1 Children's Plaza
Dayton, Ohio 45404-1815

INFORMED CONSENT FOR GENETIC TESTING

Patient Name _____ Medical Record Number _____
Date of Birth _____ /_____ /_____ Gender □ Male □ Female
Indication _____
Sample Type □ Blood □ Other (please specify) _____
Test(s) to be Performed
□ Standard Chromosome Analysis
□ Chromosomal Microarray
□ Fragile X
□ Turner syndrome/Klinefelter syndrome
□ FISH* (specify):
□ Other (specify):

I request and authorize Dayton Children's Hospital Genetics Laboratories to perform the above designated test(s) on the sample from me (or my child). My signature below constitutes my acknowledgment that the benefits, risks, and limitations of this testing have been explained to my satisfaction by a qualified health professional.

The following has been explained to me:

1. Genetic testing may:
    a) diagnose whether or not I have (or my child has) a particular condition or am at risk for developing this condition
    b) identify a genetic condition that I did not know I (or my child) was at risk for
    c) indicate whether or not I am (or my child is) a carrier of this condition
    d) predict another family member has, is at risk for, or a carrier of this condition
    e) be indeterminate or negative due to my (or my child's) clinical status at the time the sample was drawn or due to technical limitations
    f) reveal non-paternity, especially in the context of familial testing, or reveal a biological relationship between the mother and the father of the individual being tested
2. Genetic testing may provide information aiding my (or my child's) diagnosis. Clinical information and family history may be necessary for optimal test interpretation. The significance of a positive and a negative test result based on family history has been explained.
3. If a genetic abnormality is identified, insurance rates, obtaining disability or life insurance, and employability could be affected. Federal law extends some protections regarding genetic discrimination (http://www.genome.gov/10002328). It is my responsibility to consider the possible impact of these results. All test results are released to the ordering health care provider and those parties entitled to them by state and local laws.
4. Several sources of error are possible including, but not limited to: sample mishandling, sample misidentification, and sample contamination.
5. The performance characteristics of this test* were validated by Dayton Children's Hospital Genetics Laboratories. The U.S. Food and Drug Administration (FDA) has not approved this test; however, FDA approval is currently not required for clinical use of this test. Dayton Children's Hospital is authorized under Clinical Laboratory Improvement Amendments (CLIA) to perform high-complexity testing. These results are not intended to be used as the sole means for clinical diagnosis or patient management decisions.
6. Additional testing or consultation with my (or my child's) health care provider may be necessary for diagnosis or result interpretation.
7. Genetic counseling may be recommended prior to, as well as following, genetic testing.
8. My (or my child's) sample may be stored indefinitely to be used for test validation or education after personal identifiers are removed.

Patient/Guardian Signature _____ Date _____

□ Patient/Guardian consent was given verbally.

Physician/Genetic Counselor:
I have explained genetic testing and its limitations to the patient or legal guardian and answered all questions.

Printed Name _____ Date _____

Signature _____