醫院管理局
新界東醫院聯網
Hospital Authority
New Territories East Cluster

Prince of Wales Hospital
Molecular Diagnostic Service

Please use **BLOCK LETTERs** or affix **PATIENT LABEL**

Name: _____

HKID No.: _____

Sex: _____ Age: _____

Date of Birth (DD/MM/YYYY): _____

Name of Requesting Doctor: _____ 331 Code: _____ Tel: _____

Hospital and Department: _____ Email: _____

(Please fill in ink and put a '✓' inside the appropriate check boxes ☐ below. Any correction made should be crossed and signed.)

Consent Form for Genetic and Genomic Investigations

I hereby give consent to the Molecular Diagnostic Service, Prince of Wales Hospital [hereafter refer as **"the Lab"**] to use the following specimen(s):

☐ blood ☐ buccal swab ☐ urine ☐ others: (Please specify: _____)

of ☐ myself / ☐ my child / ☐ my fetus / ☐ others _____ [hereafter refer as **"Participant"**] collected on _____(DD/MM/YYYY) to perform the following test(s) because of _____ (indication/condition):

☐ Single gene testing (Gene/Disease: _____)

☐ Mitochondrial DNA hotspot(s) (Please specify: _____)

☐ Whole mitochondrial DNA sequencing

☐ Next generation sequencing (Gene/Disease Panel: _____)

☐ Others (Please specify: _____)

Type of testing

☐ Diagnostic testing

☐ Carrier testing

☐ Pre-symptomatic or predictive testing

☐ Prenatal testing

Release of genetic test results

☐ I understand that Participant's test results can be released to other doctors or healthcare workers involved in Participant's medical care without seeking further consent from me.

I ☐ agree / ☐ do not agree that if I cannot be contacted or in the event of my incapacity or death, test results may be released to a nominated individual.
Name and contact details of the nominated individual: _____

Disposal of specimen

☐ I agree that the Lab can store specimens of Participant for future testing of the aforementioned disease and related disorders (in the Lab or send to other laboratories).

Or

☐ I request that specimens of Participant be discarded after the testing is finished according to regulatory or accreditation requirements. I understand that a specimen needs to be provided again if further testing is to be performed.

Specimens of Participant may be made anonymous and used as internal control in the Lab. If Participant does not want the specimens of Participant to be kept for these purposes please tick here: ☐

Disposal of data

☐ I agree that the Lab can store data generated by the genetic testing for future re-analysis. The Lab does not reissue report automatically. A request for re-analysis in the light of new knowledge must be made in the form of a new referral.

Or

☐ I request that data be discarded after the testing is finished according to regulatory or accreditation requirements. I understand that future re-analysis is not possible once the data is discarded.

Outcomes and risks

☐	I understand that the results and interpretations in the genetic report are based on current technology and knowledge. Future advances may provide further insight and lead to amendment of the genetic report.
☐	I understand that the possible genetic result(s) include the following: 1. **Disease-causing variant(s) is found:** indicates that the diagnosis of the disease being investigated is confirmed. 2. **No disease-causing variant is found:** indicates that the diagnosis of the disease being investigated is not confirmed. It may be due to limitations of the current techniques or other unknown factor(s). Nevertheless, the result does not mean total exclusion of the diagnosis. 3. **Variant(s) of uncertain clinical significance is found:** a variant is found. With the latest medical genetic knowledge, it is still unclear whether this variant will result in any disease or is just a benign polymorphism. In this circumstance, further genetic studies may be necessary, or genetic counseling and testing for the parent(s) or other family member(s) may be indicated. Despite that, it is still possible that a conclusion cannot be drawn in the end.
☐	I understand that only genetic data relevant to the Participant's clinical indication/condition would be analyzed and reported. Genetic findings that are unrelated to the original indications of testing or genetic test(s) requested would not be reported.
☐	I understand that the test may possibly reveal incidental findings implicating diagnoses that are unrelated to the original indications of testing, including hereditary cancer syndrome, carrier status of autosomal recessive disorders (not reported in prenatal samples), late onset neurological disorders, etc. Such results may potentially affect Participant and/or family members in terms of insurance, job and academic application, psychological and social issues.
☐	I understand that the test(s) may reveal non-paternity or non-maternity, and Participant will not be informed of such findings. An error in the diagnosis may occur if the true biological relationships of the family members involved in this study are not as I have stated.
☐	Any questions that I have asked have been answered.

Data sharing

I ☐ agree / ☐ do not agree that the Lab can provide genetic testing results to online publicly available national/international databases to help clinicians, scientists and researchers understand the meanings of the DNA variants identified. The results contained in the database will be made anonymous and thus not traceable to Participant's record.

Use of samples and data in research

I ☐ agree / ☐ do not agree that clinical information and genetic testing results can be used in research. Before the Lab carries out the research, the Lab shall obtain approval from relevant regulatory body. The Lab shall contact you, inform you about details of the research and request you to sign another consent form. I understand that my decision will not affect Participant's medical care.

Use of samples and data in scientific publication

I ☐ agree / ☐ do not agree that clinical information and genetic testing results can be used in scientific publications. All direct identifiers shall be removed. However, complete anonymity cannot be guaranteed. Before the Lab publishes the results, the Lab shall obtain approval from relevant regulatory bodies. If deemed necessary, the Lab shall inform you about details of the publication.

Signatures

Name of Participant	**HKID of Participant**	**Signature**	**Date**
Name of *Parent/Legal guardian *(*Delete where appropriate)*	**HKID of *Parent/Legal guardian** *(*Delete where appropriate)*	**Signature**	**Date**
Name of Witness (optional)		**Signature**	**Date**
Name of Requesting Doctor		**Signature**	**Date**

Please keep a duplicated copy of the signed consent form in the Participant's record, and send the true copy with the Genetic and Genomic Investigations Request Form to the laboratory.