

## WHOLE EXOME SEQUENCING (WES) AND WHOLE GENOME SEQUENCING (WGS) CONSENT

Patient Last Name \_\_\_\_\_ Patient First Name \_\_\_\_\_ MI \_\_\_\_\_ Date of Birth (MM / DD / YYYY) \_\_\_\_\_ Genetic Sex \_\_\_\_\_

### WHOLE EXOME SEQUENCING (WES) AND WHOLE GENOME SEQUENCING (WGS) CONSENT

This consent form can only be used for whole exome sequencing and whole genome sequencing. Consent forms for other tests are located at Baylor Genetics' website (<https://www.baylorgenetics.com/consent/>).

For the purposes of this consent, "I", "my", "you", and "your" can refer to you, your child, your unborn child, or other individual you are the legal representative of.

### TEST INFORMATION

Your healthcare provider (doctor, genetic counselor, or other person with medical training) wants to order a genetic test called Whole Genome Sequencing (WGS) or Whole Exome Sequencing (WES). These tests look for changes, called variants, in a person's DNA that can cause health issues. DNA is our genetic material. These variants can be in certain genes, specific parts of our DNA that are needed for our health. They can also be found in other places in the genome (all DNA that a person has). Based on your known health issues, variants in your DNA that may cause these issues will be reported. This test may explain your health issues. It may also explain health issues that your family may have. Even if this test finds the cause of your health issues, this may not help treat or manage those issues.

Testing where your DNA is compared to one or more family members may be performed. This may help better understand your results or show if your family members have the same variant as you.

Before you sign this consent form, you should speak with your healthcare provider. They can help you understand this testing and what it means for your health.

### TEST RESULTS

There are several types of test results that may be reported including:

- **Positive:** A variant in the DNA was found that is related to your health issues or a health issue that you are at an increased risk of having in the future. These changes that cause disease are also known as pathogenic variants.
- **Negative:** No variants in the DNA were found that are related to your health issues or that would increase your risk of a health issue in the future.
- **Variant of Uncertain Clinical Significance (VUS):** A variant in the DNA was found that we do not know its effect, if any, on health. More testing may be needed for you or your family if a VUS is found that may be associated with your health issues.
- **Secondary and Incidental Findings (Optional):** Testing can sometimes find a variant in the DNA not related to the reason for testing but can change your medical care. **Note:** Certain issues within the brain start in adulthood and get worse over time (neurodegenerative). They often have no cure or treatment. By default, these variants will not be reported unless they are related to your health issues. However, variants in one or more of these gene(s) can be requested if needed. Your provider must write each gene needed in your test order.
- **Genes of No Known Disease Association (Optional):** Testing may find a variant in a gene that is not known to cause disease. This may be helpful to learn more about these genes in the future. These results do not currently impact medical management or indicate a diagnosis.

### SECONDARY AND INCIDENTAL FINDINGS

The following categories of variants are not expected to cause your current health issues. However, they can each be requested to be reported. Knowing about these variants might affect your future medical care.

- **ACMG Secondary Findings:** The American College of Medical Genetics and Genomics (ACMG) recommends reporting disease-causing variants in certain genes that cause health issues. Each family member can request this group of variants to be reported.
- **Incidental Findings:** Other variants known to cause health issues but that are not causing your current health issues.

### CONSIDERATIONS AND LIMITATIONS

- You should speak with your provider before signing this consent form to understand the risks, benefits, and alternatives to testing.
- Testing may show you have, or are at increased chance of having, a health issue. It may show that you have an increased chance of having a child with a health issue.
- Even if the variant(s) causing your health issues are found, how these issues might progress or improve with treatment might not be known. Affected family members with the same variant might not be affected like you are.
- Depending on the results of testing, more testing may be needed to understand these results. This testing might be needed for you and/or other family members.
- A negative result does not rule out the chance for health issues. Our knowledge of variants and how they cause disease may change over time as we learn more about genetics. Testing has limitations to what it can find as well.
- Certain factors may lead to incorrect results. These include mislabeled samples, incorrect information in the test order, and rare technical errors.
- More sample may be needed from you if the first sample is not sufficient to complete testing.

### FOR SAMPLES FROM NEW YORK STATE RESIDENTS

Samples from New York State residents shall not be included in research without written consent. Samples will not be retained for more than sixty (60) days after receipt by Baylor Genetics, unless authorized by marking below. No tests other than those authorized shall be performed on the samples.

☐ I authorize Baylor Genetics to retain sample(s) longer based on our retention policy for test development, quality assurance, and training purposes.

### PATIENT CONFIDENTIALITY AND SAMPLE RETENTION

- If several family members are tested, knowing the correct biological relationships among them is important. In rare cases, testing can show that family members are not related as expected. If this is found, we may contact the provider who ordered your testing.
- If this testing is requested to be cancelled after the order and sample are sent to the laboratory, please see our Test Cancellation Policy at [www.baylorgenetics.com/cancel-test/](https://www.baylorgenetics.com/cancel-test/).

