point (diagnosis, relapse, day 28, etc)	Collection Date:	☐ This is a banked COG sample COG #: _____

REQUIRED: A copy of *Pathology Report* is required for each submitted tumor sample – attach a preliminary report if final report is not available. *Failure can result in a delayed test processing and/or result reporting*.

To request a return of submitted tissue blocks/unused samples/slides, complete all fields below:

Ship Back to: **Name**: _____ **Phone**: _____
Address: _____
_____
FedEx Account# to use for bill for shipping (REQUIRED): _____

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BILLING INFORMATION

- Insurance bill option is only available for patients/insurance plans within the state of Ohio. For insurance bill, please attach the front and back copy of the patient's insurance card and complete the "Ohio Insurance Bill" section below
- For out-of-Ohio patients/insurance plans, we only accept institutional bill. We **DO NOT** insurance bill for patients/insurance plans outside of Ohio
- For **INTERNATIONAL** samples referred from outside the U.S.A. or Canada, we only accept institutional bill. Pre-payment or agreement of payment must be made **PRIOR TO** sending the sample. Payment can be made by wire transfer or by credit card. To arrange payment, please email *LaboratoryBilling@NationwideChildrens.org*
- We **DO NOT** offer Self-pay option at this time
- Please contact Laboratory Client Services for more information at 1-800-934-6575

☐ INSTITUTIONAL BILL (Please Print) – REQUIRED for *Out-of-State* and *International* Samples

Contact Name:	Phone	Fax
Email Address **(REQUIRED if sending from outside U.S.A.)**		
Institution / Hospital / Laboratory Name		
Street Address		

City	State	Zip Code	Country

☐ **Send a result copy to sending institution via:**
☐ Above Fax number ☐ Above Email address ☐ Other Fax/Email_____

Other information:

☐ OHIO INSURANCE BILL (Please Print) – Option Only for Ohio Patients/Insurance Plans
Please Attach a Front and Back Copy of Insurance Card

Legal Guardian Last Name	Legal Guardian First Name, MI	Legal Guardian DOB
Legal Guardian SSN	Relationship to Patient ☐ Self ☐ Spouse ☐ Parent ☐ Other_____	
Subscriber Last Name	Subscriber First Name, MI	Subscriber DOB
Subscriber SSN	Employer	
Insurance Co. Name	Policy #	Group #

Insurance Address	City	State	Zip

Secondary Insurance Co. Name

PATIENT CONSENT FOR INSURANCE BILL

I will fully abide with Nationwide Children's Hospital Laboratory Services by providing all necessary documents needed for insurance billing and appeals. I understand that I am responsible for the payment of this test whether through my insurance company or myself.

Patient Signature: X_____

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FFPE = Formalin-fixed Paraffin-embedded ; Tissue scrolls *MUST* be accompanied by H&E slide from a consecutive cut
Any H&E slide to be submitted with tumor sample must be from a consecutive cut from the submitted tumor section

HEMATOLOGIC CANCER

☐ **Hematologic Cancer Fusion Analysis** (HEMFUSN)

Identifies gene fusions for 148 gene partners (see website for list of all gene partners).
**At least 10% blasts must be present in the submitted tumor sample (based on internal pathology review).*
Sample acquisition prior to receiving treatment is strongly preferred.

Tumor Sample:
- ☐ *Banked COG sample (provide COG # on page 1)*
- ☐ *Involved peripheral blood (4mL EDTA)†*
- ☐ *Snap-frozen tissue*
- ☐ *Bone marrow (4mL EDTA)†*
- ☐ *Fresh tissue*
- ☐ *OCT-embedded tissue*

** FFPE tissues are **NOT ACCEPTED** for this test*

***†* Bone marrow and Blood samples:** Collect 4 mL of bone marrow or involved peripheral blood into EDTA tube. Transfer sample into conical vial containing 2 mL of COG ALL shipping media. If COG ALL shipping media is unavailable, send in tissue culture or transport media. Ship overnight at room temperature. Must arrive the lab within 48 hours from collection.

