National University Hospital

CONSENT FOR APEX* NEXT GENERATION SEQUENCING (NGS) TEST

This ADDENDUM provides additional information on this test to assist the patient to make an informed decision.

To be attached to the General Consent Form.

Information

Please read this consent form carefully and discuss with your physician before you provide the consent for this test. This document serves to help you gain a better understanding of our genetics/genomics test regarding its nature, purpose, benefits, potential risks and limitations, and handling of the unused samples.

This consent form needs to be completed and signed by you or your legally authorized representative and your physician before you provide your specimen(s). Should you have any questions, please discuss them with your referring physician.

Purpose and Benefits

1. The purpose of this test is to ascertain whether there are any specific genetic/genomic changes (mutations) in your tumour tissue.

2. The personalized information provided by the test may assist you and your doctor in determining a suitable treatment and management for your condition. However, the mutations identified by the test does not guarantee treatment success which depends on multiple factors, including but not limited to, tumour type, extent of the disease, individual profile, and the type of treatment(s) received.

Potential Risks and Limitations

3. As this test has been developed for detecting specific genetic changes, it is possible that some other mutations or genomic alterations may not be detected with the technology employed by this test.

4. Suboptimal specimen characteristics, nucleic acid and technical limitations of the test may result in inaccurate results.

Results and Implications

5. The test results will be explained to you by your physician and/or your genetic counsellor.

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*__A__ctionable, __P__ersonalised and __EX__press

6. Confidentiality: Your test results are strictly private and confidential. The results will be reported only to the referring physician named on the requisition form. Your test results will be part of your medical records and will be protected as required under the Personal Data Protection Act of Singapore and other relevant legislations such as the Private Hospitals and Medical Clinics Act and/or Healthcare Services Act. Your data may be anonymised and shared on publicly available clinical databases, e.g., ClinVar, which may be used for advancement of medical knowledge.

7. There is a low possibility of incidental findings, which are results that are not related to the initial reason for which the test was ordered. Some findings are not medically actionable (i.e., do not guide treatment or have therapeutic implication). Incidental findings will not be reported, unless (i) the mutation is within the test gene panel ordered by your physician and/or (ii) the laboratory has sufficient and clear evidence of a mutation with clinical utility.

Consent & Fees

8. The decision to undergo this test is entirely voluntary, and your consent is required before we can proceed with the test.

9. You may withdraw your consent at any time, or postpone the disclosure of the results.

10. Fees should be paid prior to the tests and are non-refundable.

Unused Samples

11. Unused sample material (if any) will be stored in accordance with applicable Singapore laws and regulations.

12. Remaining unused de-identified sample material may be used for purposes of maintaining clinical laboratory operations including test validation, process development, medical education and/or quality control.

Additional Notes [1]

[1] *For example: Where applicable, the healthcare professional may document under this section information pertaining to:* ***(a)*** *concerns raised or expressly communicated by the patient regarding the test, which the patient considers to be material or relevant or which the healthcare professional knows or ought to know is relevant to the patient; (b) any discussion related to or explanation provided to the patient as to why this test is appropriate for the patient; (c) any alternative options discussed with the patient, including the option of not performing this test and the treatment plan if the test is not performed.*

Referring Physician

I, _____(Name) have explained the above and answered the patient's / guardian's questions satisfactorily.

Signature: _____ MCR No.: _____ Date: _____

Patient

I, _____ (Patient's Name) _____ (NRIC/Passport No.) have read and understood the above information. I acknowledge that the nature, purpose, benefits, potential risks and limitations of the genetic/genomics testing have been explained to me and that my questions and concerns raised to my physician have been answered to my satisfaction. I therefore consent to genetic/genomics testing for _____ (test description) on the terms as set out above in this consent form.

Signature: _____ Date: _____

Patient's Guardian / Legal Representative (please delete whichever is not applicable)

I, _____ (Guardian / Legal Representative's Name) _____ (NRIC/Passport Number) have read and understood the above information. I acknowledge that the nature, purpose, benefits, potential risks and limitations for genetic/genomic testing have been explained to me and that my questions and concerns raised to my physician have been answered to my satisfaction. I therefore consent to genetic/genomics testing for _____ (Test Description) to be done on _____ (Patient's Name) _____ (NRIC/Passport No.) on the terms as set out above in this consent form.

Signed by:

^Guardian/Legal Representative's Signature: _____ Date: _____

Interpreter's Declaration (if applicable)

I confirm that I have accurately translated the information in this Addendum, any related documents to the Patient and related discussion between the Patient and Doctor on this test.

Language used in translation: _____

Interpreter's Name: _____

Signature of Interpreter: _____ Date: _____

Designation/Department: _____

(^please delete whichever is not applicable)