

Name:
NRIC:
DOB:
Race: Sex:
Case No:
Referring Doctor:

Informed Consent for Genetics/ Genomics Testing

PART 1: Declaration and Consent/Acknowledgement (by patient/ on behalf of patient)

I hereby voluntarily give consent to undergo a genetic test named _____
_____ on *myself/ child/ ward named _____.

I acknowledge that the purpose, limitations, potential benefits and risks of having genetic testing have been explained to me.

Purpose and Limitations of Genetic Testing

- a) The purpose of this genetic test is to ascertain if I and/or my family members are affected, or are carriers of the disease gene.
- b) The genetic analysis performed is specific only for this disease/condition and does not guarantee my health or the health of other family members.
- c) Finding a disease-causing alteration may or may not result in a treatment, cure, or a prognosis (knowledge about how a disease is expected to progress).
- d) Biological specimen (blood, buccal swab, tissue etc.) will be collected for the isolation of Deoxyribonucleic acid (DNA) or Ribonucleic acid (RNA) for genetic testing. The remaining sample may be stored for validation, process development and/or quality control studies after the de-identification of all protected personal information.
- e) There is a small chance of inaccurate or inconclusive results due to, but not limited to, current testing technology, knowledge and/or errors in the documentation of family history.
- f) The test is ordered after discussion and assessment by my doctor and/or genetic counsellor. The pre-test counselling includes a discussion on the implications of the test results on my family members and insurability. Disclosure of important health information revealed by genetic testing is at the individual's discretion.
- g) I may withdraw from testing at any point in time, or choose not to learn of the results. However, charges would apply once the test request has been received and processed. Such charges are not refundable in the event of a withdrawal made post-processing of a request.

Results and Implications

- a) The test results will be explained to me through a doctor and/or genetic counsellor.
- b) The types of results generated include the following:
 - **Positive:** confirmation of a genetic diagnosis, indication of a predisposition to a specific disease or condition;
 - **Negative:** no alterations identified in any of the gene(s) tested. This does not eliminate a genetic cause for your condition. It could also be due to limitations in current testing technology and/or knowledge;
 - **Variant(s) of uncertain significance:** findings that are uninterpretable due to insufficient information about the genetic change associated with the condition at the time of testing or suggestive of a condition that was different from the original diagnosis.
- c) I may be contacted in the future if new information regarding my results becomes available.
- d) The genetic results will be transmitted to my electronic medical records. Access of results is limited to authorized personnel from the hospital, testing laboratory and other parties as required by law. All results will be kept confidential and form part of the laboratory's electronic information system in accordance with the hospital policy.
- e) My de-identified health information and genetic results may be used for academic/medical education or shared on clinical databases.
- f) **Incidental findings:** There is a rare possibility of incidental findings which are results that are not related to the initial reason for which the test was ordered.

I ☐ *** AGREE** | ☐ **DO NOT AGREE** to be informed of incidental findings that are clinically significant and actionable.



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Return of genetic test results: In the event I am uncontactable or permanently lose mental capacity, I agree for my genetic test results to be shared with the following family member(s):

Name of family member Relationship Contact

Name of family member Relationship Contact

By signing this form, I consent to Tan Tock Seng Hospital Molecular Diagnostic Laboratory to collect, use and disclose my personal information as provided in this form in accordance with the Personal Data Protection Act 2012.

I hereby confirm that I shall take full responsibility and release Tan Tock Seng Hospital Pte Ltd, all hospital staff, trainees and contract medical practitioners involved in the testing from all liabilities and obligations in any way whatsoever for, bodily injury, loss of life, mishaps such as loss of property, arising directly or indirectly, as a result of or in connection with the testing.

The contents of this document have been explained to me in _____ (*language/ dialect), and I have signed this document after having fully understood the contents. I have been given the opportunity to discuss and ask for more information.

*Signature/Right Thumb Print of *Self/Patient's Representative/Donee/Court-Appointed Deputy

Name of *Self/Patient's Representative/Donee/ Court-Appointed Deputy

*NRIC/FIN/Passport number & Relationship to patient if person giving consent is not "Self"

Date

PART 2: Declaration by Doctor/Genetic Counsellor

Doctor/Genetic Counsellor: I confirm that I have explained all of the above to the patient/patient's representative/donee/Court-Appointed Deputy, the patient's medical condition as well as the nature, purpose, and confidentiality of the Genetics/Genomics testing. I have addressed the queries and advised for patient to return for post-test counselling.

Signature of Attending *Doctor/Genetic Counsellor

Name of Attending *Doctor/Genetic Counsellor

Designation/Identifier Number of Attending *Doctor/Genetic Counsellor

Date

PART 3: Declaration by Interpreter (if applicable)

I confirm that I have translated the communication of the doctor/genetic counsellor named above to the patient/patient's representative/donee/Court-Appointed Deputy.

(*language/dialect)

Signature of Interpreter

Name of Interpreter

Date

Delete if not applicable

Note: All parts of the consent form need to be completed. Write "NA" for parts that are not relevant.

MDL-CON-02-05

