

CONSENT FORM

SOMATIC GENETIC TESTING (CANCER GENETICS)

ACCOUNT NO.
NRIC NO.
NAME
ADDRESS
SEX/BIRTH DATE/RACE
DATE AND TIME OF ADMISSION

What is somatic genetic testing?

Cancer genetic tests look for specific mutations in somatic (cancer) cells and germline (normal) cells. Somatic genetic testing is performed after a patient has been diagnosed with cancer to look for specific mutations, which could improve treatment options.

Why do I need somatic genetic testing?

Somatic genetic testing may provide more information about your cancer, which may be important for diagnosis, prognosis and treatment options for you. This test is recommended on a case-by-case basis but not compulsory. Any materials obtained for this test will not be used for research purposes.

What does it involve?

Prior to the genetic testing, you may discuss your concerns about the genetic testing with the appropriate healthcare professional.

For the genetic testing, a sample of your tumour and/or blood, which could contain circulating cancer cells/nucleic acid from your tumour, will be sent to a laboratory for genetic analysis, which may involve testing a large number of genes. However, no testing other than those required for the diagnosis, prognosis and treatment determination of your cancer will be performed.

What precautions must I take for genetic testing?

Before the procedure, please inform your doctor if you had a recent blood transfusion in the past 2 weeks.

What are the *potential* risks and limitations of the genetic testing?

The genetic testing and results may come with some risks and/or limitations (non-exhaustive):

- Your somatic genetic test may reveal a possible inherited predisposition to cancer. In this situation, your doctor may arrange for you to see a Genetic counsellor/ geneticist to discuss germline testing and explain the implications involved.
- There is a small chance of error in the results due to, but not limited to, limitations in technology and clinical knowledge, sample contamination, inadequate quantity or quality of the material.
- Your test results will not indicate the likelihood of cancer recurrence.
- Cancer genetic testing is complex and the results of somatic genetic tests can be challenging to interpret. Your doctor may discuss your results with a group of other specialists for a consensus recommendation.

- Occasionally, the laboratory may need additional sample(s) from you to clarify your result.
- People react differently to receiving genetic test results. You can request for additional support before proceeding with this genetic test and/or after receiving the results.

What can I expect after the genetic test?

- A report will be generated, and it details the mutations identified in your cancer cells. Your doctor will discuss the results with you. However, results from somatic genetic testing can take up to a few weeks to be reported. Your doctor may choose to start treatment while awaiting the results or defer treatment till the report is ready depending on the situation and will discuss with you accordingly.
- The genetic test result will be stored in your electronic medical records, which will be accessible by the medical team(s) responsible for your care.
- The results are confidential and will only be released to other medical professionals currently involved in your care and/or other parties with your written consent or as otherwise allowed by law.
- Any remaining unused portion of the sample may be stored for validation, process development, and/or quality control studies, according to the laboratory's sample retention policies.
- The result(s) may reveal germline implications and this will require further testing and counselling to verify.
- Further testing and/or future re-analysis requested may incur additional charges, and/or require an additional sample to be taken and/or may delay the time taken to get a final result.
- To assist with result interpretation, your de-identified genetic results and clinical information may be added to scientific databases (local and international).

What are my options?

Somatic genetic testing may offer information for personalised treatment recommendations. Without this information, your doctor will discuss conventional treatment options with you. Somatic genetic testing may provide information for targeted therapy, which may be a viable treatment option.

You may withdraw from genetic testing at any point, before the test is completed or to postpone the receipt of test results. If consent is withdrawn, the sample will be discarded and no report will be issued. ***However, charges will apply once the test request has been received and processed.***

Since the test is optional, you may choose not to undergo the procedure. You may discuss these options in more detail with your doctor.

