SOFIVA Cancer Monitor Consent Form

SOFIVA GENOMICS www.sofivagenomics.com T: +886-2-23826615	☐ **SOFIVA Cancer Monitor v3.0**
	☐ **SOFIVA Cancer Monitor v2.2**
	☐ **SOFIVA Cancer Monitor v2.1**
☐ **EGFR Mutation Test**	☐ **SOFIVA Cancer Monitor v1.0**
☐ **Microsatellite Instability (MSI)**	☐ **SOFIVA Cancer Track (Specific gene)**
Hospital / Clinic:	**Physician (Signature):**

Patient Information

Name		Gender	☐ Male ☐ Female (Pregnancy ☐Yes ☐No)
ID / Passport No.		**Date of Birth**	(dd) (mm) (yyyy)
Phone No.		Nationality	
Address			

Clinical Information

Medical Record No.		**Collection Date**	(dd) (mm) (yyyy)
Specimen Type	☐ Blood (cfDNA tube) ☐ FFPE Tissue (50 μm of tissue put in eppendorf. Avoid putting tissue on slides.) ☐ Blood (EDTA tube, necessary for MSI) ☐ Other_____		

Family History, Clinical Details and Other Information

Cancer type: _____/☐Stage I ☐Stage II ☐Stage III ☐Stage IV

TNM: T___N___M___/ Metastasis：_____

RECIST: ☐NED/CR ☐SD ☐PR ☐PD

Have you ever had genetic testing? ☐Yes ☐No；If yes, the result is ☐normal ☐abnormal: Gene/Variant_____

I, the undersigned, understand the SOFIVA Cancer Monitor clearly. I hereby fully understand, agree and undertake the following:

1. In rare cases, poor sample quality (for example, due to coagulation, hemolysis, or insufficient sample volume) will require a repeat sampling to ensure the accuracy of the test.
2. SOFIVA Cancer Monitor & Cancer Track utilize the next-generation sequencing (NGS) for the detection of single nucleotide variants (SNVs), small insertions and deletions (indels), copy number variants (CNVs), and gene fusions in the target genes and regions. The unselected copy number variant, fusion, chromosome abnormal, balanced or unbalanced translocation, monoploidy, uniparental disomy, and chromosomal mosaicism are not included.
3. EGFR Mutation Test uses the real-time PCR to analyze 42 common mutants of EGFR gene.
4. Microsatellite Instability uses the capillary electrophoresis to analyze short tandem repeats in 5 microsatellite markers.
5. 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 the test as well as the risk of other screening tests).
6. If result is abnormal, strongly recommended that physician should be consulted to fully understand the meaning and content of the report. If necessary, physician should recommend appropriate health management.
7. 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.
8. I ☐agree / ☐do not agree to allow the remainder of my sample to be used for research purposes (Lack of response indicates consent).
9. I fully understand the above terms, statements, and declarations, and I agree to have the test 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.

_____

Signature, Date (dd/mm/yyyy)

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