ACUTE LYMPHOBLASTIC LEUKEMIA (ALL)

B-ALL Fusion Detection Tests

**At least 10% blasts must be present in the submitted sample (based on internal pathology review)*

Tumor Sample:
- ☐ *Banked COG sample (provide COG # on page 1)*
- ☐ *Bone marrow (4mL EDTA)†*
- ☐ *Involved peripheral blood (4mL EDTA)†*

***†* Bone marrow and Blood samples:** Collect 4 mL of bone marrow or involved peripheral blood into EDTA tube. Transfer sample into conical vial containing 2 mL of COG ALL shipping media. If COG ALL shipping media is unavailable, send in tissue culture or transport media. Ship overnight at room temperature. Must arrive the lab within 48 hours from collection.

☐ **Targeted B-ALL Fusion Analysis** (ALLFUSN)

Detects gene fusions involving following 13 genes as the 3' fusion partner: *ABL1, ABL2, BLNK, CSF1R, EPOR, FGFR1, FLT3, JAK2, NTRK3, PDGFRA, PDGFRB, PTK2B* and *TYK2*. This test will also detect some, but not all, *IGH-CRLF2* gene fusion.

☐ **Single Kinase Fusion Detection by Singleplex RT-PCR** (KINFS)

Detects a specific single gene fusion - please see table below for list of gene fusions that can be tested.
Specify gene fusion — 5' Fusion Partner Gene:_____ **3' Fusion Partner Gene:**_____

***ABL1* Fusions**	
5' gene	**3' gene**
NUP214	*ABL1*
*ETV6***	
ZMIZ1	
RCSD1	
RANBP2	
FOXP1	
NUP153	
SFPQ	
SPTAN1	
LSM14A	
CENPC	
SNX2	

***JAK* Fusions**	
5' gene	**3' gene**
*BCR***	*JAK2*
STRN3	
PAX5	
ATF7IP	
EBF1	
ETV6	
TERF2	
*SSBP2***	
PCM1	
ZNF274	
RFX3	

**Includes alternate breakpoints

Kinase Fusions	
5' gene	**3' gene**
ZC3HAV1	*ABL2*
PAG1	
RCSD1	
EBF1	*PDGFRB*
TNIP1	
ETV6	
ZEB2	
ATF7IP	
AGGF1	
ZMYND8	
ETV6	*NTRK3*
MYB	*TYK2*
SSBP2	*CSF1R*
TBL1XR1	
HOOK3	*FGFR1*

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ACUTE LYMPHOBLASTIC LEUKEMIA (ALL) — CONTINUED

☐ ***IL7R* Targeted Sequencing** (IL7R)

At least 50% blasts must be present in the submitted tumor sample (based on internal pathology review). Submission of a normal sample (containing 0% tumor) is recommended but not required.

1) Tumor Sample: ☐ *Banked COG sample (provide COG # on page 1)*
☐ *Bone marrow (4 mL EDTA)* ☐ *Involved peripheral blood (4 mL EDTA)*

2) Normal Sample: ☐ *Banked COG (provide COG # on page 1)*
☐ *Uninvolved peripheral blood (4 mL EDTA)* ☐ *Other (specify):*_____

☐ ***JAK1 & JAK2* Targeted Sequencing** (JAK12)

Note: this test does **NOT** include the *JAK2* gene V617F mutation commonly seen in myeloproliferative disorders.

At least 50% blasts must be present in the submitted tumor sample (based on internal pathology review). Submission of a normal sample (containing 0% blast) is recommended but not required.

1) Tumor Sample: ☐ *Banked COG sample (provide COG # on page 1)*
☐ *Bone marrow (4 mL EDTA)* ☐ *Involved peripheral blood (4 mL EDTA)*

2) Normal Sample: ☐ *Banked COG sample (provide COG # on page 1)*
☐ *Uninvolved peripheral blood (4 mL EDTA)* ☐ *Other (specify):*_____

GLIOMA

☐ ***BRAF V600 Mutation Analysis*** (BRAFV600)

At least 40% tumor must be present in the submitted tumor sample (based on internal pathology review).

Tumor Sample: ☐ *Snap-frozen tissue (**Preferred sample**)* ☐ *Fresh tissue*
☐ *FFPE tissue block* ☐ *FFPE tissue scrolls **AND** H&E slide*
☐ *OCT-embedded tissue block*

***NOTE:** Our lab does not offer BRAF-KIAA1549 fusion detection test unless the patient had previous positive result from another research/clinical lab. We only offer confirmatory testing, done under "RT-PCR Fusion Confirmation" test.*

MEDULLOBLASTOMA

☐ ***CTNNB1* (Beta-Catenin) Exon 3 Sequencing** (CTNE3)

At least 40% tumor must be present in the submitted tumor sample (based on internal pathology review). Submission of a normal sample (containing 0% tumor) is recommended but not required.

1) Tumor Sample: ☐ *Banked COG sample (provide COG # on page 1)*
☐ *Snap-frozen tissue (**Preferred sample**)* ☐ *Fresh tissue*
☐ *FFPE tissue block* ☐ *FFPE tissue scrolls **AND** H&E slide*
☐ *OCT-embedded tissue block*

2) Normal Sample: ☐ *Banked COG sample (provide COG # on page 1)*
☐ *Uninvolved peripheral blood (4 mL EDTA)*
☐ *Other (specify):*_____

☐ ***MYCN (N-MYC)* and *MYC (C-MYC)* Amplification by FISH** (FISHMB)

Tumor Sample: ☐ *FFPE unstained slides (**Preferred sample**; not decalcified; 6 slides, 3 micron) **AND** H&E slide*
☐ *Banked COG sample (provide COG # on page 1)*
☐ *Snap-frozen tissue* ☐ *Fresh tissue*
☐ *FFPE tissue block (Not decalcified)* ☐ *OCT-embedded tissue block*

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Any H&E slide to be submitted with tumor sample must be from a consecutive cut from the submitted tumor section.

NEUROBLASTOMA

☐ **Targeted Oncology Microarray Analysis** (TONCMA) — LOH and Copy Number Abnormality Detection
***Both tumor sample AND normal sample (containing 0% tumor) are REQUIRED.**
**At least 40% tumor must be present in the submitted tumor sample (based on internal pathology review)*

1) Tumor Sample:
- ☐ *Banked COG sample (provide COG # on page 1)*
- ☐ *Snap-frozen tissue (**Preferred sample**)*
- ☐ *Fresh tissue*
- ☐ *FFPE tissue block*
- ☐ *FFPE tissue scrolls **AND** H&E slide*
- ☐ *OCT-embedded tissue block*
- ☐ *Involved bone marrow (4 mL EDTA)*

2) Normal Sample:
- ☐ *Banked COG sample (provide COG # on page 1)*
- ☐ *Uninvolved peripheral blood (**Preferred sample**; 4 mL EDTA)*
- ☐ *Snap-frozen tissue*
- ☐ *Fresh tissue*
- ☐ *FFPE tissue block*
- ☐ *FFPE tissue scrolls **AND** H&E slide*
- ☐ *OCT-embedded tissue block*
- ☐ *Other (specify):*_____

☐ ***MYCN (N-MYC)* Amplification by FISH** (FISHMYCN)

Tumor Sample:
- ☐ *Banked COG sample (provide COG # on page 1)*
- ☐ *Snap-frozen tissue*
- ☐ *Fresh tissue*
- ☐ *OCT-embedded tissue block*
- ☐ *Involved bone marrow (4 mL EDTA)*
- ☐ *FFPE tissue block (Not decalcified)*
- ☐ *FFPE unstained slides (Not decalcified; 6 slides, 3 micron thick) **AND** H&E slide*

☐ ***ALK* Amplification by FISH** (FISHALK) **& *ALK* Targeted Sequencing** (ALK)
**At least 40% tumor must be present in the submitted tumor sample (based on internal pathology review).* Submission of a normal sample (containing 0% tumor) is recommended but not required.

