

## Informed Consent – Genetic Testing

<b>Patient:</b>	<b>Date:</b>
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### Treatment or Procedure:

Your doctor has suggested that you have the following treatment or procedure:

- Collection of a sample from me, my fetus, or my child to be sent to the Advanced Diagnostic Laboratories at National Jewish Health to test for the below-designated genetic condition.

Your condition and the reason for the treatment or procedure is:

Before agreeing to have this treatment or procedure it is important that you read and understand this consent form. This consent describes the treatment or procedure and any of the risks that it may involve. Please ask your doctor to explain any words or information that you do not clearly understand.

### What is involved in the procedure?

For blood specimens only: No more than 30 mL (approximately 1 ounce.) of blood will be obtained. If you agree to participate, an intravenous needle will be placed in your arm for the removal of blood samples. This may be left in for approximately 2 minutes.

### Will you need sedation during the procedure?

No

### What are the benefits of having this treatment or procedure?

The benefits include:

DNA test results may:

1. diagnose whether or not I have this condition or am at risk for developing this condition
2. indicate whether or not I am a carrier for this condition
3. predict another family member has or is at risk for developing this condition
4. predict another family member is a carrier of this condition
5. be indeterminate due to technical limitations or familial genetic patterns
6. reveal non-paternity, or some other previously unknown familial genetic patterns

### What may happen if you refuse this treatment or procedure?

May make the possibility of correct and/or appropriate treatment difficult.

### What are the risks and discomforts of the treatment or procedure?

- DNA testing may cause emotional stress; for example you may have concerns about discrimination (insurance or work-related). National Jewish Health is committed to protecting your privacy, and treating all results with medical confidentiality.
- For blood collections, there may be temporary pain and swelling at the draw site.
- Results will be released only to the physician ordering the test, an insurance provider requiring test results for reimbursement purposes, persons designated by me in writing, or as required by law.
- Although genetic analysis usually yields precise information, several sources of error are possible. These include, but are not limited to, clinical misdiagnosis of the condition, sample misidentification, sample contamination, and inaccurate information regarding family relationships.
- This genetic test is specific only for the condition named above. It will not detect all mutations possible within this gene, nor detect mutations in other genes.
- The significance of a positive and a negative test result based on my family history has been explained.

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**What are the alternatives to the treatment or procedure?**

The other options to this procedure include:

Not testing for the genetic condition.

**What are the benefits and risks of the alternatives?**

Benefits: None

Risks: If your caregivers do not know that you have the genetic condition they may not be able to offer you the best treatment.

**Will my health information be kept confidential?**

In most cases, only members of your treatment team will have access to your protected health information. Sometimes we are required to report information to a public agency such as the Colorado Department of Health and Environment. If you have certain infectious or reportable diseases, we will disclose them as required by law or regulation. Examples include HIV, meningitis, or TB.

**No Guarantee:**

- I understand that no guarantee or assurance has been made concerning the results of the treatment or procedure and that it may not cure or diagnose my condition.
- National Jewish Health may contact me if new information is learned that affects the interpretation of previously reported test results. A reasonable effort will be made to contact me through my physician, or another person designated in writing. I may indicate my desire to opt out of being contacted by checking this box .
- **DNA analysis is a fee-for-service test. I will be responsible for payment after the testing has begun, even if I decide not to receive results.**
- My (or my child's or my fetus') sample may be used for test validation or education after personal identifiers are removed. Refusal to permit the use of my sample will not affect my test result. For such use, the sample may be stored indefinitely. I can withdraw my consent at any time by contacting the laboratory at (800) 550-6227 or by checking this box . For more information about the Advanced Diagnostic Laboratories at National Jewish Health, please refer to [www.njlabs.org](http://www.njlabs.org).

**What if I have questions?**

If I have any questions about the treatment or procedure I will ask my doctor before signing this consent. I will not sign this consent unless I have read and understand the procedure.

I hereby authorize \_\_\_\_\_ and whomever he/she  
may desire as associates to perform upon \_\_\_\_\_  
the procedure described above.

**I acknowledge that my doctor has fully explained the procedure in words I can understand and that all my questions have been answered to my satisfaction.**

<b>Patient or Parent/Guardian</b>	<b>Date and Time</b>

**Physician Statement:**

**I have explained DNA testing and its limitations, benefits, risks, consequences, and alternatives, along with the benefits, risks and side effects related to the alternatives, and the risks related to not receiving the proposed care, treatment, and services with the patient or guardian. To the best of my knowledge, the patient or his/her guardian understands such consent to the proposed treatment/procedure.**

<b>Physician Signature</b>	<b>Date and Time</b>