Consent for genetic testing

Patient details (use label):

Name _____ Given name _____

☐ male ☐ female

Date of birth _____

Street _____

Post code _____ City _____

Please return to:

Zentrum Med. Genetik Würzburg
Biozentrum, Am Hubland
97074 Würzburg

The German gene testing act (GenDG) requires written informed consent to be obtained from every patient prior to genetic testing.

Please read the following carefully, make sure all your questions were answered and tick boxes as appropriate. Not ticked boxes will be valued as "NO".

My doctor has informed me about the following diagnosis / disorder / syndrome :

.....

.....

its genetic basis, options for prevention and treatment and about the scope and aims of the planned genetic test, its predictive value and its limits. I have been informed about the risk of the required blood / tissue sampling. All my questions have been answered to my satisfaction.

I consent that the results of the genetic test(s) are also sent to my other medical professionals, specifically to Dr.:	☐ yes ☐ no
The application of such screening tests can result in incidental findings, which are not associated with the above named disease. I wish to be informed of any such incidental findings. A claim of completeness or future actualization of such incidental findings doesn´t exist.	☐ yes ☐ no
By German law, surplus genetic material (blood, DNA sample) must be destroyed after the completion of the genetic test. However, with my consent it may be stored and used for subsequent additional tests (if required) and/or as control for later testing of family members and relatives. I consent to storage and subsequent use of my genetic material and/or the genetic material of my child for the above purposes.	☐ yes ☐ no
Internal quality control is an important tool to guarantee the accuracy and reliability of genetic testing methods. For this purpose, genetic material from patients with rare genetic variants is an indispensable control material. I consent to my DNA and/or the DNA of my child to be stored and used for internal quality control in the laboratory. Before such use, my sample and/or the sample of my child will be anonymised.	☐ yes ☐ no
Genetic material from patients is also important for studying biological mechanisms which contribute to the development of hereditary diseases. I consent to my DNA and/or the DNA of my child to be stored for potential disease studies in the laboratory. I consent to be re-contacted before such use.	☐ yes ☐ no
The German gene testing act requires genetic results to be stored for 10 years and then destroyed. With patient's consent they may be stored for longer. Often, genetic results are required for counselling of children and relatives even after 10 years' time. I consent to storage of my genetic results and/or the results of my child beyond the legal time-span and its use for my family only.	☐ yes ☐ no
As required the results may be used for the counselling / analysis of my relatives.	☐ yes ☐ no

Genetic data will be deposited in a database at the Institut für Humangenetik. Selected data will be anonymised and only used for the purpose of quality control and data comparison.

I agree with the collection, processing and storage of personal data in electronic and paper form appropriate the assignment of the German GenDG and the EU-DSGVO. Further information according EU-DSGVO:

https://www.biozentrum.uni-wuerzburg.de/humangenetik/patientenversorgung/datenschutz/

I have had sufficient opportunity to read the above information on the content of the genetic counselling and my rights with regard to the European Data Protection Regulation and to thoroughly consider my consent to this.

I agree that external service providers commissioned by the Zentrum Med. Genetik Würzburg may process my personal data if this is required by law or is necessary with regard to the requested examination (e.g. clearing centers or cooperating laboratories).

I consent to the storage of the results and the collection and processing of my personal data in electronic and paper form in accordance with the provisions of the Gene Diagnostics Act (GenDG) and the European Data Protection Regulation (EU-DSGVO). I am entitled to a copy of this consent in accordance with § 630e (2) Abs. 2 S. 2 BGB.

I have been informed that I can withdraw my consent at any time without giving reason and without incurring any penalty. I have further been informed that I have the right not to know about my genetic test results and to terminate the testing procedure at any time. I can request my genetic material and/or the genetic material of my child and my genetic results and reports and/or the genetic results and reports of my child to be destroyed before result reporting, if I have changed my mind.

With my signature I consent to the genetic test(s) indicated above and the sampling of blood or tissue for this purpose.

_____	_____
City, date	Signature of the patient or his/her legal representative