 瑪麗醫院 QUEEN MARY HOSPITAL	Department of Obstetrics and Gynaecology	Document No.	OGPD0036(1)-E
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	Subject Consent Form for Genetic and Genomic Investigations	Next Review Date	Jan 2028
		Approved by	Prenatal Diagnosis and Counselling Team, TYH
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Tsan Yuk Hospital
Prenatal Diagnostic Lab

Consent form for Genetic and Genomic Investigations (ENG)
TYH-REC-CONF(ENG)-GG-V1-2104

Consent Form for Genetic and Genomic Investigations

(Please put a ✓ inside the check boxes below, * Delete where appropriate)

Name: _____ Document ID: _____ Date of birth: _____ <p style="text-align: center;">or GUM LABEL</p>	Laboratory use only: Specimen no.: _____ Report no.: _____
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I hereby give consent to Prenatal Diagnostic Laboratory (the Lab), Tsan Yuk Hospital to use the Amniotic fluid Chorionic villi Placental tissue Skin biopsy Products of gestation
 Foetal blood Blood others: _____
 of myself / my child / my foetus / other _____ [hereafter refer as “Participant(s)”]
 collected on _____ (dd/mm/yyyy) to perform the following test(s) because of _____ (indication/condition):

- Copy number analysis (* CMA/sWGS) [a,b,c,d]
- Rapid aneuploidy detection (Chr 13,18,21,XY) [a]
- Fragile X testing [a]
- Uniparental disomy testing [a,c,d]
- Methylation PCR for _____ [a]
- FISH for _____ [a]
- Single gene testing (Gene/Disease: _____) [a,b,c]
- Next Generation Sequencing (* WES/WGS/Gene/Disease Panel: _____) [a,b,c,d]
- Karyotype [a]
- 22q11.2 microdeletion [a]

Type of testing

- Prenatal testing
- Diagnostic testing
- Carrier testing
- Pre-symptomatic or predictive testing

Release of genetic test results

I understand that Participant(s)'s test results can be released to other doctors or healthcare workers involved in Participant(s)'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(s)
 - for future testing of the aforementioned disease and related disorders (in the Lab or send to other laboratories).
 - for use as a control in genetic tests unspecified. I understand that the sample(s) will be made anonymous.

Or


- I request that specimens of Participant(s) 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.

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.

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Outcomes and risks

(Please put a ✓ inside the check boxes below if applicable. Please write "NA" in front of the check box to indicate not applicable.)

- [a] 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.
- [b] I understand that the possible genetic result(s) include the following:
- Disease-causing variant(s) is found:** indicates that the diagnosis of the disease being investigated is confirmed.
 - 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.
 - 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.
- [c] 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(s) and/or family members in terms of insurance, job and academic application, psychological and social issues. I choose to be / not to be informed of such incidental findings.
- [d] I understand that the test(s) may reveal non-paternity or non-maternity, and participant(s) 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.

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)'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 researchers carry out the research, researchers shall obtain approval from relevant regulatory body. Researchers may further contact me to sign another consent form if necessary. I understand that my decision will not affect Participant(s)'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 will be removed. However, complete anonymity cannot be guaranteed. Before researchers publish the results, researchers shall obtain approval from relevant regulatory bodies. If deemed necessary, researchers shall inform me about details of the publication.

Signatures

Name of patient & HKID: _____ Signature: _____

Name of *parent/legal guardian & HKID: _____ Signature: _____

Witness Name (optional): _____ Signature: _____

Name of Doctor: _____ Signature: _____ Date: _____

Please keep a duplicated copy of signed consent form in patient record, and send the true copy with laboratory request form to the laboratory.