OncoStrands®

HEREDITARY CANCER RISK TESTING | INFORMED CONSENT

This informed consent outlines the purpose, process, risks, benefits, and implications of genetic/genomic testing for inherited cancer risk. By signing, the Patient (or their authorized representative if the Patient cannot consent) acknowledges understanding of the Test's scope, potential outcomes, and privacy considerations, including optional disclosure of incidental findings. Completion of this form is required prior to testing.

Purpose of Testing

Genomic testing is being recommended to determine whether you may have inherited a specific genetic change in one or more genes currently known to confer an elevated risk of developing specific types of cancer. Knowing that you have inherited specific harmful genetic change(s) (also known as mutations) may help guide management of your cancer or help prevent you and/or your relatives from developing cancer in the future. Knowing that you have not inherited specific harmful genetic change(s) will provide reassurance that you and your descendants do not have higher risk of developing cancer than the general population.

Types of Testing

Diagnostic testing is a genomic test to screen for and identify the specific harmful genetic change(s) that have caused or contributed to your cancer.
Predictive testing is a single-gene genetic test to identify whether healthy individuals with a genetic relative with a specific harmful genetic change known to cause or contribute to cancer have or have not inherited that specific change.
Carrier testing is a test to identify gene changes that may not affect the tested individual but which many increase the risk of their children developing cancer. Identification of such changes may be unexpected and unrelated to the tested individual's cancer type.
Somatic testing is a test of tumour tissue to identify non-inherited genetic changes, primarily to guide treatment options. Sometimes, somatic tests cannot distinguish a non-inherited from an inherited genetic change, so the individual may need to undergo diagnostic inherited testing afterward.

Testing Process and Consent

It is my choice to have cancer genomic testing. I understand that:

- I will need to provide one or more blood samples for genomic testing.
- I will be provided with genetic counselling by a qualified heath professional prior to testing and following testing if a specific harmful genetic change is found.
- Testing will be performed in a diagnostic pathology laboratory accredited to perform cancer genomic testing.
- A copy of this signed and witnessed consent form will be provided to the testing laboratory.
- I may choose to stop the test or delay receipt of the results.

Possible Outcomes and Limitations

- This test is being done specifically to assess inherited cancer risk and will not predict all health problems.
- Results will be based on current knowledge, standard of care, and best practice, which may change in the future.
- In the event that new data become available that has the potential to alter the clinical significance of my test results, I accept that the laboratory would need to receive a new request from my health care practitioner to re-examine my data or analyse a new sample.
- Results may or may not find a cause for my cancer or may be of uncertain significance.

Implications for Family Members and Incidental Findings

- The results may have implications for the person being tested and their family and may recommend that other family members also be tested.
- You will be given an opportunity to self-disclose your genetic results to family members.
- If your test results need to be shared with healthcare providers caring for your genetic relatives, efforts will be made not to disclose your identity if you have not self-disclosed or consented to sharing.
- Testing of other family members may show unexpected family relationships.

Privacy and Confidentiality

- Genetic results are private and confidential and will only be shared with consent or as required or permitted by law.
- Your de-identified (removed of all personal information) genetic results and health-related information may be deposited in cancer-specific or population genetic databases to help other health professionals interpret genetic findings for their patients.

Financial and Insurance Considerations

- Results may affect your ability to obtain certain types of insurance including life, income protection, and travel insurance. This will not affect your ability to obtain health insurance.
- Some genomic tests are not funded or reimbursed, and you may be liable for the cost of sample collection, counselling, and laboratory testing.

Future Research Participation

I may be contacted in the future about participation in ethically approved research studies and I understand that I may not be informed of the research results or may not benefit personally from the research. I may decline any such request.

Patient's Signature:

Full Name:

Date (DD/MM/YYYY):

Counsellor's Signature:

Full Name:

Date (DD/MM/YYYY):