Tufts Medical Center

Division of Genetics
GENETIC TESTING INFORMED CONSENT

I,_____, agree to participate / allow my child to participate in testing for_____, which may include a DNA-based test. I understand that a sample of blood will be drawn from me/my child by venipuncture, a procedure which carries very little risk. I understand that the blood will be used for the purpose of attempting to determine if I/ my child is a carrier of, is affected with, or is at future increased risk to be affected with this / these genetic condition (s).

I understand that:

1. In most cases, a DNA test directly detects an abnormality (mutation) in a gene. These tests are highly sensitive and specific. However, due to limitations in existing technology or to incomplete knowledge of possible disease-causing mutations and /or disease-related genes, a mutation may not be detected in me / my child even if affected by this disease. In such cases, either the percentage of mutations detectable by the test or the remaining risk of having a disease–causing mutation will be discussed with me when the test results are reported. Some genetic testing may return with a result of uncertain significance. If this were to occur, my/my child's doctor will explain this in detail or refer me/my child to genetic counseling.

2. An error in interpretation of the test may occur if the true biologic relationships of the family members involved in testing are not as I have stated. In addition, testing may inadvertently detect non-paternity (that the stated father is not truly the biologic father).

3. Although testing is quite accurate, there is a very low error rate even in the best laboratories (1 in 1000). An error in diagnosis can lead to incorrect diagnosis for other relatives.

4. Because of the complexity of DNA based testing and the important implications of the test results, all results will be reported to me only by my physician or genetic counselor. The results are confidential. They should only be released to my/ my child's:
   - D primary care physician
   - D referring physician
   - D additional physicians: _____

5. The blood provided will not be used for future clinical studies or research purposes without my written consent.

6. My signature acknowledges voluntary participation in the above testing, but in no way releases the laboratory and staff from their professional and ethical responsibility to me.

_____	_____
Patient Signature (Name if Minor)	Parent Signature (if needed)
_____	_____
Witness Signature	Date

Physician or Counselor's Statement: I have explained DNA testing to this individual, including the limitations outlined above, and have answered all questions.

_____	_____
Physician/Counselor	Date