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Informed Consent of Patient (Legal Representative) with Genetic Laboratory Examination

Name of patient (examined person):	Personal identification number (ID):
Date of birth: (if different from Personal ID)	Medical Insurance Company Code:
Patient's permanent residence: (or other address)	
Name of legal representative:	Personal identification number:

Type of examination:

Genetic laboratory examination, sampling and storage of biological material

Purpose of laboratory examination

☐ Confirmation of disease diagnosis: ……

☐ Determination of disease predisposition:……

☐ Determination of disease transmission (carrier):……

☐ Assessment of fetal disease/malformation:……

☐ Examination of circulating fetal DNA in peripheral blood of the mother:……

☐ Preimplantation diagnostics: ……..

☐ For treatment optimization: ……

Nature of the examination

The examination requires collection of a tissue sample (usually venous blood) for subsequent laboratory assessment.

Expected benefit of examination

Determination of a disease cause leads to improved diagnostics, treatment management and prevention of complications. If genetic condition is confirmed in a fetus, parents can consider termination of pregnancy. In a predisposition to genetic disease, follow-up by a specialist can facilitate early diagnosis and thus improve prognosis.

Alternative examinations

No alternative examinations are available.

Consequences of the procedure

1. Positive result of DNA analysis can have consequences for the patient and other family members at risk.
2. Possible unexpected findings (e.g., carriership of a genetic disease or non paternity)
3. Possible abnormal findings the impact of which on current or future health of patient/family members is uncertain or unknown according to the current knowledge.

Statement of physician and patient

A. Statement of the physician

Herewith I declare, that I clearly and understandably explained the purpose, nature, expected benefit, consequences and possible risks of the above mentioned genetic laboratory examination to the examined person/legal representative. I also informed the examined person/legal representative about possible risks and consequences in case of refusal of the examination. Laboratory results will be confidential and will not be conveyed to a third party without consent of the examined person/legal representative, unless applicable laws determine otherwise.

Name of physician, who provided instruction	**Signature of the physician,** who provided instruction	Date:	Time:

B. Statement of examined person / legal representative

Herewith I declare, that I obtained genetic counselling concerning the above mentioned laboratory examination. I was informed on all facts clearly and understandably. I had an opportunity, including a sufficient time frame, to consider all aspects properly. I had an opportunity to ask the physician everything I considered substantial and I had an opportunity to discuss anything that I needed to clarify. My questions were answered clearly and understandably.

B. 1 For the above mentioned purpose, I agree with the following:

Please circle your answer:		
1. Sampling of biological material and laboratory genetic examination	YES	NO
2. Storage of my DNA sample in a laboratory biobank for further analysis performed to my benefit; further genetic laboratory examinations will be performed only after my approval and with my informed consent	YES	NO
3. Anonymous utilization of my DNA for medical research	YES	NO
4. Anonymous publication of my genetic laboratory results and relevant information on my condition, including photodocumentation, for scientific and educational purposes.	YES	NO

B. 2 Furthermore, I wish the following:

Please circle your answer:		
I wish to receive genetic laboratory tests results	YES	NO
I wish to be informed about unexpected findings	YES	NO

The following people will be informed about the examination results and/or unexpected results:

……

Consent of patient / legal representative

Based on this instruction, I agree with sampling of biological material and with genetic laboratory examination, under conditions mentioned above. I am aware that I can withdraw my consent at any time.

Olomouc, date	Time	**Signature of patient (legal representative)**
Relation to examined person (if signed by legal representative):		

If the patient cannot sign, indicate the reasons for this limitation:			
The way the patient showed his/her will:			
Name and surname of the medical professional / witness	Signature of the medical professional / witness	Date	Time