Laboratory of Personalized Genomic Medicine
Department of Pathology and Cell Biology

COLUMBIA UNIVERSITY MEDICAL CENTER

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Internal Use Only CUMC MRN:_____ Acc #:_____

Informed Consent – Mitochondrial Disease

Please read the following carefully and discuss with your person obtaining consent before signing.

1. Mitochondrial diseases are diagnosed using one or a combination methodologies: biochemical (protein amount and/or activity), and molecular genetic (DNA sequence and/or configuration determined by various molecular methods such as PCR or gene sequencing).

2. The purpose of this analysis is to test for genetic disorders of mitochondria related diseases, in which mitochondria fail to create enough energy to prevent cell injury or cell death in tissue, such as liver, muscle, brain, heart, kidney, glands, lungs.

2a. You (or the person for whom you are signing) may want genetic counseling before signing for consent.

3. This is a test for genetic susceptibility ("genetic predisposition"). The risk of having the disorder may be altered by family history and/or other factors. If the test is positive for the disorder or for an increased risk of the disorder, you may wish to have further independent testing, consult your physician or have genetic counseling.

4. The condition being tested is mitochondrial defects that affect or could lead to mitochondrial diseases.

5. A positive test increases the likelihood of having mitochondrial disease. A negative result does not exclude the possibility of disease, as other mutations or tissues other than those tested could be affected. Because levels of mitochondrial DNA mutations vary in different tissues, the risk of developing a mitochondrial disease cannot be determined based on a DNA test of a single tissue.

6. The results of the above test become a part of the patient's medical record, and may be made available to individuals/organizations with legal access to the patient's medical record, on a strict "need-to-know" basis, including, but not limited to the physicians and nursing staff directly involved in the patient's care, the patient's current and future insurance carriers, and others specifically authorized by the patient/authorized representative to gain access to the patient's medical records. Columbia University, NewYork-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 health care 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, NewYork-Presbyterian sites, Weill Cornell Medicine and their related entities.

7. No additional tests will be performed on this sample, without specific, signed authorization by the patient. After 60 days, unless consent is given the sample will be destroyed – please see below.

8. Medicare/Insurance Carriers may not pay for the test, in which case the responsible party will be billed for the test.

Requesting Physician or Licensed Nurse Practitioner

Name: _____ **Title:** _____

Name of person obtaining consent: _____

Physician Signature: _____ **Date:** _____

I have read and fully understood the above, and give my consent for this testing. ☐

Patient Name:_____

Patient Signature:_____ **Date:** _____ **If consent is given by parent or legally authorized representative:**

Name: _____

Relationship to Patient: ☐PARENT ☐SPOUSE ☐CHILD ☐OTHER _____

Signature: _____ _____**Date:** _____

Consent for Sample Retention

I consent to the retention of this sample for routine laboratory use. (check and initial on line below):

□ _____ **Unless consent is given the sample will be destroyed after 60 days.**