

► GENETIC CONSULTATION

Informed consent

Dear patient,

You have made an appointment for genetic consultation with a medical specialist. Genetic consultation is a session conducted for specialist evaluation and diagnosis of a genetic disease and to answer patient-specific questions on hereditary conditions in detail. The aim is to provide affected patients, (expectant) parents, as well as relatives who may themselves be carriers of a genetic condition with detailed information about diagnostic testing, inheritance patterns/heredity and possible risks, while also advising them on available therapy options.

Should the information you provide during this session give us indications of any other risks you were previously unaware of, we will proactively point these out to you. However, during our entire counselling session it is up to you to decide whether and to what extent you wish to be informed.

Reasons for seeking genetic counselling may include a suspected genetic condition or developmental disorder, deformities, the inability to conceive, questions during pregnancy (e.g. advanced age of a parent or abnormal ultrasound findings) or increased familial incidence of tumours.

Specialist genetic consultation generally includes the following:

- Identifying your personal questions and the objective of counselling,
- Review of your personal and familial medical history (anamnesis, genealogical analysis),
- Evaluation of any existing medical reports and findings,
- If necessary: physical examination of yourself or of relatives, including photo documentation where relevant to your questions,
- Advice on general genetic risks and assessment of specific genetic risks,
- Where indicated and requested by you: initiation of genetic testing,
- Establishment of a medical/genetic diagnosis with the highest possible degree of precision,
- Provision of detailed information on the specific condition/symptoms
- Detailed discussion about the possible consequences this information has for your life and family planning and, where applicable, for your health.

Medical reports issued by other specialists are very helpful for effective genetic counselling and efficiency in establishing a diagnosis and initiating any further testing. Ideally, you will send us your medical records in advance. Where necessary, we will obtain any missing documents with your consent. For these purposes we ask you to sign the **enclosed informed consent to transmission of medical records**.

Today, we already have knowledge of a large and continually growing number of genetic conditions. Although knowledge of genetic variants is rapidly increasing, it is not possible to provide full information on all conceivable conditions in which genetics play a causative or contributing role, nor is it possible to issue a precise risk assessment or prognosis in all cases.

If you decide to undergo genetic testing after having received genetic counselling, this is usually possible by having a blood sample taken. Genetic testing is only carried out with your active consent. Medical genetic testing may reveal genetic modifications that are not known to cause any health issue according to the current medical knowledge. We will only inform you of such results if they are necessary to fulfil the objective of the requested examination.

Once a genetic analysis has been completed, the findings will be explained to you in a further counselling session.

The aim of genetic consultation is to help you make decisions, assess risks of illness and take any necessary steps. It remains up to you to decide what results you wish to be informed of, and what conclusions you draw from the consultation.

The main points discussed in the consultation session will be summarized and made available to you in a report in plain language. You are welcome to contact us again at any time if you have any further questions or if anything is unclear. Our collaboration with other physicians is subject to the code of medical ethics, according to which you have a say regarding the transmission of information to other physicians. The physician who referred you will also receive a copy of the consultation report (*).

I/we consent to my/our general physician) _____
receiving a copy of the consultation report.

Yes No

In addition, I/we consent to the following physicians receiving a copy of the consultation report:

1. _____

2. _____

All individuals involved are bound by the medical profession's obligation to confidentiality, and all legal requirements, in particular with regard to data protection, will be complied with. I/we have read and understood the above text. I/we request that genetic counselling be carried out as described.

Yes No

The legislature has passed provisions regarding storage, stipulating that personal data must be completely destroyed after 10 years. However, such information may continue to be of personal relevance beyond this period of time. With your express consent, we may continue to store the data collected beyond the statutory period of 10 years.

I/we consent to data/documents that have relevance to me/us, or my relatives, being stored for a period exceeding 10 years.

Yes No

I/we agree for data collected to be made available for scientific purposes in a pseudonymized form.

Yes No

I/we were informed that at any time we may withdraw, in whole or in part, my/our consent to continue with any examination that has been initiated, to be informed of any test results (right not to know) or to store data, without stating reasons, and that in such case only the services provided until such time will be invoiced. In the event of a withdrawal, care will be taken, upon my/our declaration, that all sample materials, all components extracted from them, and all results and reports generated from them, will be destroyed in accordance with section 12, subsection 1, no. 2 and section 13, subsection 1 of the German Genetic Diagnostics Act (Gendiagnostikgesetz, GenDG). Access to the Genetic Diagnostics Act is made available by us.

The German Civil Code (Bürgerliches Gesetzbuch, BGB) provides that I/we must be issued copies of any documents signed by me/us regarding any information received or consent given (to a medical procedure). I/we know that I/we can, as a matter of principle, also request access to my/our patient records at a later time.

(*) Please delete as applicable

I/we were issued a copy of this page.

Place, date

Signature of patient or legal representative (if legal representative: last name, first name in capitals)