Informed Consent Form for Germline Genetic Testing

Genecast Innotech Pte. Ltd. (hereinafter referred to as "Genecast" or the "Company") provides testing services for next-generation sequencing analysis of inherited (germline) gene variants associated with hereditary cancer predisposition and other inherited conditions, upon request from licensed medical practitioners. The following information is fully disclosed to ensure subject understands the nature, risks, and limitations of the service. Written consent will be obtained only after subject has read, understood, and agreed to the disclosed information and related authorizations.

Roles & Regulatory Framework

1. In accordance with Singapore's Healthcare Services Act (HCSA):
   - 1.1 Laboratory Role: Genecast operates strictly as a licensed Clinical Laboratory Service provider. Genecast is responsible for sample processing, technical variant analysis, and issuing analytical laboratory reports. Genecast does not offer direct patient consultation, clinical diagnosis, medical treatment, or genetic counseling.
   - 1.2 Ordering Provider Role: The ordering medical practitioner or genetic counselor is responsible for determining test appropriateness, ordering the correct test, clinical interpretation, disclosure of results, pre/post-test genetic counseling, and ongoing patient management.
   - 1.3 Genetic Counseling & Report Release: Pre-test and post-test genetic counseling must be offered by qualified personnel. Test reports are released only to the ordering healthcare provider/institution and not directly to the Subject.

Testing and Risk Disclosure

1. Germline genetic testing
   - 1.1 This test detects inherited (germline) gene variants in blood, saliva, or other tissue samples that may be associated with hereditary cancer predisposition and certain inherited conditions. It may provide information regarding the Subject's own risk of developing specific conditions and the potential implications for biological relatives.
   - 1.2 The test is based solely on the samples provided by the Subject. Results are for medical reference only and do not constitute a clinical diagnosis.
   - 1.3 Due to multiple complex factors, the principles and criteria for data analysis cannot be absolutely precise or objective. Any information contained in the report does not imply that other drugs or treatments are ineffective, nor does it constitute a guarantee of therapeutic efficacy.
   - 1.4 The test results are primarily intended for the purposes explicitly stated in this Consent Form. Should Genecast wish to use the test results for any other purpose not described herein, separate, explicit consent will be obtained from the Subject.
   - 1.5 Possible errors or limitations in the results, which are not attributable to Genecast, may arise from factors including but not limited to: (i) limits of current research on mutations and genomic biomarkers; (ii) sample quality and preparation; (iii) the inherent limitation that not all disease-causing variants can be detected by the test performed; and (iv) misinterpretation arising from incomplete or inaccurate clinical or family history provided to the ordering physician.
   - 1.6 Genecast will provide testing strictly in accordance with standard procedures but is not liable for disclosed or undisclosed risks beyond its control. By signing this Consent Form, the Subject acknowledges the risks, limitations, and benefits of germline genetic testing as described herein.
   - 1.7 The result may be reported as pathogenic/likely pathogenic (a variant that increases disease risk), negative (no such variant detected), or a variant of uncertain significance (VUS), where the clinical meaning is currently unknown and may be reclassified over time. A negative does not exclude a genetic cause for the Subject's condition could be due to limitations in current technology and/or knowledge. Further testing may be required.
   - 1.8 Testing may also reveal unexpected findings, including medically actionable variants in genes unrelated to the primary reason for testing, and may reveal non-paternity/maternity of a presumed parent not previously known to the Subject.
   - 1.9 The test result may have implications for the Subject's blood relatives and can change the estimation of their genetic risk. The Subject should consider sharing relevant results with family members so that they may seek appropriate genetic counselling and testing through their own healthcare providers.
   - 1.10 The Subject should be aware that a genetic test result may result in some forms of discrimination (insurance, employment or other) as they form part of the Subject's medical records and may be accessed by and/or disclosed to a third party who has obtained the Subject's necessary consent or when such access is allowed or required by law. The Subject is encouraged to discuss this with the ordering physician or a qualified genetic counsellor before testing.

Matters Needing Attention in Testing

1. Genecast will provide testing services only after receiving the ordering physician's request form, the Subject's signed informed consent, full payment of testing fees, and qualified samples. No tests other than those authorized will be performed by Genecast.
2. Genecast does not collect or prepare samples. Samples must be transferred or delivered in accordance with standard procedures, and collection, preparation, and transportation are the responsibility of the ordering physician or the Subject.
3. If the submitted sample is insufficient or of inadequate quality, Genecast may request a replacement. Failure or refusal to provide one will make the Subject solely responsible for all resulting consequences, including the inability to issue a report.
4. Genecast will issue the report within the agreed timeframe; however, any delays occurring for reasons unrelated to testing (such as incomplete sample information, transportation issues, poor sample quality, or the need for additional confirmatory analysis) are not the responsibility of Genecast.
5. Genecast will safeguard submitted samples but is not liable for loss or damage caused by accidents or force majeure.
6. Residual samples may be retained in a deidentified form for one (1) year from the date of testing and stored at Genecast Laboratory, Singapore for quality control, test development, validation, and authorised research. Any use of the Subject's residual samples or genetic information for research purposes will be subject to a separate consent form obtained.

© 2024 Genecast #02-01/02, The Kendall, 50 Science Park Road. Singapore Science Park 2, Singapore 117406
Genecast Innotech Pte Ltd is Licensed by the Ministry of Health (Singapore) as a Clinical Laboratory (No.: L/25I0501/CLB/001/252) in accordance with the Healthcare Services Act 2020.

Testing Results and Personal Information

1. **Data Protection Notice**

   PERSONAL DATA PROTECTION NOTICE

   This notice explains how Genecast collects, uses, and protects your personal data in accordance with Singapore's Personal Data Protection Act 2012 (PDPA).

   Data Protection Officer Contact:

   Email: clinicalrequest@genecast.com.sg

   Address: #02-01/02, The Kendall, 50 Science Park Road. Singapore Science Park 2, Singapore 117406

   Your Rights Under the PDPA:

   (i) Right to access your personal data
   (ii) Right to correct inaccurate data
   (iii) Right to withdraw consent (where applicable)
   (iv) Right to request deletion of data (subject to legal requirements)
   (v) Right to data portability

   To exercise these rights, contact our Data Protection Officer using the details above.

2. The Subject has received from the ordering physician or genetic counsellor a clear explanation of the meaning and value of the test results, or has otherwise understood this information, and acknowledges the following:
   (i) The results reflect only the submitted samples as tested under Genecast's standard procedures and do not represent the Subject's overall health status at the time of testing;
   (ii) Any link between the results and the Subject's health or identified disease does not constitute a judgment or guarantee regarding health, disease, or treatment outcomes;
   (iii) The results serve only as reference information to support clinical decision-making by the ordering physician, and cannot be the sole basis for diagnosis or treatment, nor replace or discourage ongoing treatment of value;
   (iv) The interpretation of the results and any resulting clinical decision are made by the ordering physician or genetic counsellor, and not by Genecast;
   (v) Because germline variants may be inherited, the results may have implications for the Subject's biological relatives; the Subject should consider discussing relevant findings with family members and with a qualified healthcare provider or genetic counsellor;
   (vi) A variant of uncertain significance may be reclassified in future as further evidence becomes available. Genecast does not undertake to re-analyse or re-issue a report unless separately requested by the ordering physician in accordance with its reanalysis policy, and any decision to recontact the Subject rests with the ordering physician;
   (vii) The Subject is encouraged to receive genetic counselling before and after germline testing to understand the meaning of the results and their implications for the Subject and the Subject's family;
   (viii) The Subject, or the person(s) authorised to give consent on the Subject's behalf under the Mental Capacity Act (Cap. 177A) where the Subject is a minor or an adult who lacks mental capacity, shall act upon the results only in consultation with the ordering physician or genetic counsellor, and bears the legal consequences of the use of the results;
   (ix) You may withdraw from this test at any time before the test is completed, or postpone the receipt of the test results, by notifying the ordering physician or Genecast in writing. Fees already paid or incurred for services rendered prior to such withdrawal or postponement will not be refunded.
3. Genecast will keep the Subject's personal information confidential and implement reasonable security arrangements to protect personal data from unauthorised access, collection, use, disclosure, copying, modification, disposal, or similar risks, in accordance with the PDPA.
4. The Subject confirms that the personal information and materials provided regarding the Subject are true, accurate, and complete. The Subject agrees to authorise Genecast, its parent, affiliates, and authorised service providers to collect, use, and disclose the Subject's personal information and biological samples for the following purposes:
   (a) completing the testing service and issuing the laboratory report to the ordering physician or requesting healthcare institution;
   (b) improving testing techniques and methods;
   (c) conducting scientific research and publishing results (using anonymised or pseudonymised data where practicable) and for the publication of scientific results (only in an anonymised or aggregated form).
5. Optional Authorisations for Direct Marketing and Other Services (Requires Separate Opt-in Consent): I agree that Genecast and its affiliates may use my personal information to provide me with additional product and service information, health management suggestions, and related notifications.
   [ ] Yes, I agree to receive such information and services.
   [ ] No, I do not agree. I understand that I am providing my consent for my own personal information only, and Genecast will not use the personal information of my family members for the above purposes without their separate consent.
6. The Subject understands and agrees that their personal information may be transferred to Genecast's parent company, affiliates, or data processors located outside of Singapore (e.g., in countries where the data protection level may differ), subject to appropriate safeguards under the PDPA.
7. Any refusal explicitly stated in the "Special Authorization Content" section of this Consent Form will be deemed a prohibition on Genecast exercising these rights, except for personal information necessary to perform the testing services requested.
8. Right to Access and Correction: The Subject has the right to request access to their personal data held by Genecast and to request corrections to any inaccurate or incomplete personal data. To make such a request, the Subject may contact Genecast's Data Protection Officer.
9. Withdrawal of Consent: The Subject may withdraw their consent for the collection, use, or disclosure of their personal data for any purpose, at any time, by providing reasonable notice to Genecast's Data Protection Officer. Withdrawal does not affect the lawfulness of data processed before the withdrawal, and may affect Genecast's ability to provide the testing services.
10. Unless required or permitted by applicable law, Genecast will not use or disclose the Subject' s genetic information or residual samples for any purpose not authorised in this Consent Form after the Subject's death. The Subject may record additional instructions in the Special Authorization Content section below.

© 2024 Genecast #02-01/02, The Kendall, 50 Science Park Road. Singapore Science Park 2, Singapore 117406
Genecast Innotech Pte Ltd is Licensed by the Ministry of Health (Singapore) as a Clinical Laboratory (No.: L/25I0501/CLB/001/252) in accordance with the Healthcare Services Act 2020.

Statement and Warranty of the Subject

1. The Subject fully understands and acknowledges that if any provisions stipulated by laws, regulations, normative documents, or policies regarding genetic testing affect this testing service and its results, such provisions shall prevail.
2. The Subject understands the value and significance of this testing, and voluntarily agrees to undergo the testing and pay the corresponding testing fee.
3. The Subject understands and accepts that Genecast's role is limited to the performance of the laboratory analysis and the issuance of the laboratory report, and that the ordering of the test, the provision of counselling and genetic counselling, the interpretation and disclosure of the results, and the Subject' s clinical management are the responsibility of the ordering physician or genetic counsellor.
4. The Subject fully understands the nature, risks, and necessity of the testing, and authorizes Genecast to handle and utilize the testing samples and any resulting wastes.
5. The Subject guarantees that all clinical data and family history information provided are true, complete, and accurate. If the information is incomplete, inaccurate, or misleading, the Subject shall bear the corresponding legal responsibilities and any losses or compensations.
6. The Subject agrees to keep confidential all undisclosed information acquired during the testing process regarding Genecast's testing procedures, methods, and costs, and shall not disclose such confidential information to any third party without authorization.
7. The Subject fully understands, acknowledges, and agrees to all the terms of this Informed Consent Form, and grants Genecast the relevant rights and permissions after careful consideration.
8. The Subject agrees that the Germline Genetic Testing Request Form and this Informed Consent Form for Germline Genetic Testing constitute an integral part of confirming the legal relationship between the Subject, the ordering physician, and Genecast.

Please read the Informed Consent Form and statement carefully and sign or write special authorization contents separately. Subject represents:

I have been fully informed of the contents and the detailed explanation of this Informed Consent Form. I have carefully read this Informed Consent Form and/or had the information explained to me (and/or translated in the relevant language, if necessary) and confirm that I fully understand the purpose, significance, risks, and limitations of germline genetic testing. I acknowledge that the risks and limitation(s) listed are not intended to be exhaustive.

I have received pre-test counselling and/or genetic counselling from my ordering physician or genetic counsellor, and I understand that post-test counselling and/or genetic counselling will be offered to me when the result is available.

I understand that my laboratory report will be released to my ordering physician or healthcare institution and not directly to me by Genecast, and that the interpretation of my result will be provided to me by my ordering physician or genetic counsellor.

I acknowledge and promise to provide true, complete, and accurate personal information, clinical data, and family history of the Subject.

I voluntarily and personally sign this Informed Consent Form and agree to comply with all commitments, rights, and authorizations stated herein.

Special Authorization Content:

I hereby consent to undergo the following test below

Name of the genetic test:

Subject Signature: **Date:**

(For a subject who lacks, or has limited, capacity to provide informed consent, the Subject's Parent / Legal Guardian signature may be used)

Relationship to Subject: **Date:**

Ordering Physician's declaration:

I confirm that I have explained to the Subject, or the Subject's Parent / Legal Guardian (if applicable), the Subject's medical condition as well as the nature, purpose, risks, limitations, and alternatives regarding the test and have addressed queries of the Subject, or the Subject's Parent / Legal Guardian (if applicable).

Ordering Physician Signature: **Date:**

Ordering Physician Name:

© 2024 Genecast #02-01/02, The Kendall, 50 Science Park Road. Singapore Science Park 2, Singapore 117406
Genecast Innotech Pte Ltd is Licensed by the Ministry of Health (Singapore) as a Clinical Laboratory (No.: L/25I0501/CLB/001/252) in accordance with the Healthcare Services Act 2020.

Interpreter's Declaration (if applicable):

I confirm that I have interpreted to the Subject, or the Subject's Parent / Legal Guardian (if applicable), the physician's explanation of the Subject's medical condition, nature, purpose, risks, limitations, and alternatives with regard to the Test and the physician's response to the Subject's, or the Subject's Parent / Legal Guardian (if applicable) queries in _____ (language).

Interpreter's Signature: **Date:**

Interpreter's Name:

© 2024 Genecast #02-01/02, The Kendall, 50 Science Park Road. Singapore Science Park 2, Singapore 117406
Genecast Innotech Pte Ltd is Licensed by the Ministry of Health (Singapore) as a Clinical Laboratory (No.: L/25I0501/CLB/001/252) in accordance with the Healthcare Services Act 2020.