Others (to be filled by Healthcare Professional) [if applicable]

Part I – Patient’s Declaration

1. I, _____ (NRIC/Passport No. _____) have read this information sheet and confirm that I understand the nature, purpose, risks, complications, and alternatives with regard to **Somatic Genetic Testing (Cancer Genetics)** (“Test”).
2. I acknowledge that the risks and limitations(s) listed are not intended to be exhaustive. I have had an opportunity to ask for more information about (i) the above-mentioned risks and limitations; (ii) the risks in general; and (iii) specific concern(s) of relevance to me.
3. I hereby consent to undergo the Test.
4. I understand and agree that the Test will be performed either by the appropriate SingHealth institution (with the involvement of external providers if necessary) or by an appropriate external laboratory deemed suitable by the managing Healthcare Professional. I will also be admitted and/or registered as a patient of that SingHealth institution.
5. I consent for the remaining unused portion of my sample to be stored for validation, process development, and/or quality control studies.
6. I understand that my result(s) may have germline implications that will require further testing and counselling to verify.
7. In the event I am uncontactable, the test results may be made known to:
Name: _____ NRIC (last 4 digits): _____
Contact details: _____ Relationship: _____
Name: _____ NRIC (last 4 digits): _____
Contact details: _____ Relationship: _____

(Signature/[*Left/Right] Thumbprint of Patient)

(Date of Signing)

(Name of Witness)

(Designation of Witness)

(Signature of Witness)

(Date of Signing)

*** Please delete accordingly**

Part II – Parent’s / Legal Guardian’s / Donee’s / Deputy’s Declaration (herein referred to as the “Authorised Person”) (if applicable)

1. I, _____ (NRIC/Passport No. _____), the ***Parent / Legal Guardian / Donee / Deputy** of _____ (NRIC/Passport No. _____) (“Patient”), have read this information sheet and confirm that I understand the nature, purpose, risks, complications, and alternatives with regard to **Somatic Genetic Testing (Cancer Genetics)** (“Test”).
2. I acknowledge that the risks and limitation(s) listed are not intended to be exhaustive. I have had an opportunity to ask for more information about (i) the above-mentioned risks and limitations; (ii) the risks in general; and (iii) specific concern(s) of relevance to the Patient.
3. I hereby consent for the Patient to undergo the Test.
4. I understand and agree that the Test will be performed either by the appropriate SingHealth institution (with the involvement of external providers if necessary) or by an appropriate external laboratory deemed suitable by the managing Healthcare Professional. The Patient will also be admitted and/or registered as a patient of that SingHealth institution.
5. I consent for the remaining unused portion of the Patient’s sample to be stored for validation, process development, and/or quality control studies.
6. I understand that the Patient’s results may have germline implications that will require further testing and counselling to verify.
7. In the event I am uncontactable, the test results may be made known to:
Name: _____ NRIC (last 4 digits): _____
Contact details: _____ Relationship: _____
Name: _____ NRIC (last 4 digits): _____
Contact details: _____ Relationship: _____

(Signature/**[*Left/Right]** Thumbprint of Authorised Person)

(Date of Signing)

(Name of Witness)

(Designation of Witness)

(Signature of Witness)

(Date of Signing)

*** Please delete accordingly**

Part III – Healthcare Professional’s Declaration

I confirm that I have explained to the Patient, or the Authorised Person (if applicable), the Patient’s medical condition as well as the nature, purpose, risks, complications, and alternatives with regard to the Test and have addressed queries of the Patient, or the Authorised Person (if applicable).

(Signature, Full Name, and
Professional Registration/*Employee No.
of Healthcare Professional)

(Date of Signing)

**Only for those without professional registration number*

Part IV – Interpreter’s Declaration (if applicable)

I, _____, confirm that I have interpreted to the Patient, or the Authorised Person (if applicable), the Healthcare Professional’s explanation of the Patient’s medical condition, nature, purpose, risks, complications, and alternatives with regard to the Test and the Healthcare Professional’s response to the Patient’s, or the Authorised Person’s (if applicable), queries in _____ (language / dialect).

(Signature of Interpreter)

(Date of Signing)