DEPARTMENT OF PATHOLOGY AND LABORATORY MEDICINE
PRECISION DIAGNOSTICS – INHERITED DISEASE

Consent Form

Note: If Consent Form is absent, incomplete or unsigned, our policy is to extract DNA and wait for the paperwork before running the test.

Patient's Last Name: _____ **First Name:** _____ **MI:** ____
Hospital/ID Number: _____ **DOB** _____/_____/_____ (MM / DD / YYYY) **Sex:** M____ F____ O ____
Guardian's Name(s) and relationship to patient (if patient is a minor): _____
Patient's full mailing address + zip_____
_____
Phone, H: _____ **W:** _____ **ext.** _____ **Mobile:** _____
Email address: _____
I request DNA analysis for (genetic condition): _____
Test Number(s) _____ **The intended purpose is:**

__ Diagnostic __ Carrier identification __ Prenatal diagnosis __ Other
__ Sequencing __ Specific known mutation(s) __ Panel of mutations __ Deletion/Duplication

I give my consent to have my sample(s) sent to the CHCO Precision Diagnostics Laboratory for DNA testing for the above-designated genetic condition(s)/test number(s). I have discussed the principles, benefits and risks of this testing with a physician / geneticist / genetic counselor, and I have had my questions answered. I understand the following benefits, risks and limitations:

1. While DNA testing is a valuable diagnostic tool, it may not always give a definite answer about the genetic status of an individual. More specific information will be reported with the results of the test. Results will be sent to the referring healthcare provider / facility.
2. This DNA test is specific only for the condition(s)/ test(s) named above.
3. While mutation analysis often gives precise information, there are several possible sources of error. These include but are not limited to: clinical misdiagnosis of the condition, sample misidentification, incorrect paternity identification, & sample contamination.
4. The test is complex. It is not FDA approved. It uses some reagents produced for research purposes only. There is always a possibility that a diagnostic error may occur. Also, the laboratory may have difficulties analyzing my sample and a second sample may be requested. In the unlikely event that the test fails to produce a result, a repeat test will usually be offered at no extra charge.
5. The test may reveal previously unrecognized biological relationships, such as non-paternity. DNA tests may also reveal a genetic condition in another family member.
6. **After the DNA testing of my sample is completed, the DNA may be used for medical research or test development.**
Please check here YES_____ NO_____

Refusal to permit use of my sample for research will **not** affect this test procedure. I am free to withdraw this consent at any time without prejudice to future care. I can withdraw my consent by contacting the laboratory director.

7. **I understand there will be a fee for this DNA testing** _____ (signature)
8. DNA testing may involve emotional stress and may result in discrimination (insurance-or work-related). The results of this testing will be treated in the standard manner to ensure medical confidentiality. The laboratory is obligated to release test results to my insurance provider or other payer if the provider / payer asks for them in order to pay for the test.
9. For additional questions regarding the results I can contact the laboratory at (720) 777-6711 and speak with a lab director or genetic counselor.
10. I can decide not to receive the results of the test, but I will still be responsible for the cost of the test.
11. In the event of physical injury resulting from this procedure the Children's Hospital Colorado is not able to offer financial compensation or to absorb the cost of medical treatment.
12. Any disputes that may arise in relation to the DNA testing shall be governed by the laws, rules and regulations of the State of Colorado, as are now in effect or as may be later amended or modified, without reference to the choice of law or rules of any state. I submit to the exclusive jurisdiction and venue of any court having subject matter jurisdiction located in the City and County of Denver, State of Colorado, including the United States District Court for the District of Colorado, in the event of any litigation concerning the DNA testing, regardless of where this consent is executed or where I reside.

A. Name of Physician / Geneticist / Genetic Counselor: _____
Statement by Physician / Geneticist / Genetic Counselor: I have explained DNA testing to this person. I have addressed the limitations outlined above and have answered his / her questions. **Signature:** _____ **Date:** _____
B. Patient or Legal Guardian (print name): _____
Signature of Consent: _____ **Date:** _____
C. Person who is witnessing the consent, Printed Name: _____
Signature of Witness: _____ **Date:** _____

Children's Hospital Colorado complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. • ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1-720-777-1234. • CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1-720-777-1234.