Informed Consent and Authorization Form

for genetic analysis of a tumor (1B)

Information

For medical or scientific purposes, my healthcare provider offers me to perform a genetic analysis on my tumor. My consent is necessary for this analysis.

The purpose of this analysis is to evaluate genetic variations on the tumor that I presented, which can be useful for diagnostic or therapeutic procedures. This test is called a "somatic analysis". The potential results could be :

- **Positive:** a genetic information that may be used for diagnosis or therapeutic purposes is identified.
- **Negative:** the genetic information of my tumor does not impact my diagnosis nor treatment.
- **An Inconclusive Variant:** a genetic change is detected but it is currently unknown. This is called a Variant of Uncertain Significance (VUS).
- **Secondary findings:** in rare instances, this test may reveal a genetic change in a gene predisposing to cancer that is not directly related to the primary indication of testing but relevant and susceptible to preventive measures or care for me and/or my family members. According to my choice, this information may be disclosed to me and my ordering health care provider if it is likely to impact my medical care.

Consent for genetic analysis for diagnostic or therapeutic purposes

I, the undersigned, *(first and last name)* ……
date of birth ……../……../……,
☐ certify that I have been informed about the genetic variations sought on the biological samples practiced on myself for the analysis of the genetic characteristics of my tumor. My questions have been answered to my satisfaction by ……, prescriber.

☐ I consent to the biological sampling practiced on myself for genetic testing for the condition(s) listed above.

Disclosure of the results and secondary findings

The result of the primary analysis will be returned to me and explained, in the current state of knowledge, by the prescribing doctor during an individual consultation.

I agree to be informed of:
☐ Secondary findings, that is to say a genetic result not directly related to the indication of the prescription but relevant and susceptible to cancer preventive measures or care for me and/or other members of my family.
I understand that my refusal to be informed of the result of secondary findings does not modify my healthcare for the disease (major outcome) and that I can, at any time, change my mind about this consent.

☐ I authorize, respecting medical confidentiality, the transmission of information from my medical record to my doctors.

Disclosure to relatives in case of secondary findings

My results can impact on my health and/or that of my family. It may reveal that I have and/or my family members have a hereditary predisposition to cancer and that we are at risk of developing a cancer linked to this genetic disorder. Therefore,

☐ I will disclose the genetic information about myself to my family members who may be affected.

☐ I don't want to disclose myself my genetic information to my family members. I authorize the prescribing physician to perform this information without mentioning my identity according to the regulation of my country.

☐ When one of my relatives goes to consult, I authorize, in a confidential manner, the use of my results, including the secondary findings if I be aware of it, by the prescribing doctor for the benefit of the members of my family if these results appear medically useful for their care management.

Biomedical research and conservation

I understand that sharing medical and genetic data with scientific experts is essential as well as biomedical research to improve knowledge of the links between genetic variants, the mechanisms of human biology and the occurrence and treatment of diseases.

Therefore,

☐ I authorize the conservation of my samples for use in medical research.
The data concerning me will be considered as confidential and treated anonymously. I understood that these scientific studies will be done without any benefit or prejudice for me.
☐ I consent to the prescribing physician contacting me if there is a clinical research protocol in which I can be included.
☐ I authorize the laboratory to preserve my biological samples in a biological resource center for future tests concerning me or my family members.

Reassessment

Knowledge in the field of genetics evolves continuously and the interpretation of the result can evolve over time. Therefore, the re-evaluation / re-analysis of the samples could reveal a new diagnosis.
☐ I authorize, in respect of medical confidentiality, preserving a sample of biological material from my samples and its subsequent use for further investigation as part of the same diagnostic approach, depending on the evolution of knowledge.

☐ I agree to be contacted if a secondary finding related to cancer predisposition is revealed, by re-analysis, with prevention measures, including genetic counseling or care, are available for me or my relatives.
☐ I agree that on this sample, further tests and further analyzes may be carried out, depending on the progress of knowledge.

Consent and data protection act

I understand that I have the right to change or withdraw, at any time, each of my consents, for the various points detailed above.

☐ I consent, respecting the medical confidentiality, the conservation of data useful for the management of the diagnostic procedure and my file in computer databases declared according to regulation and law of my country.

	Date
Signature of the patient:	Signature and seal of the prescriber: