**Genetic Insights / Dr. Michael P Vaughn**

**Patient Registration / MR # \_\_\_\_\_\_\_**

Full Legal Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ DOB \_\_\_/\_\_\_/\_\_\_\_

Preferred Contact number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Alternate number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Mailing Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

E-mail: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \*Required by Testing Services

Legal Guardian: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Contact Number:\_\_\_\_\_\_\_\_\_\_\_\_\_

**Consent for Medical Care and DNA Testing by Genetic Insights**

When Genetic Consultation services are requested to determine the appropriate testing for a suspected disease, the patient authorizes the Physician to create a medical record of the office visit and to store any DNA testing results in that record. The Physician will protect the information in their record, as per applicable HIPAA guidelines / regulations, and will release this information to others *only* after a written consent is signed by the patient or their legal guardian. Consent for DNA testing will be required by the Genetic Diagnostic Services used for testing (Galleri, InVitae, GeneDx).

 A person’s “Genome” is the term used to describe the collection of all the genes (DNA code) in their cells. Each person carries 2 copies of every gene in their cells, one originated from their mother’s egg and the other from their father’s sperm. A gene either makes a protein that has a specific function in the body or it plays a role in controlling the activity of the protein producing genes as an on-off switch (Regulatory genes). Genetic testing is extremely accurate for identifying genetic abnormalities (Variants or mutations) in a person’s DNA code. A single genetic anomaly may have no adverse effect on a person’s health, especially if a disease is only possible when **2** abnormal genes are present in a cell (Recessive inheritance). The services you receive from “Genetic Insights” will provide you with the information you need to know about how a gene may affect you personally and also how this gene (trait) may be passed on to your offspring.

The epigenetic modifications of DNA evaluated by the “Galleri” Cancer screening test detects changes that result in turning off tumor suppressor genes. When this occurs, unrestricted cell growth can result (Cancer). The Galleri test does not test for DNA mutations that cause cancer. Epigenetic modifications of DNA can change a gene function but these changes are not permanent and therefore are not transmittable to an offspring (not inherited). If Galleri testing identifies a “tumor signal”, based on the reported tissue of origin, you will be referred to an appropriate Specialist trained in performing “tumor hunts” and if found, a biopsy of a suspected tumor is typically needed to confirm any malignant features.

 If a patient seeks Counseling from “Genetics Insights” for a DNA test that was already completed, they must bring the test report to their initial consultation for entry into their medical record.

 If applicable, suggestions will be made concerning possible changes a patient can make to decrease the impact of a genetic variant (mutation) on their health. If requested, genetic testing results will be provided to any Physician designated by the patient or guardian. **You can provide your DNA testing results to your siblings and / or children however, if we have not established a Professional Medical relationship with them, counseling them on how your DNA testing results might impact their health is not a part of your medical service. Please be aware that the counseling materials we provide you may not always be applicable to them**. \*If you share your DNA testing results with a relative, they can establish a Doctor-Patient relationship with us for their own personal consultation and if appropriate, DNA testing.

I understand the limitations on the Medical Services Genetic Insights will provide me.

Patient / Guardian signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ date \_\_\_/\_\_\_/\_\_\_\_

\*I am authorized to use the Credit Card listed below and I accept the charge for an appointment reservation fee of $150. I understand that this will be charged immediately and credit for this charge will be applied to my office visit fee for only the day of my scheduled appointment. This charge is fully refundable if a cancellation is made 24 hrs. or more prior to the appointment (Cancellation notices can be left for us on our time stamped voice mail). \*When a Physician see a patient who arrives late for their appointment, this adversely impacts the scheduled appointments for all patients who come after them and also inappropriately reduces the physician’s time that was committed to each of them. Therefore, arriving more than 10 minutes late will automatically result in ***your*** appointment cancellation and deposit forfeiture. Traffic into Stone Oak can be unpredictably heavy, plan accordingly.

Appointment date assigned: \_\_\_/\_\_\_/\_\_\_\_ Time : \_\_\_\_\_\_\_\_\_

CC# \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ / Exp. Date \_\_\_/\_\_\_\_ CCV# \_\_\_\_\_\_\_

Name on Card: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Verbal consent taken by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_/\_\_\_/\_\_\_\_

*Complaints concerning a breach of medical ethics or inappropriate medical care provided by any Physician or Physician Assistant should be reported to the Texas State Medical Board by calling 800-248-4062 or visiting their web site:www.tmb.state.tx.us*

