Informed Consent and authorization form

for germline genetic analysis (1A)

Information

For medical or scientific purposes, my healthcare provider offers me to perform a genetic test. My consent is necessary for this analysis.
The purpose of this analysis is to evaluate if I carry a genetic variant causing a genetic disorder or to determine the risk for me to develop or transmit to my offspring, a genetic disorder. This test is called a "germline analysis". The potential results could be :

- **Positive:** a genetic variant responsible of a genetic disorder or a predisposition risk to a specific disease in the future is identified.
- **Negative**: no disease-causing genetic variant is identified with the test performed.
- **Uncertain:** a genetic change is detected but it is currently unknown whether that change is associated with a genetic disorder or a disease risk (Variant of Uncertain Significance).
- **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 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 purposes

I, the undersigned, *(first and last name)* ……
date of birth …../……../……,
☐ certify that I have been informed about the disease sought on the biological samples practiced on myself that is the analysis of the genetic characteristics for *(specify the name of the disease or indication of the analysis)* ……

☐ certify that I have been informed about the disease sought, the means to diagnose it, the possibilities of prevention and care. I have received explanations of the effectiveness and limitations of this genetic test and I have been informed about how I will receive the result. My questions have been answered to my satisfaction by the prescriber ……

☐ I hereby 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 test will be reported to me and explained in the current state of knowledge by the prescriber during an individual consultation.

I agree to be informed of:
☐ Secondary findings, which are genetic variants not directly related to the indication of the prescription but relevant and susceptible to 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 care for the disease (major outcome) and that I can, at any time, change my mind about this consent.

☐ I authorize, in keeping with medical confidentiality, the transmission of information from my medical record to my physicians.

Disclosure to relatives

My results can impact 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 my genetic status to my family members who may be affected.

☐ I do not want to disclose myself my genetic status to my family members. I authorize the prescribing physician to perform this disclosure without mentioning my identity, according to the regulations of my country.

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

Biomedical research and storage

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

Therefore,

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

Reassessment

Knowledge in the field of genetics evolves continuously and the interpretation of the results can evolve over time. Therefore, the re-evaluation / re-analysis of the samples can potentially reveal a new diagnosis.

☐ I authorize, in keeping with medical confidentiality, the storage of biological material from my samples and its subsequent use for further investigations as part of the same diagnostic approach, according to the evolution of knowledge.

☐ I agree to be contacted if a secondary finding related to cancer predisposition is revealed by re-analysis, if prevention measures, including genetic counseling or care, are available for me or my relatives.

☐ I agree for further tests and further analyzes on this sample, according to the progress of knowledge on the genetic causes, the genetic variations and the disease as well as my susceptibility towards drug treatment.

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 items detailed above.

☐ I consent, in keeping with 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: