INFORMED CONSENT FOR 3B-GENOME

3billion, Inc. ("**3billion**") requires a completed Informed Consent Form ("**ICF**") to be received before the Whole Genome Sequencing Test ("**3B-GENOME**") can begin. The ICF must be completed by the patient, patient's parent (in case the patient is a minor or not capable of consenting) or a legally authorized representative of the patient ("**you/your child**")

What Is Whole Genome Sequencing?

Whole Genome Sequencing (WGS) is a method of genomic sequencing that reads an individual's entire genomic DNA sequence. 3billion's WGS test, 3B-GENOME, is an effective method for identifying genetic changes causing rare genetic disorders.

What Is the Purpose of This Test?

Your Authorised Health Professional ("**AHP**") or your child's AHP is recommending that you or your child receive 3B-GENOME to find a genetic change (i.e., variant) that could explain the medical condition you or your child may have. The test is voluntary.

What Is Needed for This Test?

If you consent to 3B-GENOME, your AHP will take a sample (e.g., whole blood) from you. The sample will be sent to 3billion's laboratories located in South Korea. Under some circumstances, an additional sample may be requested. Should you decide to withdraw from receiving the test, 3billion will destroy the sample and the data upon test cancellation.

What Type of Results Are Reported from This Test?

1. Primary Findings

Positive results: pathogenic or likely pathogenic variants are reported. These variants are clinically significant genetic change(s) that are very likely to cause the medical condition you or your child has.

Inconclusive results: variants of uncertain significance are reported. These variants are genetic change(s) that may cause the medical condition you or your child has but with insufficient evidence. Additional phenotyping and/or family testing may be recommended to help determine the significance of the results.

Negative results: no variants are reported. This means that at the time of testing, there were no variants that can explain the medical condition you or your child has. However, this does not mean that you or your child do not have a genetic condition or are free from genetic disorders or other medical conditions. It is still possible that the causal variant cannot be identified by 3B-GENOME due to (i) certain limitations set forth under the "Test Limitations and Risks" section below and/or (ii) the underlying genetic disorder not being known at the time of testing.

2. Secondary Findings

3B-GENOME may reveal genetic changes that are not directly related to the reason for ordering this test. If "Secondary Findings" are requested, pathogenic or likely pathogenic variants in genes that are considered 'medically actionable' will be reported as set forth in the "Secondary Findings" section.

3. For Family Members

If you are a family member being simultaneously tested as part of a trio testing to aid in the interpretation of 3B-GENOME, your clinical information may also be requested. However, even if you share the same variant reported for your child (i.e., proband), **the information will only appear in the proband's report.** You will receive a separate report for the secondary findings if you opted-in to receive such information in accordance with the "Secondary Findings" section.

Test Limitations and Risks

1. There are certain genomic regions that cannot be sequenced due to technical difficulties with amplification, sequencing and/or alignment. If variants within these regions are suspected, it is recommended to perform alternate testing that are designed to sequence those regions/genes adequately.
2. 3B-GENOME can reliably detect single nucleotide variants, insertions and deletions of 1-50bp in size, structural variants (including copy number variants), and mitochondrial genome variants. If other types of variants are suspected, it is recommended to perform appropriate testing that is designed to detect those types of variants.
3. Your test results are interpreted based on the scientific and medical information currently available; therefore, a negative result does not rule out a specific condition. As medical knowledge evolves, your Authorized Healthcare Provider (AHP) may request a reanalysis of your genetic data. 3billion provides reanalysis as follows: a) Automatic Reanalysis: Certain test types may undergo periodic automated reanalysis based on predefined criteria. If clinically significant updates are identified, an updated report will be sent to your AHP. The Automatic Reanalysis service is valid for 10 years from the initial result, and your physician may renew your consent to extend the service for an additional 10 years. b) Reanalysis Upon Request: For some test types, reanalysis is performed only when requested by your AHP, and may incorporate any new clinical or phenotype information provided. c) No Reanalysis: Certain test types do not include reanalysis services.
4. 3B-GENOME was validated to be highly accurate. However, inaccurate results may still occur. The reasons include, but are not limited to, mislabeled samples, low-quality samples, inaccurate order information, inaccurate medical/scientific information in public databases and/or technical errors. In the event that the patient has undergone a bone marrow or hematopoietic stem cell transplant, it is the patient's responsibility to disclose this medical history to the ordering physician prior to sample collection. If donor DNA is detected and the sample fails final quality control (QC), testing will be terminated and the testing fee will not be refunded with our terms and conditions.
5. 3B-GENOME can identify genetic change(s) that are not directly related to the medical condition 3B-GENOME is being performed for but are considered medically actionable (see the "**Secondary Findings**" section). However, 3B-GENOME should not be considered a screening test for all medical conditions or medical risks that you may experience later.
6. When family members are simultaneously tested as part of a duo or trio testing, there is a risk that other genetic information not related to the medical condition may be revealed. Such information includes medical risk in the family member, non-paternity or non-maternity (i.e., father or mother is not the biological parent). As these types of information can be critical in correctly interpreting the test results, it may have to be shared with your AHP and documented on the report. Alternative testing options, such as proband-only testing, single gene or gene panel testing, are available that will not uncover these types of findings. Consult with your AHP if you are concerned.

