



Consent for Whole Genome or Exome Testing Using Next Generation Sequencing (NGS)

To give the best medical care, we have ordered genetic testing for you or your child. We may also ask for your family’s health history.

Genes carry information for making and growing cells in your body. The information in your genes gets passed on when you have children. Some health problems are linked to changes in genes, called “mutations.” Genetic testing can help us find these changes. Newer genetic tests let us study thousands of different genes in one test.

We have ordered the genetic test checked below:

- Whole Genome Sequencing (WGS)** finds changes in your whole genome, which contains **all** 3 billion letters of genetic code in your cells.
- Whole Exome Sequencing (WES)** finds changes in only the **part** of the genome that tells your cells how to make proteins.

What you should know before genetic testing

Here’s a list of things you and your doctor should talk about **before** you sign this consent. If there’s anything in this list you **don’t** know or **don’t** understand, please ask a member of your care team.

Please write your initials if you agree and fill in where needed:

- ____ The reason for my (or my child’s) genetic testing is for this health problem:

- ____ I know what type of genetic test is being done and how you will use the results.
- ____ I know the possible benefits and risks of having this test.
- ____ I know my other choices if I decide not to have genetic testing.
- ____ I have told my doctor if I have any special concerns. My special concerns are:

Notes to clinician: •If an item doesn’t apply, write N/A. •If the patient does NOT agree, they should cross out the line and initial it. •If the patient refuses to initial a line, write “patient refuses to initial” and write your own initials.

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Please write your initials if you agree.

- I agree that you may collect and test genetic information in the sample you take from me or my child. This testing is for the health problem listed on page 1 of this form.
- I understand that the lab uses a kind of test called next generation sequencing (NGS). The lab will look at all the genes tested.
- I understand that the lab will study the data from the sample. They will look for a genetic cause for the health problem listed on page 1 of this form. The lab will send a report to my doctor.
- I understand that genetic testing may not find a clear cause for the health problem. Studies show that only 2 or 3 patients out of 10 get a clear answer from genetic testing.

Secondary findings

Because the test looks at thousands of different genes, the lab may find other genetic changes, or mutations. These may have nothing to do with the health problem that prompted the tests. We call them “secondary findings.” They could be important to the health of the person tested. (For example, a mutation may raise your risk of getting cancer.)

Please initial only one choice below:

If there are secondary findings that are **important to the health** of the person tested:

- I want to get these results.
- I **don’t** want to get these results.

Variants of Uncertain Significance

This test may find many gene changes. These changes are called “variants.” Some variants are harmless. Others can cause disease. Sometimes it’s **not** clear if a certain variant is important. These variants are called “variants of uncertain significance.” We **don’t** report these variants unless we strongly suspect a link to disease. If you’d like a list of any variants we find, ask the doctor who ordered your genetic test.

<p>Notes to clinician: •If an item doesn’t apply, write N/A. •If the patient does NOT agree, they should cross out the line and initial it. •If the patient refuses to initial a line, write “patient refuses to initial” and write your own initials.</p>

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Data storage and using data in research

Please initial if you understand and agree:

____ The lab will keep the genetic sample taken from me or my child for more testing in the future.

____ The lab will keep all the information used for the report for 90 days after the report comes out. This follows federal law. I understand that the lab may use both the information and the sample again if more tests are ordered during this time.

____ After 90 days, the lab can't use my information for any more testing. The lab may give the information to the University of Minnesota for research. The lab will assign unique code numbers to the information. That way, no one will know that the information is about me or my child. I understand that I won't get the results of any research.

If you do not want your information used for research in the future, initial the line below:

_____ **I do not want the information from my genetic testing used in any type of research.** The lab may only keep records about the test that was ordered. They must destroy all other information.

Please sign below.



_____ Relationship to patient _____ Date _____ Time

Patient, parent or authorized decision-maker

If you have questions, please talk to the doctor who ordered your tests.

Staff to complete: I have explained the collection and testing of genetic material to the patient, parent or legal representative. I have also explained how we will use this information.

Signature

Printed Name

Date and Time

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