Clinic for Special Children®

Informed Consent for Molecular Genetic Testing

Patient					CSC ID number	
Street address						
City		State		Zip code		
Telephone		Birthdate				
Father		Mother				
Paternal grandmother (with maiden name)		Maternal grandmother (with maiden name)				
Paternal grandfather		Maternal grandfather				
Spouse (with maiden name)		Spouse's birthdate				

The diagnosis of a genetic disease or the identification of people at risk for having a child with a genetic disease requires the testing of DNA for the presence of an abnormal gene. You and/or your healthcare provider are requesting the Clinic for Special Children (CSC) to perform a genetic test on you or your child. The purpose and accuracy of this test has been explained to you and your questions have been satisfactorily answered.

Development and performance of this testing was determined by the CSC. This clinical testing has not been approved by the FDA; however, the FDA has determined that such approval is not necessary. Some reagents used in this testing are produced for research purposes only. There is always a chance that an error may occur (including, but not limited to, sample contamination and sample misidentification). A negative test result does not necessarily exclude a genetic disease. Results of genetic testing should be considered with the results of other laboratory testing as well as clinical evaluation. The results of these tests will be handled in the standard medically confidential manner.

You and/or your healthcare provider acknowledge permission to (1) obtain about 3 ml of blood from a vein (2) isolate DNA from this sample, (3) perform the requested diagnostic tests (if any), and (4) store the DNA sample at the Clinic for Special Children. By signing this form, you acknowledge that any remaining DNA may be used further for quality-control purposes or additional research. Your name or other personal identifying information will not be used in or linked to the results of any studies or medical publications. However, you have the right to learn of any medically significant findings identified in the course of that process.

☐ **I DO** *or* ☐ **I DO NOT** agree to be re-contacted for future research studies relevant to the CSC's mission. I understand that my decision to opt-out of such follow-up contacts will *not* affect my ability to obtain testing or receive medical care at CSC.

Plain Insight Panel (PIP) ONLY: By choosing to do the Plain Insight Panel, I am electing to learn the following genetic information from the test: 1. Genetic variants that are pathogenic and are associated with *known conditions* manifesting in childhood or adulthood; 2. Genetic variants *predicted to cause conditions* (e.g., variants that have not yet been confirmed to cause disease); for the genetic variants that have uncertain pathogenicity, I understand I could be contacted if pathogenicity becomes defined and the inheritance risks of my PIP result are updated.

I acknowledge that genetic testing can identify medically actionable findings not related to the indication for testing, and carrier status for genetic conditions that have not occurred in my family.

CONSENT: My signature below documents consent for testing indicated on this requisition.

Signature of patient *or* parent/legal guardian **Date**

Alternate consent: As a health care provider, I have explained the benefits and limitations of genetic testing to the patient and/or their legal guardian and have received verbal consent to order genetic testing.

Signature of healthcare provider **Date**

Laboratory Requisition

Clinic *for* Special Children®
535 Bunker Hill Road, PO Box 128, Strasburg, PA 17579 T 717.687.9407 F 717.687.9237

Patient

_____ _____
 # Name *# Date of birth*

_____ _____
 # Address *# Phone number*

If you or your spouse is pregnant, what is the expected due date? _____ ☐ *Not applicable*

Sample *(Ship Monday thru Thursday ONLY by overnight delivery; please call the Clinic for urgent testing)*

☐ **Peripheral blood** ☐ **Cord blood** ☐ **Filter card** ☐ **Saliva kit** ☐ **Other**

Indication for Testing

☐ **Carrier screening**

☐ *Healthy adult; no known family history of disease*
☐ *Family history of* _____
☐ *Spouse with family history of* _____
☐ *Spouse is a known carrier for* _____

☐ **Parental testing - parental testing to identify the genetic basis for their child's health concerns**

Child's name _____ *Date of birth* _____

☐ **Diagnostic testing**

Please provide clinical indication/medical issues _____

_____

Testing Requested

☐ **DNA isolation only** *(for long term storage and possible future testing; peripheral or cord blood only)*
☐ **Single targeted mutation tests** *(please see test list at http://www.clinicforspecialchildren.org)*

_____ _____ _____
Disease (e.g., MSUD) Gene (e.g., BCKDHA) Variant (e.g., c.1312T>A)

_____ _____ _____
Disease *Gene* *Variant*

☐ **Chromosomal microarray** *(peripheral blood only)*
☐ **Plain Insight Panel™** *(peripheral blood only)*
☐ **Amino acid quantitation** *(peripheral blood or filter card only)*
☐ **Other** _____

Reporting

☐ *The requesting provider will disclose results to the patient/family* *

_____ _____
 # Requesting physician/ midwife/ counselor *Institution*

_____
 # Address

_____ _____ _____
 # Phone number ☐ *# Fax number* ** ☐ *# Email* **

Billing

☐ *Bill patient*

_____ _____
 # Guarantor *Institution*

_____
 # Address

_____ _____ _____
Phone *Fax* *Email*

 # These items are REQUIRED. ***Failure to provide proper documentation may result in delayed testing or rejection of sample.***

* ***Checking this box indicates that a genetic counselor from the CSC does NOT need to disclose results to the patient/family.***

** ***Results are sent by fax or email (check preference).***

Submit