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### PATIENT CONFIDENTIALITY AND SAMPLE RETENTION (CONTINUED)

- Only Baylor Genetics and its contracted partners will have access to your sample for the ordered testing. Results from testing will only be released to: (i) a licensed healthcare provider, (ii) those authorized in writing, (iii) the patient or their personal representative, and (iv) those allowed access to test results by law. You have the right to access your test results from Baylor Genetics by providing a written request. You also have the right to request raw data obtained from your sample by providing a written request or HIPAA Authorization Form.
- In rare cases, people with genetic diseases may have problems with health insurance and employment. The U.S. Federal Government has several laws that prohibit discrimination based on test results by health insurance companies and employers. These laws also prohibit unauthorized disclosure of this information. For more information, please visit [www.genome.gov/10002077](http://www.genome.gov/10002077).
- Samples will be kept in the laboratory based on our retention policy. Once testing is completed, the de-identified sample may be used for test development, quality assurance, and training purposes. Samples are not returned to patients or providers unless requested prior to testing. You and your heirs will not receive payments, benefits, or rights to any resulting products or discoveries.
- The information from your testing may be used in scientific research, publications or presentations, but your specific identity will not be revealed. We may contact your provider to obtain more clinical information about you. Baylor Genetics also performs other types of scientific research and may contact you to see if you would like to be involved.
- Variants found may be submitted to databases. The medical community uses these databases to collect information about how variants might cause disease to improve testing and treatment for patients. An example is ClinVar, a free, public archive of reports on human genetics. Limited clinical information may need to be shared with these databases. In rare cases, this information may be enough to allow you or your family members to be identified.
- For more information on privacy practices at Baylor Genetics, please visit [www.baylorgenetics.com/privacy-practices/](http://www.baylorgenetics.com/privacy-practices/).

### FINANCIAL AGREEMENT

By signing below, I hereby authorize Baylor Genetics to provide my insurance carrier any information necessary, including test results, for processing my insurance claim. I understand that I am responsible for any co-pay, co-insurance, and unmet deductible that the insurance policy dictates. I designate Baylor Genetics as my designated representative for purposes of appealing any denial of benefits by my insurance carrier. I irrevocably assign associated payment to Baylor Genetics, and direct that payment be made directly to Baylor Genetics. Please note, some payers may not cover certain screening tests.

If my health insurer does not cover the test or I do not have health insurance, I have received a good faith estimate of the cost for the genetic testing ordered by my provider and agree to pay for the cost of the genetic testing billed to me by Baylor Genetics based on that good faith estimate. More information is available in Baylor Genetics' No Surprises Act and Good Faith Estimate Notice located at <https://www.baylorgenetics.com/no-surprises-act/>.

A Medicare Advance Beneficiary Notice (ABN) is required for services Medicare identifies as not medically necessary.

### PATIENT AUTHORIZATION

By signing this statement of consent, I acknowledge that I have read, understand, and hereby grant my informed consent for genetic testing. I have received appropriate explanations from my healthcare provider about the planned genetic test(s) and possible results. I have been informed by my healthcare provider about the availability and importance of genetic counseling and have been provided with written information identifying a genetic counselor or medical geneticist who can provide such counseling services. All my questions have been answered, and I have had the necessary time to make an informed decision about the genetic test(s).

**Note: If Prenatal WES was ordered, please leave the Patient section blank and complete only a section for each relative tested below.**

I hereby give permission to Baylor Genetics to conduct genetic testing as recommended by my healthcare provider.\*

Patient Name \_\_\_\_\_ Patient Signature \_\_\_\_\_ Date Signed (MM / DD / YYYY) \_\_\_\_\_

Relationship to Patient Name Signature Date

Relative 1

Relative 2

Relative 3

If one or more family members have a Representative signing on their behalf:

Name Signature Date (MM / DD / YYYY) Representative For Relationship to Represented Person(s)

\*If you are signing on behalf of the patient as the parent(s) and/or person with legal authority to act on behalf of the patient or parent, you may be required to provide evidence of your authority.

### FOR SURROGATES PREGNANCIES – FOR PRENATAL WES ONLY:

Maternal cell contamination (MCC) studies use blood or another sample from a pregnant person. MCC studies are used to determine that the sample being tested belongs to the fetus and not the pregnant person. The results of MCC studies are not used for the treatment or management of the fetus, pregnant person, or other individuals, and are not part of the pregnant person's designated medical record.

I hereby give permission for my sample to be used for MCC studies:

Surrogate Name \_\_\_\_\_ Surrogate Signature \_\_\_\_\_ Date Signed (MM / DD / YYYY) \_\_\_\_\_