Informed consent for a genetic analysis

PATIENT	
Surname	
Name	
Address	
Date of birth	
Telephone	
Family N°	

PARENT OR LEGAL REPRESENTATIVE	
Surname	
Name	
Address	
Date of birth	
Telephone	
Family N°	

I, undersigned patient/parent or legal representative, consent that the required body sample(s) (e.g. venous blood, buccal swab, biopsy, other tissue sample *: …….) is/are taken, and DNA, cultured cells and/or original body sample are stored to analyze the condition present in myself/my child/my fetus/the individual whom I am legally responsible for or a (deceased) member of my family.

in order to:
□ perform a "**targeted" analysis** of the gene(s) known to be associated with the condition (single gene or targeted gene panel analysis)
□ perform an "**untargeted" genome-wide analysis** (e.g. CGH or SNP array, mendeliome/exome/genome massive parallel sequencing)*
□ other:……
for the following **working hypothesis/ presumptive diagnosis/condition,**:……

*delete as appropriate

Genetic analysis for diagnostic purposes:

Medical interpretation of the results: I understand that *authorized* personel from the hospital/genetic center may inspect my medical records in order to collect medical information necessary to interpret the obtained genetic test results, in respect with the legislation relative to the protection of private life.

Incidental findings: I understand that a genetic analysis could lead to the incidental discovery of genetic findings unrelated to the condition for which it was realized.
I □ **agree** / □ **do not agree** to be contacted if an incidental discovery is found within a framework of actionable genes (e.g. variant(s) in gene(s) involved in cancer, heart disease or other genetic disorders, and assessed as medically important and useful according to the literature and good medical practice at the time of analysis). I understand that these incidental results will be explained to me only through a genetic counseling clinic in an authorized genetics facility.

Data sharing for improving medical interpretation of genetic analysis for diagnostic purposes and academic research: I understand that sharing of medical and genetic data with (external) scientific experts/collaborators is crucial to gain better insight into the molecular changes and mechanisms of human biology and diseases. I am informed that data sharing and expert assessment of medical and genetic data can lead to better diagnosis, better health care in general and to improved prevention and therapeutic means in particular.
I □ **agree** / □ **do not agree** that my genetic data, and relevant selected medical data, are shared in a safeguarded de-identified or anonymised way (choice according to the purpose of the collaboration) with (external) scientific experts/collaborators approved by relevant ethical committees.

I understand that knowledge on mechanism of human biology and diseases, analysis and interpretation of the genetic results are evolving. Re-analysis of the data could release new diagnosis.

I □ **agree** / □ **do not agree** that my genetic data, and relevant selected medical data be re-analyzed on a research basis, as part of research projects approved by the relevant ethical committees.
I □ **agree** / □ **do not agree** to be contacted if a diagnosis is made in that context of re-analysis.
I □ **agree** / □ **do not agree** to be contacted if an incidental finding is made in that context of re-analysis.

I □ **agree** / □ **do not agree** that the sample(s) extract(s)) can be used in academic research or as control material in a de-identified manner, and can be shared with other internal or external scientific experts/collaborators in order to constantly improve our understanding of human biology. I understand that such academic partnerships and sharing will be submitted to the relevant ethical committee approval.

I understand that the data may be published in scientific journals, or communicated in scientific meetings, and I therefore □ **I consent** □ **I do not consent** to their anonymous publication. I recognize to have no rights on hypothetical commercial benefits (e.g. patent).
I □ **agree** / □ **do not agree** that photographs of myself / my above named child/fetus or the above named individual whom I am legally responsible for be published in scientific journals.

I understand that I retain the right to withdraw my consent at any time, for the various points detailed above. The withdrawal of my consent will have no negative impact on the non-genetic medical treatment of the person concerned by this consent. I understand that my withdrawal will not concern the results and information obtained prior to my request.

TO BE COMPLETED BY PATIENT, PARENT OR LEGAL REPRESENTATIVE	
I confirm having been well informed about the nature and aims of the above-mentioned test(s) that should be undertaken for the described genetic condition. I received the due information from the undersigned health professional or associate and/or have read the corresponding information leaflet. I have had the time and the opportunity to ask questions and I am satisfied with the answers and additional explanations.	
Surname	
Name	
Date	
Signature	

TO BE COMPLETED BY THE HEALTH PROFESSIONAL OR ASSOCIATE	
I confirm having informed and answered the questions of the undersigned patient/parent/guardian to the best of my ability regarding the possible results and the limitations of the above-mentioned test(s) that should be undertaken for the described genetic condition.	
Surname	
Name	
Date	
Signature	

These consent documents were jointly developed by ULB and VUB Genetics Centers, and the GEHU at De Duve Institute at UCL.

Modifications par rapport à la version précédente : Nouvelle version pour identifier les intervenants.