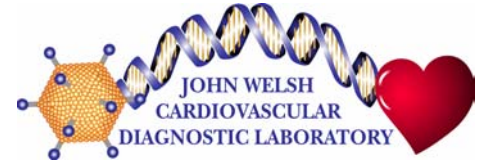

CONSENT FORM

JOHN WELSH CARDIOVASCULAR DIAGNOSTIC LABORATORY



INFORMED CONSENT FOR DNA TESTING

I, _____, hereby agree to participate in testing for (name of disease) _____, using a DNA-based test. I understand that samples of blood/tissue/bodily fluid will be taken from me and/or members of my family. I understand that the blood/tissue/bodily fluid samples will be used for attempting to determine if I and members of my family are carriers of the disease gene, or are affected with, or at increased risk to someday be affected with this genetic disease. Potential risk and benefit of the invasive procedures such as tissue biopsy and fetal cell sampling have been explained to me by the physician who performed the procedures on me. The possible risks associated with blood drawing are pain from the needle, bruising, and very rarely infection. In addition, I hereby give permission to collect blood/tissue/bodily fluid samples from my minor children, named below, to be used for DNA testing for the disease listed above.

Child's Name

Date of Birth

Sex

_____	_____	_____
_____	_____	_____

I understand that:

1. In some cases the DNA directly detects an abnormality, called a mutation, in the gene, and the test is approximately 99% accurate. Rare variations in the DNA of individuals can also cause uncertainty in predicting carrier status or diagnosis. Thus the test is not 100% accurate.
2. An error in the diagnosis may occur if the true biological relationships of the family members involved in this study are not as I have stated. For example, non-paternity means that the father of an individual is not the person stated to be the father. This test may detect non-paternity, and it may be necessary to report this finding to the individual who requested the testing.
3. Any erroneous diagnosis in a family member can lead to an incorrect diagnosis for other related individuals in question. I understand that the DNA analysis performed at the John Welsh Cardiovascular Diagnostic Laboratory for this disease is specific only with respect to it and in no other way guarantees my health or the health of my child. The accuracy of the DNA analysis is entirely dependent on the clinical diagnosis made elsewhere, and the John Welsh Cardiovascular Diagnostic Laboratory cannot be responsible for erroneous clinical diagnoses made at other centers.
4. Generally, these tests are relatively new and are being improved and expanded continuously. The tests are not considered research, but are considered to be the best and newest laboratory service which can be offered. This testing is often complex and utilizes specialized materials so that there is always some small possibility that the test will not work properly or that an error will occur. There is a low error rate (perhaps 1 in 1000 samples) even in the best laboratories. My signature below acknowledges my voluntary participation in this test, but in no way releases the laboratory and staff from their professional and ethical responsibility to me.
5. I understand that my sample is not being banked. The laboratory does not return DNA samples to individuals or physicians. However, in some cases it may be possible for the laboratory to reanalyze my remaining DNA upon request. The request for additional studies must be ordered by my referring physician/counselor and there will be an additional fee.
6. Once my test result is completed, an aliquot of my DNA may be made anonymous (name and all other identifiers removed) and used for research purposes. Any results obtained could not be related to the original source, so no results would be reported.
7. I indicate my desire to opt out of anonymized research studies using my DNA sample by checking this box .
8. Because of the complexity of DNA based testing and the important implications of the test results, results will be reported to me only through the physician or genetic counselor whom I designate. The result reports are confidential; they will only be released to other medical professionals or other parties with my written consent. All laboratory data is confidential and will not be released within legal limit. Participation in DNA testing is completely voluntary.
9. I will receive a copy of this consent form.

Signed

Date

Signed

Date

Physician's/Counselor's Statement: I have explained DNA testing to this individual. I have addressed the limitations outlined above, and have answered this person's questions.

Signed

Date