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

# Informed Consent for Molecular Genetic Testing

| | | | | | |
|---|---|---|---|---|---|
| **Patient** | | | CSC ID number | | |
| Address | | | | | |
| City | | State | | Zip code | |
| Telephone | | Birthdate | | | |
| Spouse | | | | | |
| Father | | Mother | | | |
| Paternal grandparents | | | | | |
| Maternal grandparents | | | | | |
| **Genetic test(s) requested (see list):** | | **Disease** | | | |
| | | **Gene** | | | |
| | | **Mutation** | | | |

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 physician 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 physician acknowledge permission to (1) obtain about 3 mls of blood from a vein in your arm, (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 your DNA sample remaining after diagnostic testing may be used further for quality-control purposes. 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. Please select your preference below:

**[ ] 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.

**[ ] I DO** *or* **[ ] I DO NOT** want to be informed of incidental findings (medically actionable findings not related to the indication for testing).

**Patient *or* Parent/legal guardian** **Date**

Alternate consent: I, the health care provider requesting the above testing, 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.

**Healthcare provider** **Date**

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# Laboratory Requisition Form

**Section A**

| **Patient:** | Birthdate: |
|---|---|

**Section B**

| **Sample:** | ☐ Venous blood | ☐ Serum/plasma | ☐ Filter paper | ☐ Urine |
|---|---|---|---|---|
| | ☐ Cord blood | ☐ Other _____ | | |

**Section C**

**Tests:**

☐ Amino acid quantitation by HPLC

☐ Organic acid analysis by GC/MS

☐ Targeted mutation detection * (see Mutation List)

**Disease**

**Gene**

**Mutation**

* All molecular genetic testing MUST be accompanied by signed consent forms.

**Section D**

| **Referrer:** | ☐ Physician | ☐ Midwife | ☐ Genetic counselor | ☐ Other |
|---|---|---|---|---|
| Name: | | | | |
| Institution: | | | | |
| Address: | | | | |
| City: | | State: | Zip: | |
| Telephone: | | Fax: | | |
| **Reporting:** Please provide **one** address and/or fax number for test reporting. | | | | |
| Name: | | | | |
| Institution: | | | | |
| Address: | | | | |
| City: | | State: | Zip: | |
| Telephone: | | Fax: | | |
| **Billing:** Please provide an address for billing purposes (if different from **Reporting**, above). | | | | |
| Name: | | | | |
| Institution: | | | | |
| Address: | | | | |
| City: | | State: | Zip: | |
| Telephone: | | Fax: | | |

Revision 12/1/2008