**GeneDx Consent for Testing:**

What is genetic testing? DNA provides instructions for our body’s growth and development. Genes are distinct sequences of DNA, and are arranged on chromosomes. The DNA in a gene contains instructions for making proteins, which determine things like growth and metabolism as well as traits like eye color and blood type. Genetic disorders are caused by certain changes in DNA affecting the structure or number of chromosomes. Genetic testing is a laboratory test that tries to identify these changes in chromosomes or the DNA. Genetic testing can be a diagnostic test, which is used to identify or rule out a specific genetic condition. Genetic screening tests are used to assess the chance for a person to develop or have a child with a genetic condition. Genetic screening tests are not typically diagnostic and results may require additional testing. The purpose of this test is to see if I, or my child, may have a genetic variant or chromosome rearrangement causing a genetic disorder or to determine the chance that I, or my child, will develop or pass on a genetic disorder in the future. ‘My child’ can also mean my unborn child, for the purposes of this consent. If I/my child already know the specific gene variant(s) or chromosome rearrangement that causes the genetic disorder in my family, I will inform the laboratory of this information. What could I learn from this genetic test? The following describes the possible results from the test: 1) Positive: A positive result indicates that a genetic variant has been identified that explains the cause of my/my child’s genetic disorder or indicates that I/my child am at increased risk to develop the disorder in the future. It is possible to test positive for more than one genetic variant. 2) Negative: A negative result indicates that no disease-causing genetic variant was identified by the test performed. It does not guarantee that I/my child will be healthy or free from genetic disorders or medical conditions. If I/my child test negative for a variant known to cause the genetic disorder in other members of my/my child’s family, this result rules out a diagnosis of the same genetic disorder in me/my child due to this specific change. 3) Inconclusive/Variant of Uncertain Significance (VUS): A finding of a variant of uncertain significance indicates that a genetic change was detected, but it is currently unknown whether that change is associated with a genetic disorder either now or in the future. A variant of uncertain significance is not the same as a positive result and does not clarify whether I/my child is at increased risk to develop a genetic disorder. The change could be a normal genetic variant or it could be disease-causing. Further analysis may be recommended, including testing parents and other family members. Detailed medical records or information from other family members also may be needed to help clarify results. 4) Unexpected results: In rare instances, this test may reveal an important genetic change that is not directly related to the reason for ordering this test. For example, this test may tell me about the risk for another genetic condition I/my child is not aware of or it may indicate differences in the number or rearrangement of sex chromosomes. This information may be disclosed to the ordering health care provider if it likely impacts medical care. Result interpretation is based on currently available information in the medical literature, research and scientific databases. Because the literature, medical and scientific knowledge are constantly changing, new information that becomes available in the future may replace or add to the information GeneDx used to interpret my/my child’s results. Providers can contact GeneDx at any time to discuss the classification of an identified variant. In addition, I or my/my child’s health care providers may monitor publicly available resources used by the medical community, such as ClinVar (www.clinvar.com), to find current information about the clinical interpretation of my/my child’s variant(s). For tests that evaluate data from multiple family members, my spouse, or partner concurrently, results may be included in a single comprehensive report. What is Trio/Duo-based genetic testing? For some genetic tests, including samples from the biological parents and/or other biological relatives along with the patient’s sample can help with the interpretation of results. These tests are often referred to as “trio tests” since they typically include samples from the patient and both parents. Samples from relatives should be submitted with the patient’s sample. Clinical information must be provided for the patient and any relative who submits a sample. I understand that GeneDx will use the relative sample(s) when needed for the interpretation of my/my child’s test results. The patient report may include clinical and genetic information about a relative when it is relevant to the interpretation of the results. Relatives do not receive an independent analysis of data nor a separate report. What are the risks and limitations of this genetic test? • Genetic testing is an important part of the diagnostic process. However, genetic tests may not always give a definitive answer. In some cases, testing may not identify a genetic variant even though one exists. This may be due to limitations in current medical knowledge or testing technology. • Accurate interpretation of test results may require knowing the true biological relationships in a family. Failing to accurately state the biological relationships in my/my child’s family may result in incorrect interpretation of results, incorrect diagnoses, and/or inconclusive test results. In some cases, genetic testing can reveal that the true biological relationships in a family are not as they were reported. This includes non-paternity (the stated father of an individual is not the biological father) and consanguinity (the parents of an individual are related by blood). It may be necessary to report these findings to the health care provider who ordered the test. • Genetic testing is highly accurate. Rarely, inaccurate results may occur for various reasons. These reasons include, but are not limited to: mislabeled samples, inaccurate reporting of clinical/medical information, rare technical errors, or unusual circumstances such as bone marrow transplantation, or the presence of change(s) in such a small percentage of cells that the change(s) may not be detectable by the test (mosaicism). • This test does not have the ability to detect all of the long-term medical risks that I/my child might experience. The result of this test does not guarantee my health or the health of my child/fetus. Other diagnostic tests may still need to be done, especially when only a genetic screening test has been performed previously. • Occasionally, an additional sample may be needed if the initial specimen is not adequate. Patient Confidentiality and Genetic Counseling It is recommended that I receive genetic counseling before and after having this genetic test. I can find a genetic counselor in my area here: www.nsgc.org. Further testing or additional consultations with a health care provider may be necessary. To maintain confidentiality, the test results will only be released to the referring health care provider, to the ordering laboratory, to me, to other health care providers involved in my/my child’s diagnosis and treatment, or to others as entitled by law. The United States Federal Government has enacted several laws that prohibit discrimination based on genetic test results by health insurance companies and employers. In addition, these laws prohibit unauthorized disclosure of this information. For more information, I understand that I can visit www.genome.gov/10002077. International Specimens If I/my child reside outside the United States, I attest that by providing a sample for testing, I am not knowingly violating any export ban or other legal restriction in the country of my/my child’s residence. Additional information about the specific test being ordered is available from my health care provider or I can go to the GeneDx website, www.genedx.com.This information includes the complete gene lists, the specific types of genetic disorders that can be identified by the genetic test, the likelihood of a positive result, the limitations of genetic testing, as well as information about how specimens and information are stored and used. Specimen Retention After testing is complete, the de-identified submitted specimen may be used for test development and improvement, internal validation, quality assurance, and training purposes. DNA specimens are not returned to individuals or to referring heath care providers unless specific prior arrangements have been made. I understand that samples from residents of New York State will not be included in the de-identified research studies described in this authorization and will not be retained for more than 60 days after test completion, unless specifically authorized by my selection. The authorization is optional, and testing will be unaffected if I do not check the box for the New York authorization language. No tests other than those authorized shall be performed on the biological sample. Database Participation De-identified heath history and genetic information can help health care providers and scientists understand how genes affect human health. Though {I/my child} may not personally benefit, sharing this information helps health care providers to provide better care for their patients and researchers to make discoveries. GeneDx shares this type of information with health care providers, scientists and health care databases. No personal identifying information will be shared, as it will be replaced with a unique code. Even though only a code is used for the reporting to the database, there is a risk that {I/my child} could be identified based on the genetic and health information that is shared. GeneDx believes that this is unlikely, though the risk is greater if I have already shared {my/my child’s} genetic or health information with public resources, such as genealogy websites. Recontact for Research Participation Separate from the above, GeneDx may collaborate with scientists, researchers and drug developers to advance knowledge of genetic diseases and to develop new treatments. If there are opportunities to participate in research relevant to the disorder in {my/my child’s} family, and if I have consented for recontact, GeneDx may allow my healthcare provider to be recontacted for research purposes, such as the development of new testing, drug development, or other treatment modalities. In some situations, such as if my health care provider is not available, I may be contacted directly. Any research that results in medical advances, including new products, tests or discoveries, may have potential commercial value and may be developed and owned by GeneDx or the collaborating researchers. If any individuals or corporations benefit financially from these studies, no compensation will be provided

