SOFIVA Non-Invasive Prenatal Screening Consent Form

SOFIVA GENOMICS www.sofivagenomics.com T: +886-2-23826615	☐ **SOFIVA NIPS v1.0** ☐ **SOFIVA NIPS v2.0** ☐ **SOFIVA NIPS v3.0**
Hospital / Clinic:	**Physician (Signature):**

Patient Information

Name			
Medical Record No.		**Gestational Age**	weeks days
ID / Passport No.		**Estimated Date of Confinement**	(dd) (mm) (yyyy)
Date of Birth	(dd) (mm) (yyyy)	Day of Last Delivery	(dd) (mm) (yyyy)
Nationality		Gravida / Para / Abortion	/ /
Nationality of Spouse		Previous Pregnancy Affected by Chromosomal / Genetic Defects	☐ No ☐ Yes (_____)
Height / Weight	cm kg	Family History of Genetic Disease	☐ No ☐ Yes (_____)

Clinical Information

Ultrasound	☐ Singleton ☐ Twins (☐Identical ☐Non-identical) ☐ Multiple ( ) Results: _____		
In Vitro Fertilization (IVF)	☐ No ☐ Yes (☐ Patient ☐ Donor) (Patient / Donor age at egg retrieval: _____Years)		
Prior Screening Test	☐ None ☐ 1st-trimester screen ☐ 2nd-trimester screen ☐ NT only The estimated risk of T21 (1:_____) The estimated risk of T18 (1:_____) The estimated risk of T13 (1:_____) NT result (_____)		
Blood Collection Date	(dd) (mm) (yyyy)	**Fetal Sex Report**	☐ Yes ☐ No
Clinical Details – include reason for test request:			

I, the undersigned, understand the SOFIVA Non-Invasive Prenatal Screening (SOFIVA NIPS) serve as the examination of fetal chromosomal abnormalities. I hereby fully understand, agree and undertake the following:

1. SOFIVA NIPS is a non-invasive screening with no risk of causing miscarriage which may be induced by conventional invasive methods.
2. The cell free fetal DNA (cff-DNA), which is extracted from 10 ml maternal blood, will be processed by next generation sequencing and bioinformatics analysis for SOFIVA NIPS.
3. SOFIVA NIPS is suggested for at least 10 weeks gestation. The detection rates of NIPS v1.0, v2.0 and v3.0 for Trisomy 21, 18, and 13 are around 99%, 99.5% and 99.5%, respectively. The detection rates for specific selected microdeletions, specific genetic mutations and other chromosomes are around 99%, 99%, and 90%, respectively. If pregnant women with less than 10 weeks gestation, the detection rate will be decreased. However, the result might end up in false negative or false positive because of certain rare conditions or factors.
4. NIPS v1.0 specifically focuses on common chromosomal aneuploidies (Trisomy 21, 18, and 13) and sex chromosome aneuploidies. NIPS v2.0 and v3.0 are intended for detection of whole chromosomal aneuploidies, including sex chromosome and specific selected microdeletions. NIPS v3.0 can also detect the specific genetic mutations.
5. SOFIVA NIPS cannot detect all numerical and structural chromosomal abnormalities. Specific selected microdeletions for NIPS v2.0 and v3.0 are targeted more than 2 Mb in size. The microdeletions less than 2 Mb in size as well as highly repeat regions are not included in NIPS v2.0 and v3.0. The unselected chromosomal aneuploidies (for NIPS v1.0), unselected microdeletions and microduplications (for NIPS v2.0/v3.0), unselected genetic mutations (for NIPS v3.0), recombination, inversions, balanced and unbalanced translocations, chromosomal mosaicism, uniparental disomy and polyploidy are not included, either.
6. Due to the limitation of the sensitivity and specificity in recent clinical technology and the variation between individuals, if women with multiple fetuses (three or more offspring), the detection rate of SOFIVA NIPS will be decreased.
7. The result of SOFIVA NIPS may be affected if the mother with chromosomal aneuploidies, specific microdeletions, specific genetic mutations or blighted ovum.
8. Repeated blood collection may be required to ensure the accuracy of SOFIVA NIPS when the sample quality is poor or the fetal fraction is less than 4%.
9. Sofiva Genomics provides karyotyping for further confirmation if the result of NIPS v1.0 is chromosomal aneuploidy, and provides karyotyping and array-CGH if the results of NIPS v2.0 and v3.0 are chromosomal aneuploidy or microdeletion. Furthermore, specific genetic testing will be provided if a genetic mutation is detected by NIPS v3.0.
10. I, the undersigned, hereby undertake that, after birth in case of false negative results for Trisomy 21, Trisomy 18 , Trisomy 13, selected microdeletion syndromes and the 20 common skeletal dysplasia genetic mutations of NIPS v2.0/v3.0 (only singletons and identical twins), and after birth in case of false negative results for Trisomy 21 of NIPS v1.0 (only singletons and identical twins), Sofiva Genomics shall, at its own discretion, compensate the undersigned, upon a set of reasonable proof of evidence or a final and binding court verdict, a maximum cap of 50,000 USD (for NIPS v1.0) or 66,000 USD (for NIPS v2.0/v3.0), which (the actual monetary amount of compensation) shall be supported by solid legal and notarized documents, for each of the said false negative cases , if the outcome of the said false negative cases is substantially due to Sofiva Genomics' gross negligence or intention. Upon receiving the above-mentioned monetary amount of a maximum cap of 50,000 USD (for NIPS v1.0) or 66,000 USD (for NIPS v2.0/v3.0), the undersigned shall deem to settle with Sofiva Genomics for liabilities in law and/or at equity, no matter whether civil, and/or criminal, or any and all other liabilities. The above-mentioned maximum cap of 50,000 USD (for NIPS v1.0) or 66,000 USD (for NIPS v2.0/v3.0) shall serves as the full consideration that the undersigned fully agree to settle with Sofiva Genomics and shall not further claim from Sofiva Genomics on any ground or/and shall not proceed, take or file any legal action against Sofiva Genomics and its related directors, consultants, or employees.
11. I hereby agree that the hospital/clinic and Sofiva Genomics may collect, process or use my personal information such as medical records, medical treatment, genetic information and health examination records under the specific purpose of medical care, health treatment etc.
12. I ☐agree / ☐do not agree to allow the remainder of my sample to be used for research purposes (Lack of response indicates consent).
13. 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 SOFIVA NIPS as well as the risk of other screening tests).
14. I fully understand the above terms, statements, and declarations, and I agree to have SOFIVA NIPS performed at my own expense. I understand and accept that SOFIVA NIPS may be the most appropriate choice at this time, but it cannot guarantee the prevention of the tested disorders.

Signature, Date (dd/mm/yyyy) _____

Copy 1: Laboratory Retain (White) Copy 2: Hospital/Clinic Retain (Blue) Copy 3: Patient Retain (Red)