uchealth

INFORMED CONSENT FOR GENETIC TESTING

_____ _____ _____ - _____ - _____

Patient Name (please print) *MRN* *Date of Birth*

Clinical diagnosis/Analysis of gene(s):_____

I hereby consent to participate in testing for _____using a genetic test.
(Provide corresponding CPT codes)

- I understand that a biologic specimen (blood, tissue, amniotic fluid, or chorionic villi) will be obtained from me and/or members of my family.
- I understand that this biologic specimen will be used for the purpose of 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.

Please select:

This testing is for carrier status or prenatal testing (predictive testing)? ☐ Yes ☐ No

If yes, has genetic counselling been performed? ☐ Yes ☐ No

It has been explained to me and I understand that:

- A positive result is an indication that I may be predisposed to or have the specific disease, or condition. Further testing may be needed to confirm the diagnosis. I understand I will be given the opportunity to talk with my physician or a genetic counselor about these results.
- There is a chance that I will have this genetic condition but that the genetic test results will be negative. Due to limitations in technology and incomplete knowledge of genes, some changes in DNA or protein products that cause disease, may not be detected by the test.
- There may be a possibility that the laboratory findings will be uninterpretable or of unknown significance. In rare circumstances, findings may be suggestive of a condition different than the diagnosis that was originally considered.
- In many cases, a genetic test directly detects an abnormality. Molecular testing may detect a change in the DNA (mutation). Cytogenetic testing may identify whether there is extra, missing or rearranged genetic material. Biochemical methods are sometimes used to look at abnormalities in the protein products that are produced by the genes. Most tests are highly sensitive and specific. However, sensitivity and specificity are test dependent.
- The accuracy of the test depends on correct family history. An error in diagnosis may occur if the true biological relationships of the family members involved in this study are not as I have stated. In addition, testing may inadvertently detect non-paternity. Non-paternity means that the father of an individual is not the person stated to be the father.
- An erroneous clinical diagnosis in a family member can lead to an incorrect diagnosis for other related individuals in question.
- The tests offered are considered to be the best available at this time. This testing is often complex and utilizes specialized materials. However there is always a small chance an error may occur.
- Because of the complexity of genetic testing and the important implications of the test results, results will be reported only through a physician, genetic counselor, or other identified health care provider. The results are confidential to the extent allowed by law. They will only be released to other medical professionals or other parties with my written consent or as otherwise allowed by law. Participation in genetic testing is completely voluntary.
- I understand that the University of Colorado Hospital Clinical Laboratory is not a specimen banking facility and my sample and my sample will not be available for future clinical studies I understand that my specimen will only be used for the genetic testing as authorized by my consent and that my sample will not be used in any identifiable fashion for research purposes without my consent.

My signature below acknowledges my voluntary participation in this test. I understand that the genetic analysis performed is specific only for this disease and in no way guarantees my health, the health of an unborn child, or the health of other family members.

I understand that I may have higher out-of-pocket costs, including deductible expenses for non-covered testing services based on my benefit plan. I also understand that if I receive non-covered services, I may responsible for the entire cost of the services.

Patient Signature_____ Date: _____

Witness Signature_____ Date: _____

Provider's or Counselor's Statement: I have explained genetic testing (including the risks, benefits, and alternatives) to this individual. I have addressed the limitations outlined above, and I have answered this person's questions to the best of my ability.

Provider/Counselor Signature_____ Date: _____