Laboratory of Personalized Genomic Medicine
Department of Pathology and Cell Biology

COLUMBIA UNIVERSITY MEDICAL CENTER

630 West 168th Street
P&S 11th Floor, Room 453
New York, NY 10032
Tel: 212-305-9706
Fax: 212-342-0420

Internal Use Only CUMC MRN:_____ Acc #:_____

Informed Consent for SNP Oligonucleotide Microarray Analysis (SOMA) Testing

Please read the following form carefully and discuss with your ordering physician/genetic counselor before signing consent.

I voluntarily consent for microarray analysis to be performed on my specimen.

Description and purpose of the test: The chromosome constitution of a patient with a suspected DNA copy number change is compared to the DNA of a known reference control set of normal individuals. The purpose of this test is to determine whether my (or my child's or my fetus') sample has changes in the DNA copy number that may explain the clinical presentation. This test will reveal major chromosome abnormalities and sub-microscopic chromosomal imbalances and is considered to be greater than 99% accurate.

Chromosome abnormalities and sub-microscopic imbalances may be associated with:

- Developmental delay
- Congenital abnormalities
- Infertility
- A history of miscarriage
- Embryonic and fetal death
- Short stature
- A family history of a chromosome abnormality, intellectual disability, or birth defects.

In the event a chromosomal aberration is identified, genetic counseling is highly recommended to explain the meaning of the result as well as discuss options for clinical management.

The following points have been explained to my satisfaction by a qualified health professional and my signature below indicates that I understand the benefits, risks, and limitations of this testing and accept them:

1. I have the option of receiving genetic counseling before and after the test.

2. The nature and scope of the conditions tested for have been explained to me and I have been given access to a list of these conditions.

3. If the test is "positive," this would be an indication that I (or my child or my fetus) may be predisposed to or have the specific condition(s) tested for, and I may wish to consider further independent testing, consult my physician, or pursue genetic counseling.

4. A normal ("negative") test results does not exclude the possibility that my child/my fetus may have a genetic condition, which is not surveyed by the microarray analysis. Microarray analysis assesses DNA copy number changes and does not rule out genetic disorders caused by single gene mutations.

5. The test may be unsuccessful on rare occasions.

6. Additional testing may be needed to confirm or refine the interpretation of test results.

7. The specimen may be forwarded, by the Columbia University Medical Center Laboratories, to another accredited laboratory for testing if the Columbia University Medical Center Laboratories cannot perform the requested test.

8. The test results will be a part of my medical record and will be available to physicians and genetic counselors involved in my care. Columbia University, New York-Presbyterian and Weill Cornell Medicine and their related entities participate in an Organized Health Care Arrangement (OHCA). This allows us to share health information to carry out treatment, payment and our joint healthcare operations, including integrated information system management, health information exchange, financial and billing services, insurance services, insurance, quality improvement, and risk management activities. Organizations that will follow this Notice include Columbia University, New York-Presbyterian sites, Weill Cornell Medicine and their related entities.

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9. I have been given the opportunity to ask questions about the ordered tests and told how I will get the test results.

10. No tests other than those authorized shall be performed on the biological sample and the sample will be destroyed at the end of the testing process or not more than sixty days after the sample was taken, unless a longer period of retention is expressly authorized in the consent or unless consent is given for additional purposes.

11. Upon completion of testing, a portion of my specimen (or my child's or my fetus') may be made anonymous and used for test validation, research or educational purposes. Once the material has been made anonymous, its original source can no longer be identified.

I do not wish to allow my specimen (or my child's or my fetus') sample to be used for test validation, research or education. Therefore, I am checking this box to indicate that the sample should be used only for the test specified above and will be destroyed after sixty (60) days. ☐

All of the above has been explained to me to my satisfaction, and my signature below attests to the same.

Patient (person being tested):

_____ _____ **Date:** _____

Print Name of Patient/Authorized Representative Signature of Patient/Authorized Representative

Person obtaining consent:

_____ _____ **Date:** _____

Print Name of Person Obtaining Consent Signature of Person Obtaining Consent