1) Tumor Sample:
- ☐ *Banked COG sample (provide COG # on page 1)*
- ☐ *Snap-frozen tissue (**Preferred sample**)*
- ☐ *Fresh tissue*
- ☐ *FFPE tissue block (Not decalcified)*
- ☐ *Involved bone marrow (4 mL EDTA)*
- ☐ *OCT-embedded tissue block*

2) Normal Sample:
- ☐ *Banked COG sample (provide COG # on page 1)*
- ☐ *Uninvolved peripheral blood (**Preferred sample**; 4 mL EDTA)*
- ☐ *Snap-frozen tissue(**Preferred sample**)*
- ☐ *Fresh tissue*
- ☐ *FFPE tissue block (Not decalcified)*
- ☐ *OCT-embedded tissue block*
- ☐ *Other (specify):*_____

☐ **DNA Ploidy Analysis** (DNAP)

Tumor Tissue Type:
- ☐ *Banked COG sample (provide COG # on page 1)*
- ☐ *Snap-frozen tissue*
- ☐ *Fresh tissue*
- ☐ *FFPE tissue block*
- ☐ *FFPE tissue scrolls*
- ☐ *OCT-embedded tissue block*
- ☐ *Involved bone marrow (4 mL EDTA)*

** Slides are NOT ACCEPTED for this test*

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SARCOMA / SOFT TISSUE TUMOR

☐ **Sarcoma Fusion Analysis** (SCMFUSN)
Identifies gene fusions for 26 gene partners (see website for list of all gene partners).
**At least 10% blasts must be present in the submitted tumor sample (based on internal pathology review).*
Sample acquisition prior to receiving treatment is strongly preferred.

Tumor Sample: ☐ *Snap-frozen tissue*
☐ *Fresh tissue*
☐ *OCT-embedded tissue*
** FFPE tissues are **NOT ACCEPTED** for this test*

Soft Tissue Sarcoma Tumor Analysis by RT-PCR (RTPCR)

Tumor Sample: ☐ *Snap-frozen tissue (**Preferred sample**)*
☐ *Fresh tissue*
☐ *OCT-embedded tissue block*
** FFPE tissues are **NOT ACCEPTED** for this test*

☐ **Full Panel (includes all listed below)**

or Specific RT- PCR for the following selected sarcoma types:

☐ **Ewing sarcoma** *EWS-FLI-1* and *EWS-ERG* fusions [t(11;22)(q24;q12) and t(21;22)(q22;q12)]
☐ **Alveolar rhabdomyosarcoma** *PAX3-FOXO1* and *PAX7-FOXO1* fusions [t(2;13)(q35;q14) and t(1;13)(p36;q14)]
☐ **Synovial sarcoma** *SYT-SSX1/SSX2* fusion [t(X;18)(p11.2;q11.2)]
☐ **Desmoplastic small round cell tumor** *EWS-WT1* fusion [t(11;22)(p13;q12)]
☐ **Congenital fibrosarcoma/cellular mesoblastic nephroma** *ETV6-NTRK3* fusion [t(12;15)(p13;q25)]

WILMS TUMOR

☐ **Targeted Oncology Microarray Analysis** (TONCMA) — LOH and Copy Number Abnormality Detection
***Both tumor sample AND normal sample (containing 0% tumor) are REQUIRED.**
**At least 40% tumor must be present in the submitted tumor sample (based on internal pathology review)*

1) Tumor Sample: ☐ *Banked COG sample (provide COG # on page 1)*
☐ *Snap-frozen tissue (**Preferred sample**)* ☐ *Fresh tissue*
☐ *FFPE tissue block* ☐ *FFPE tissue scrolls **AND** H&E slide*
☐ *OCT-embedded tissue block*

2) Normal Sample: ☐ *Banked COG sample (provide COG # on page 1)*
☐ *Uninvolved peripheral blood (**Preferred sample**; 4 mL EDTA)*
☐ *Snap-frozen tissue* ☐ *Fresh tissue*
☐ *FFPE tissue block* ☐ *FFPE tissue scrolls **AND** H&E slide*
☐ *OCT-embedded tissue block* ☐ *Other (specify):*_____