Sample Retention

Your sample may be de-identified and used for test development, validation, improvement or training purposes. 3billion will not return the remaining samples to you or your AHP, unless specific prior arrangements had been made.

Data Retention

The Test Requisition Form, Consent Form, Sequencing Data, and Final Report are classified as Pseudonymized Information to protect privacy. 3billion will redact personally identifiable information found in the designated fields of the Test Requisition Form and Consent Form upon receipt. However, 3billion does not screen unstructured data. It is the sole responsibility of the ordering provider to ensure that any personally identifiable information contained in clinical symptom descriptions, free-text notes, or supplemental attached files is redacted prior to submission.
The Final Report will be retained for a minimum of twenty (20) years from the report date to comply with statutory medical record retention obligations. The Original Sequencing Data and associated Clinical and Administrative Data will be retained for a minimum of ten (10) years to support potential re-analysis services. Upon the expiration of the retention period, the data will be processed as follows: 1) If valid re-consent is obtained, the data will continue to be retained as is to support ongoing re-analysis services, 2) If re-consent is not obtained, the data will be considered Research Data and retained for scientific research, statistical, and archiving purposes in the public interest indefinitely under strictly restricted access controls.

Scientific Contributions

The de-identified results of this test may be summarized and used anonymously in case studies at meetings, scientific journals, or uploaded on public genetic variant databases such as ClinVar to improve understanding, diagnosis, and treatment of similar clinical conditions.

Confidentiality/Privacy Protections

To maintain confidentiality of your sample and your Protected Health Information (collectively "**PHI**") collected for the test, 3B-GENOME results will only be released to your AHP, to the ordering laboratory, to you, to other AHPs involved in your diagnosis and treatment upon your request, or as otherwise required by law or regulation. Unless required by law, 3billion will not disclose your PHI to any person or entity without obtaining prior written consent from you. However, the report may become part of your medical record, and your health insurance provider or other entities may have legal access to the information. Furthermore, you have the right to request access to your PHI or request corrections of any errors in your PHI. You also have the right to ask that your PHI be erased, subject to the applicable laws or regulations. If requests for access, correction, completion, or erasure cannot be fulfilled, you will be informed and provided with the reasons why it cannot be fulfilled.

Accreditations and Certifications

CAP License #	**CLIA ID #**
8750906, AU-ID# 2052626	99D2274041

CONSENT & SIGNATURE

Unique ID _____ Date of birth YYYY / MM / DD

For Proband

This page must be completed and submitted with the requisition before testing can begin.

Secondary Findings and Reanalysis

The American College of Medical Genetics and Genomics (ACMG) recommends that secondary findings identified in a specific subset of medically actionable genes associated with various inherited disorders be reported for individuals undergoing 3B-GENOME (PMID: 40568962). Accordingly, 3billion will report secondary findings within this gene list if you agree to receive them. Somatic mosaicism or carrier status in these genes will not be reported.
If you do wish to receive secondary findings, please check the box:

Yes ☐

When primary findings do not yield positive results, 3billion can include your data for the daily variant reclassification using new medical and scientific knowledge.
If you do wish to have your data reanalyzed, please check the box:

Yes ☐

By signing this form, I acknowledge that I have read this Informed Consent Form and understand its content. I had the opportunity to ask questions and my questions have been adequately answered. I also understand that I can withdraw my consent with effect for the future in full or in part at any time, and I have the right not to know the results of the test as mentioned in the preceding description. If the undersigning is the legal guardian of the research participant, he/she herewith confirms to provide the above consent declarations not for himself/herself but on behalf of the respective research participant.

Patient

3billion ID G _____ - _____ (e.g. GPE25-ABCD)

To be filled out by a healthcare provider

Date YYYY / MM / DD

Signature _____

if patient is a minor, Relationship _____

Date YYYY / MM / DD

Signature _____