Preimplantation Genetic Diagnosis (PGD)
Consent Form

Clinical Information (Recorded by health care providers) **Sample No.**_____

Disease/Target Gene			
Pedigree and Clinical Details:			
Medical Institute/ Physician		Phone No.	
Fax No.		E-mail	

Patient Information (Completed by the patients)

Husband

Name		Medical Record No.	
ID/Passport No.		Nationality	☐ Taiwan ☐ Other_____
Mobile Phone No.		DOB (d/m/y)	/ /
Address			

Wife

Name		Medical Record No.	
ID/Passport No.		Nationality	☐ Taiwan ☐ Other_____
Mobile Phone No.		DOB (d/m/y)	/ /
Address			

I, the undersigned, have read the terms and realize the Preimplantation Genetic Diagnosis (PGD) clearly. I hereby fully understand, agree and undertake the following:

1. I ☐ agree / ☐ do not agree to allow the remainder of my sample to be used for research purposes. (Lack of response indicates consent.)
2. I have carefully read the Terms of Preimplantation Genetic Diagnosis (provided on the following page). According to my situation, the physician has answered all my questions and adequately explained to me (included but not restricted to the information about the necessary, process, potential risk and successful rate of this Test as well as the risk of alternative tests).
3. I fully understand the above terms, statements, and declarations, and I agree to have the PGD performed at my own expense. I understand and accept that this Test may be the most appropriate choice at this time, but it cannot guarantee the prevention of the tested disorders.
4. I agree to provide my personal and/or confidential information, including my National Identification Card number, birthdate, and mobile phone numbers in this consent form.

(Wife) _____ (Husband) _____

Signature, Date (dd/mm/yyyy) **Signature, Date (dd/mm/yyyy)**

Terms of Preimplantation Genetic Diagnosis (PGD)

The following terms explain the benefits, risks and alternatives of preimplantation genetic diagnosis (PGD), and provide additional information that can be discussed with your physician. It is important that you fully understand these terms, so please read carefully. If you have any further questions regarding the PGD, please consult with your physician prior to signing the consent form.

Eligible subjects:

Preimplantation genetic diagnosis is suitable for individuals with family history of hereditary single-gene disorders in which point mutations can be detected using molecular biology techniques.

Procedure:

After the mutated gene is located, SOFIVA GENOMICS will design customized probes used in PGD, followed by in vitro fertilization. An embryo biopsy is performed when the embryos reach the blastocyst stage (day 5)*, and the embryos undergo cryopreservation subsequently. The extracted embryo cells process DNA amplification and mutation analysis later to determine whether the embryos contain the genetic mutation. Furthermore, the normal embryos will be implanted during the next menstrual cycle.

*To meet the highest standards of accuracy, the PGD uses a highly advanced dual-platform system. Therefore, blastocyst-stage biopsies are strongly advised.

Alternatives:

Chorionic villus sampling or amniocentesis can also be performed during pregnancy to determine whether the fetus has genetic mutations.

Benefits:

PGD reduces the risk of the fetus suffering from the hereditary disease, and prevents the same genetic disorder from recurring.

Risks:

(1) The results of PGD may indicate that all of the embryos are abnormal, in which case no embryos will be feasible for implantation. Nevertheless, testing fees still be charged in these cases.

(2) Even if the PGD results indicate that an embryo is normal, it does not guarantee that the embryo will develop normally or be implanted successful.

(3) DNA amplification of embryonic cells is required before PGD. The success rate of the amplification procedure is approximately 90%, which means that roughly 10% of embryo biopsies will not be able to undergo this test.

(4) If an embryo shows mosaic mutations, this indicates that some embryo cells are abnormal, which will decrease the accuracy of PGD.

(5) The accuracy of PGD is greater than 95%. However, current science and technology are not without limits. Therefore, the international standards still recommend that chorionic villus sampling or amniocentesis be performed during pregnancy to further confirm the presence or absence of genetic mutations.

(6) I fully understand the above terms and agree to have the PGD performed at my own expense.