|  |  |  |
| --- | --- | --- |
| **HOSPITAL AUTHORITY****CONSENT FORM FOR****BRCA1/2 GENE MUTATION TEST FOR PARP INHIBITOR** |  |  |
| Admission/Clinic No.: |  | ID No.: |  |  |
| Name: |  |  |
| (in Chinese) |  |  |
| Date of birth: |  | Sex: |  | Dept: |  |  |
|  |  |

***(Please put a ✓ inside the check boxes* □ *below as appropriate)***

1. I have read the information leaflet on *“BRCA1/2 Gene Mutation Test For PARP Inhibitor”* given by the healthcare staff, and had relevant discussion with them.
2. I understand that the results and interpretations in the test report are based on the current technology and knowledge. Future advances may provide further insight and possibly lead to a different understanding of the results.
3. I understand that the possible genetic result(s) include the following:
4. **Disease‑causingmutation(s) was/were found**: this indicates that I may be suitable for the specific targeted therapy. If disease‑causing mutation(s) was/were detected in the blood sample (germline), it is highly probable that I am affected by hereditary breast and ovarian cancer syndrome. If disease‑causing mutation(s) was/were detected in the tumor tissue sample (somatic) only but not in the blood sample (germline), it indicates that the mutation is not hereditary. If I have only undergone tumor BRCA 1/2 (somatic) mutation test but not blood BRCA1/2 (germline) mutation test, I understand that there is a possibility of missing a small proportion (around 5%) of germline mutations and it is uncertain whether the disease‑causing mutation(s) found is/are hereditary or not. Further clinical assessment and medical advice from specialist(s) is/are required on whether I am suitable for the specific targeted therapy.
5. **No disease‑causing mutation was found**: this indicates that the molecular diagnosis of the gene being investigated was not confirmed or substantiated, and I am not suitable for the specific targeted therapy. It may be due to the absence of disease‑causing mutations in the blood or/and tumor tissue, or due to limitations of current techniques or other unknown factor(s). However, the result does not totally exclude the possibility of BRCA1/2 gene mutations in my blood or/and tumor tissue samples.
6. **Variant(s) of uncertain clinical significance (VUS)**: a mutation was found but whether this mutation will result in any disease or is just a benign polymorphism is uncertain with the latest medical genetic knowledge, and I may not be suitable for the specific targeted therapy. Polymorphism means the mutation is present in more than 1% of the general population that likely does not have harmful effects on health. When “VUS” was detected, genetic counseling and further genetic studies may be indicated. Nevertheless, a definitive conclusion may still not be made after the additional work up.
7. I understand that the results of blood BRCA1/2 (germline) mutation test may potentially affect myself and/or my family members in terms of insurance applications, psychological or social issues.
8. I give consent to the Hospital Authority to perform the following gene mutation test(s) for ovarian tumor treatment:
* To perform both blood BRCA1/2 (germline) mutation test and tumor BRCA1/2 (somatic) mutation test.
* Only perform tumor BRCA1/2 (somatic) mutation test. I understand that there is a possibility of missing a small proportion (around 5%) of germline mutations if only tumor BRCA1/2 (somatic) mutation test is performed, and it is uncertain whether the disease‑causing mutation(s) found (if any) is/are hereditary or not.
1. If the test results cannot be released to me due to my incapacity or death, the blood BRCA1/2 (germline) mutation test results may be released to a nominated individual upon request within 3 months after the test results are available.

Name and contact of the nominated individual: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. The doctor (who signs this Form) has fully explained the nature, effect/benefits and the potential risks/implications of the BRCA1/2 gene mutation test(s) to me and my family.

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Signature of Patient |  | Signature of Patient’s parent or guardian/Patient’s legal guardian appointed under the Mental Health Ordinance |
|  |  |  |
| Signature of Doctor |  | Name of Doctorin Block Letters and Staff Rank |
|  |  |  |
| Signature of Witness |  | Name of Witness in Block Letters(and Staff Rank if applicable) |
|  |  |  |
| Signature Date |  |  |