**By signing this form, I acknowledge as the patient or relative being tested that I have read the GeneDx Informed Consent document available from my healthcare provider or at genedx.com/ forms, and I authorize GeneDx to perform genetic testing as ordered.** I understand that, for tests that evaluate data from multiple family members concurrently, results from these family members may be included in a single comprehensive report that will be made available to the tested individual and their ordering healthcare provider.

For insurance billing, I understand and authorize GeneDx to bill my health insurance plan on my behalf, to release any information required for billing, and to be my designated representative for purposes of appealing any denial of benefits. I irrevocably assign to and direct that payment be made to GeneDx. I understand that my out-of-pocket costs may be different than the estimated amount indicated to me by GeneDx as part of a benefit investigation and agree to be financially responsible for any and all amounts as indicated on the explanation of benefits issued by my health insurance plan. I am aware that my insurance provider may send payment directly to me for services performed by GeneDx on my behalf. I agree to endorse the insurance check and forward it to GeneDx within 30 days of receipt as payment towards GeneDx’s claim. If I do not have health insurance, I agree to pay for the full cost of the genetic testing that was ordered by my healthcare provider and billed to me by GeneDx. I further understand and agree that, if I fail to make payment for genetic testing, in accordance with the payment policies of GeneDx, my account may be turned over to an external collection agency for non-payment and I agree to pay any associated collection costs, including attorney fees. More information, including the GeneDx Notice of Privacy Policies, is available on GeneDx’s website: www.genedx.com Medicare: A completed Advance Beneficiary Notice (ABN) is required for Medicare patients. Please visit our website, www.genedx.com/billing for more information. **By initialling here:** \_\_\_\_, I confirm that I am a New York state resident, and I give permission for GeneDx to retain any remaining sample longer than 60 days after the completion of testing, and to be used as a de-identified sample for test development and improvement, internal validation, quality assurance, and training purposes. Otherwise, New York law requires GeneDx to destroy my sample after 60 days, and it cannot be used for the studies listed above. **Initial on this line \_\_\_\_\_** if you wish to opt out of being contacted for research studies.

***By my signature below, I accept full and complete financial responsibility for all genetic testing ordered by my healthcare provider. I wish to pay GeneRx directly for my testing services (do not bill my insurance carrier) or release my genetic testing results to them Initial here \_\_\_\_.***

Name of Patient\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_/\_\_\_/\_\_\_\_

Name of Guardian \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_/\_\_\_/\_\_\_\_