Informed Consent for Genetic Testing

Testing for genetic conditions can be complex. If warranted, obtain professional genetic counseling prior to giving consent to fully understand what the risks andbenefits are to having the testing completed.
I understand that a biologic specimen (blood, tissue, saliva, amniotic fluid, or chorionic villi) will be obtained from me and/or members of my family.
I understand that this biologic specimen will be used for the purpose of attempting to determine if I and members of my family are carriers of the disease gene, or are affected with, or at increased risk to someday be affected with this genetic disease.
I hereby consent to participate in testing for following purpose(s) using a genetic test.

It has been explained to me and I understand that this test is specific for :

Purpose of the genetic test	☐ Diagnostic ☐ Screening ☐ Others : _____
Name of the genetic test	

• A positive result is an indication that I maybe predisposed to or have the specific disease, or condition. Further testing may be needed to confirm the diagnosis. I understand I will be given the opportunity to talk with my physician or a genetic counselor about these results.

• In many cases, a genetic test directly detects an abnormality. Molecular testing may detect a change in the DNA (mutation). Cytogenetic testing may identify whether there is extra, missing or rearranged genetic material. Biochemical methods are sometimes used to look at abnormalities in the protein products that are produced by the genes. Most tests are highly sensitive and specific. However, sensitivity and specificity are test dependent.

• I understand that GC Genome is not a specimen banking facility and my sample will be discarded directly after testing. I understand that my specimen will only be used for the genetic testing as authorized by my consent and that my sample will not be used in any identifiable fashion for research purposes without my consent.

• The tests offered are considered to be the best available at this time. This testing is often complex and utilizes specialized materials. However, there is always a small chance an error may occur.

• There is a chance that I will have this genetic condition but that the genetic test results will be negative. Due to limitations in technology and incomplete knowledge of genes, some changes in DNA or protein products that cause disease, may not be detected by the test.

• Because of the complexity of genetic testing and the important implications of the test results, results will be reported only through a physician, genetic counselor, or other identified health care provider. The results are confidential to the extent allowed by law. They will only be released to other medical professionals or other parties with my written consent or as otherwise allowed by law. Participation in genetic testing is completely voluntary.

• I understand that my sample's raw data will be available at least for 2 years and the report will be available at least for 20 years in the format of electronic or paper for future clinical studies.

• An erroneous clinical diagnosis in a family member can lead to an incorrect diagnosis for other related individuals in question.

• There may be a possibility that the laboratory findings will be uninterpretable or of unknown significance. In rare circumstances, findings may be suggestive of a condition different than the diagnosis that was originally considered.

• The accuracy of the test depends on correct family history. An error in diagnosis may occur if the true biological relationships of the family members involved in this study are not as I have stated. In addition, testing may inadvertently detect non-paternity. Non-paternity means that the father of an individual is not the person stated to be the father.

• Additional testing information can be found at : www.gc-genome.com

Signatures

My signature below acknowledges my voluntary participation in this test. I understand that the genetic analysis performed by GC Genome is specific only for this disease and in no way guarantees my health, the health of an unborn child, or the health of other family members.

Patient Printed Name :	**Birth Date (YYYY/MM/DD) :**
Patient Signature :	**Date (YYYY/MM/DD) :**

Physician's Statement : I have explained genetic testing (including the risks, benefits, and alternatives) to this individual.
I have addressed the limitations outlined above, and I have answered this person's questions to the best of my ability.

Physician Signature :	**Date (YYYY/MM/DD) :**

CAP ACCREDITED
COLLEGE of AMERICAN PATHOLOGISTS

GC Genome Headquarters | 107, Ihyeon-ro 30beon-gil, Giheung-gu, Yongin-si,Gyeonggi-do,South Korea | Online : gc-genome.com | Contact : +82)31-280-9900