Consent for Prenatal Genetic Screening

(Updated 1/2019)

FENWAY HEALTH

PLACE PATIENT IDENTIFICATION LABEL HERE

Introduction: Doctor/Nurse Practitioner _____ has explained that I may have "Prenatal Genetic Screening." The testing is voluntary.

Test Procedures: Samples of my blood and/or tissue will be taken. The sample(s) will be analyzed at Quest Diagnostics, Counsyl Genetic Testing, or at an approved reference laboratory. I may need some follow-up tests to confirm or refine the diagnosis.

Purpose: This test may show whether I or my baby may be at risk to be a carrier of (or to be affected by):

Alpha Thalassemia (HBA1/HBA2), ABCC8-Related Hyperinsulinism (ABCC8), Bloom Syndrome (BLM), Canavan Disease (ASPA), Cystic Fibrosis (CFTR), Dystrophinopathies (including Duchenne/Becker Muscular Dystrophy) (DMD), Familiar Dysautonomia (IKBKAP), Fanconi Anemia, Type C (FANCC), FKTN-Related Disorders (including Walker-Warburg Syndrome) (FKTN), Fragile X Syndrome (FMR1), Gaucher Disease (GBA), Glycogen Storage Disease, Type Ia, (G6PC), Hb Beta Chain-Related Hemoglobinopathy (including Beta Thalassemia and Sickle Cell Disease) (HBB), Hexosaminidase A Deficiency (including Tay-Sachs Disease) (HEXA), Mucolipidosis IV (MCOLN1), Niemann-Pick Disease, SMPD-1 Associated (SMPD1), PKHD1-Related Autosomal Recessive Polycystic Kidney Disease (PKHD1), Pompe Disease (GAA), Smith-Lemeli-Opitz Syndrome (DHCR7), Spinal Muscular Atrophy (SMN1).

I understand that this screening does not guarantee my or my baby's health or necessarily predict a problem.

Benefits and Alternatives to Treatment: This test may benefit me by showing whether I or my baby may be at risk to be a carrier of (or affected by) this disease. I have been given a description of the disease(s) being tested for. I have been able to ask my health care provider/genetic counselor questions, and my questions have been answered. They have discussed alternative procedures with me.

Risks: Side effects of having blood drawn are uncommon, but may include: dizziness, fainting, soreness, bleeding, bruising, and (rarely) infection.

Test Results and Interpretation: The results of testing will be reported to the provider who has ordered the tests. The test results will become part of my Fenway Health medical record, including the electronic medical record. The results are confidential and will not be further disclosed without my written authorization.

I have met with a genetic counselor to discuss this test or I have been told how and where I can get genetic counseling. The doctor/nurse practitioner, who ordered my screening, or my genetic counselor, will go over the results with me.

This testing is complex. There is always a small possibility that the test will not work properly or that a mistake will happen. I have discussed with my health care provider the reliability of positive or negative test results, and what a positive test result may mean.

I understand that I must be honest about the true biological relationships of my family members. Otherwise, the test results may not be interpreted correctly. In addition, testing may

detect non-paternity. Non-paternity means that the biological father of an individual is not the person stated to be the father.

Disposal of Tissues: I understand that my sample will only be used for this test as authorized by my consent and that my sample will not be made available for future clinical studies or research purposes in any identifiable fashion without my consent. I understand that my sample will be disposed of in a manner required by law.

The Healthcare Team: I understand that the treatment and care will be provided by a team of healthcare providers headed by a staff doctor. I understand that this healthcare team may include resident doctors, nurses, and clinical students/staff. These healthcare team members may also watch or take part in my treatment and care.

I have read this form and I understand what it says. I have had the opportunity to talk with my doctor. All of my questions have been answered in a language that I understand. I agree to prenatal genetic screening as described in this form.

X_____ _____ OR
Patient's Signature Print Name

X_____ _____and_____
Signature of Person Authorized to Sign for Patient Print Name Relationship to Patient

Date: _____/_____/_____ Time: _____:_____ AM/PM (circle one)

( ) Telephone Consent Obtained:

Discussed with: _____ Relationship to Patient: _____
Print Name

Contact Telephone Numbers: ( ) _____ - _____ ( ) _____ - _____

Significant Aspects of Conversation: _____

_____

_____

X_____ _____ ____/____/____ ____:____
Witness Signature and Credentials Print Name Date Time

I have obtained either face-to-face or telephone consent. I have explained the above statements, answered the patient or legal representation's questions and I am authorized to obtain consent.

X_____ _____ ____/____/____ ____:____
Circle: Physician /NP / PA Print Name Date Time
