

Sanford Medical Genetics

Informed Consent for Genetic Testing

This testing is for _____ (Condition and/or Test Name), as ordered by my, or my child/dependent's, healthcare provider and I give permission for a sample to be collected for the ordered test above.

I understand and consent (agree) to the following:

- If I choose to consent to or refuse the above testing that is completely up to me.
- I understand that this genetic testing may not be paid for by insurance and that I may have to pay for this genetic testing.
- My provider or a member of their team have discussed with me:
 - Relevant health and family history
 - The condition being tested for
 - The purpose, description, and potential uses of this test
 - Positive and negative results and the level of certainty that a positive result for a genetic condition will lead to the condition developing
 - The availability and importance of genetic counseling
 - I was provided with information for a genetic counselor or medical geneticist that can provide counseling on all of the above topics and understand that I may ask for counseling before signing this consent.

Results of the testing

- Genetic test results may include but are not limited to:
 - Positive result (showing a genetic finding) means that:
 - A diagnosis of a genetic condition, and/or
 - A carrier status of a genetic condition, and/or
 - The possibility of getting a genetic condition in the future.
 - Negative result (no genetic change found)
 - This does not mean the genetic condition being tested for will not occur or is not already present.
- Variant of uncertain significance (a genetic change whose effect is not known)

I understand:

- A positive test result may mean that I am at risk for or have a genetic condition.
- More testing may be recommended by my healthcare provider.
- The results may help me make informed choices about future health care, but some genetic results do **not** have health care guidelines.
- Genetic testing may reveal facts not related to the reason for the test. For example, finding someone is not the biological parent, or some other previously unknown family relationships.



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Limits of testing

- This test is only looking for genetic changes in the areas covered by the test.
- There may be a genetic change outside the area tested. This change will **not** be found by the test.
- It is possible that the quality or amount of sample sent for testing may not be good enough for testing or that a genetic change is **not** found.
- Although genetic results are usually without error, there may be an error in the test results. This can be caused by:
 - Incorrect information provided regarding family history
 - Sample mislabeling or contamination of the sample
 - Past blood transfusions or bone marrow transplantation

Privacy

I understand:

- My genetic test results will be a part of my health record and I will receive notice when they are available.
- The confidentiality of my medical record is protected by the federal privacy law known as HIPAA (Health Insurance Portability and Accountability Act).
- How information in my medical record is accessed, used, and disclosed is explained in Sanford Health's Notice of Privacy Practices.
- Federal law does **not** allow health insurers and employers to discriminate based on genetic information. This law is known as the Genetic Information Non-discrimination Act of 2008 (Public Law 110-233).
- I can consult with my legal advisor to find out what impact the genetic test results may have on my life, long term care, or disability insurance.

Sample Storage

- The laboratory will keep the sample after the result is issued for a period of time in the case that follow-up testing is needed.
- After follow-up testing, personal information will be removed from your sample.
- Samples without personal information will be kept and may be used for research and making new clinical tests or improvements to current tests.
 - If you do not want us to keep your sample for any reason other than follow-up diagnostic testing, call (605) 404-4350

My signature below indicates: I have read this form, or it has been explained to me. I have been given the chance to ask all my questions. I have been told and understand the risks and choices I have related to genetic testing. I agree to have the genetic test indicated above.

Patient/Parent/Guardian Signature

Date

Time

If not the patient, state relationship to patient: _____

Witness

Date

Time