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CONFIRMATION TESTS

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TARGETED TUMOR FUSION ANALYSIS - Confirmatory Test for a Known Gene Fusion

☐ **RT-PCR Fusion Confirmation** (FUSNCON)
A copy of the previous research/clinical tumor fusion result is **REQUIRED**.
At least 10% tumor must be present in the submitted liquid/solid tumor sample (based on internal pathology review)

Test for fusion between these 2 genes: Gene #1 (5' Fusion Partner):_____
Gene #2 (3' Fusion Partner):_____

Test for additional gene fusions (specificy):_____

Previous tumor fusion analysis performed at (Lab Name): _____
Previous tumor fusion analysis performed as a ☐ *Clinical testing* ☐ *Research testing*

☐ Liquid Tumor: **specify tumor diagnosis**: _____
Sample: ☐ *Bone marrow (4 mL EDTA):* Blast %:_____
☐ *Involved peripheral blood (4 mL EDTA):* Blast %:_____
☐ *Other (specify):*_____

☐ Solid Tumor: **specify tumor diagnosis**: _____
Sample: ☐ *Snap-frozen tissue (**Preferred sample**)* ☐ *Fresh tissue*
☐ *OCT-embedded tissue block* ☐ *Other (specify):*_____
** FFPE tissues are **NOT ACCEPTED** for this test*

TARGETED TUMOR VARIANT ANALYSIS - Confirmatory Test for a Known Somatic Variant

☐ **Targeted Tumor Variant Analysis** (TTVA)
A copy of the previous research/clinical tumor sequencing result is **REQUIRED**.

1. Gene Name:_____ Mutation/Variant:_____
2. Gene Name:_____ Mutation/Variant:_____
3. Gene Name:_____ Mutation/Variant:_____

Previous tumor sequencing performed at (Lab Name): _____
Previous tumor sequencing performed as a ☐ *Clinical testing* ☐ *Research testing*

***Submission of tumor sample is REQUIRED; Submission of a normal sample (containing 0% tumor) is recommended but not required.**

☐ Liquid Tumor: **specify tumor diagnosis**: _____
Must contain at least 50% blasts (based on internal pathology review)
Sample: ☐ *Bone marrow (4 mL EDTA):* Blast %:_____
☐ *Involved peripheral blood (4 mL EDTA):* Blast %:_____

☐ Solid Tumor: **specify tumor diagnosis**: _____
Must contain at least 40% tumor (based on internal pathology review)
Sample: ☐ *Snap-frozen tissue (**Preferred sample**)* ☐ *Fresh tissue*
☐ *FFPE tissue block* ☐ *FFPE tissue scrolls **AND** H&E slide*
☐ *OCT-embedded tissue block*

☐ Normal Sample: ☐ *Peripheral blood (**Preferred sample**; 4 mL EDTA)* ☐ *Other:* _____

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Please Ship Samples and Completed Test Requisition Form to:

Nationwide Children's Hospital Laboratory
700 Children's Drive, Room C1955
Columbus, OH 43205 U.S.A.

Ship samples via Overnight Courier. Samples must arrive the laboratory within 48 hours. Saturday deliveries accepted. Please check "Saturday Delivery" on shipment label.

For testing requested on banked COG samples, please FAX the completed Test Requisition Form to FAX number (614) 722-2887.

For questions regarding testing, specimen requirements or transport, please call IGM Clinical Laboratory at (614) 722-2866 or Lab Client Services at (800) 934-6575.

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Institute for Genomic Medicine (IGM) Clinical Laboratory
700 Children's Drive, Columbus, OH 43205
Phone: (614) 722-2866 / Fax: (614) 722-2887

Informed Consent for Genetic Testing

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 (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 (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 (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 (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 (child's) sample will be kept with identifiers intact, and it may be available for additional testing as ordered by my 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 (child's) sample **(please choose ONE):**
[Please note: if neither option is marked, the first option will apply and consent to research will be implied.]

- ☐ **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.