INFORMED CONSENT FOR GENETIC TESTING

Apply Patient Label

I understand that testing for genetic conditions can be complex. My or my child's physician has explained to me the risks, benefits and limitations of the testing, as well as the purpose of this genetic test, which is to look for changes in the genes (called mutations) known to be associated with the following genetic condition or disease:

_____.

I understand:

1. This testing will be done on a small sample of blood or body fluid.
2. Changes in genes (called mutations) often vary in different populations. I understand that the laboratory may need information about my family history and ethnic background for the most accurate interpretation of the test results.
3. Some genetic tests may impact a patient's life in certain ways. Genetic test results may lead to emotional or stressful reactions and may affect family relationships. Test results may also affect a person's ability to obtain life, disability, or long-term care insurance.
4. In some families genetic testing might discover someone is not the biological father (non-paternity), or some other previously unknown information about family relations.
5. No test(s) will be performed and reported on my sample other than the one(s) authorized by my doctor.
6. I know who may have access to my genetic test results, including:
    a. The person tested or their health care decision maker;
    b. Any person specifically authorized in writing by the person tested or that person's health care decision maker;
    c. A researcher for medical research or public health purposes, only if the research is done under federal or state law governing clinical and biological research, or if the identity of the individual is not disclosed;
    d. A third person if approved by a human subjects review committee or a human ethics committee, for individuals subject to an Arizona cancer registry;
    e. An authorized agent or employee of the health care provider, if they perform the test or are authorized to obtain the test results, provide patient care, treatment or counseling, and need to know the information to perform or improve the patient care, treatment, or counseling;
    f. The hospital or provider, for purposes of quality assurance; and
    g. Federal, state or county health agencies, as they may be authorized.
7. When genetic testing shows a mutation, then that person is a carrier or has that condition or disease. Consulting a doctor or genetic counselor is recommended to learn the full meaning of the results and to learn if more tests might be necessary.
8. When genetic testing does not show a known mutation, the chance that the person is a carrier or has that condition or disease may be reduced. There is still a chance to be a carrier or to be affected because the current testing cannot find all the possible changes within a gene.
9. The decision to consent to, or to refuse, the above testing is entirely mine.

10. I have discussed with my or my child's physician the specific disease(s) or condition(s) tested for, and the specific test(s) I am having, including the test descriptions, principles and limitations. I have had the opportunity to discuss the purpose and possible risks of this testing with my physician or someone my physician has designated. I have all the information I want, and all my questions have been answered.

11. In some cases, genetic testing may be performed on the patient's family members in order to assess potential genetic conditions that may be inherited. If genetic testing will be performed on the parents and/or siblings of the patient, I understand that I am consenting to testing on behalf of myself and my children. If I am not a patient of PCH, I understand that PCH may only be analyzing the results of such testing for purposes of diagnosis and treatment of my child, and I should follow-up with my own physician regarding any results pertaining to me. I also understand that the results of my genetic testing or of the patient's siblings, as applicable, may be placed in my child's medical record.

12. After testing is complete, the de-identified specimen may be used for test development and improvement for the testing laboratory, internal validation, research (in compliance with applicable law governing clinical and biological research), quality assurance, and training purposes. Specimens are not returned unless specific prior arrangements have been made.

SIGNATURES

By signing below, I consent to my voluntary participation in the testing, or my child or children receiving such testing. I understand that the genetic analysis performed by PCH in no way guarantees my health or the health of my child/children. I have full legal authority, on behalf of myself and/or the minor children listed above, to consent to such testing.

Patient/ Legally Authorized Representative Signature _____ Date _____

Patient/ Legally Authorized Representative Printed Name _____ Relationship to Patient _____

Witness Signature _____ Witness Printed Name _____ Date _____

(I have explained the above genetic testing, including the risks, benefits, alternatives, and expected results, to the patient/patient's legally authorized representative named above and answered any questions to his/her apparent satisfaction.)

Practitioner Signature _____ Practitioner Printed Name _____ Date _____ Time _____

Interpreter Signature/Telephonic ID Number _____ Interpreter Printed Name _____ Date _____