

for performing genetic analysis according to GenDG

To be filled out by the patient!

The informed consent is part of the physician's documentation.

Patient data	Indication / question
Surname, First name: _____ Date of birth: _____ Gender: <input type="radio"/> m <input type="radio"/> f Street: _____ Zip code, City: _____ Country: _____	

The Genetic Diagnostics Law (GenDG) demands detailed information and written consent for genetic analysis as well as genetic counselling before prenatal and predictive analysis. In addition, the German Society for Human Genetics (GfH) and the Association of German Human Geneticists (BVDH) recommend clarifying the issues listed below as part of the consent.

Please read this consent carefully and tick the appropriate answers:

I have received, read and understood a general written explanation (and possibly additional written explanations) about genetic analysis according to GenDG. With my signature, I give my consent to the genetic analysis that are necessary to clarify the disease / disorder / diagnosis in question as well as the requisite blood / tissue sampling. I have had sufficient opportunity to discuss open questions.	yes <input type="checkbox"/>	no <input type="checkbox"/>
I have been informed, that I may withdraw my consent in whole or in part at any time without stating any reasons, without incurring any inconvenience (§ 8 GenDG, Art. 21 GDPR) and that I have the right not to receive results of the investigation (right of not knowing). I am aware that I can stop initiated examination proceedings at any time until the results are communicated and demand the destruction of the examination material, including all components derived from it, as well as all results and findings obtained so far.	yes <input type="checkbox"/>	no <input type="checkbox"/>
I am aware, that the laboratory service costs are not necessarily covered by the health insurance and have therefore covered by me.	yes <input type="checkbox"/>	no <input type="checkbox"/>
I would like to be informed about the results of the genetic analysis only to the extent that it is practically relevant for my family and me to the question above. I renounce the notification of incidental findings.	yes <input type="checkbox"/>	no <input type="checkbox"/>
I also ask for notification of all incidental findings.	yes <input type="checkbox"/>	no <input type="checkbox"/>
I understand, that the law requires the complete destruction of my personal data and medical results / findings after 10 years. If you need a longer storage period, this must be agreed in writing before the end of the 10 years.	yes <input type="checkbox"/>	no <input type="checkbox"/>
I agree, that collected data / results of the disease in question could be used in an encrypted (pseudonymised) form for scientific purposes and published anonymously in journals.	yes <input type="checkbox"/>	no <input type="checkbox"/>

Please note reverse side!

The Gene Diagnostics Law requires, that unused material has to be destroyed after completion of the investigation. Nevertheless, with your approval it may be kept. Please decide if and how unused test material may be used.		
I wish the immediate destruction after final completion of the analysis according to GenDG.	yes <input type="checkbox"/>	no <input type="checkbox"/>
OR (multiple answers possible): I agree with the storage:		
• for the purpose of verifiability of the results obtained.	yes <input type="checkbox"/>	no <input type="checkbox"/>
• for the purpose of quality assurance, student teaching, researching the above mentioned disease and improving diagnosis and treatment of genetic disorders in encrypted (pseudonymised) form.	yes <input type="checkbox"/>	no <input type="checkbox"/>
• for the use for future new diagnostic options for my above mentioned question.	yes <input type="checkbox"/>	no <input type="checkbox"/>
• I would like to be informed about clinically meaningful results.	yes <input type="checkbox"/>	no <input type="checkbox"/>
I agree, that my personal data, which are only used for the proper execution of the resulting contractual relationship, will be processed based on legal regulations.	yes <input type="checkbox"/>	no <input type="checkbox"/>
I agree, that my health data may be processed by my attending physician as well as transmitted from PharmGenomics to the assigned physician according to the GenDG. The transmission and processing of my health data is exclusively based on the GenDG.	yes <input type="checkbox"/>	no <input type="checkbox"/>
<p>Inquiry, correction, locking and deletion: According to Art. 15 GDPR of the European law, you are entitled to request information from PharmGenomics concerning your saved personal data at any time. Based on Art. 16, 17, 18 GDPR you are allowed to demand any correction, locking and deletion of your personal data from PharmGenomics at any time. According to §630a ff. of the German BGB, your health data will be saved for 10 years. If a desired deletion is not corresponding to current law, your data will be locked instead.</p>		
Place, date	Signature (patient / (legal) representative)	If representative: name, address