I consent to genetic testing on a sample obtained from

- ◯ me
- ◯ my (unborn) child
- ◯ the person I represent

Name, First name (in capital letters)

Born on

to test for

1. General Information

I have been informed by a specialist about the nature, scope, significance, limitations, and consequences of the genetic test, as well as about any potential risks associated with the sample collection. I consent to the analysis of my own free will. I may withdraw my consent at any time before the results are reported - without providing a reason - or decline to receive the results. I may also change or revoke the other decisions made at any time by sending a written notice to the institute listed above. This applies whether the decisions relate to me, my (unborn) child, or a person for whom I am acting as legal representative.

2. Documentation and Reporting of Findings

According to the Austrian Genetic Engineering Act (GTG), genetic testing requires informed consent. A distinction is made between different types of testing: Type 2 = diagnosis or clarification of an existing disease; Type 3/4 = Determination of a disease risk (predisposition) or carrier status, of which Type 3 is for a preventable or treatable disease and Type 4 stands for a disease that is NOT preventable or treatable. Results from a Type 4 analysis may not be documented in physician's letters or medical records. For results from Type 2 and 3 analyses, documentation in physician's letters and medical records is usually advisable to ensure optimal treatment. However, you may also decline this below:

I object to the documentation of diagnostic or treatment-related findings (Type 2/3 GTG)

◯ in medical reports ◯ in ELGA (Austrian electronic health record)

The results of your genetic testing will be summarized in one or more reports. Unless you specify otherwise, these reports will be sent only to the physician/specialist who ordered the testing for you. For certain genetic tests, it may be medically necessary to include results from relatives (e.g., children and parents) and present them together in a single report in order to provide a meaningful interpretation. If you do not wish this information to be included in a joint report, please let us know in writing. Other specialists/physicians will only receive a report from us if you expressly request and authorize it.

Please send the results of the genetic testing additionally to the following specialist/physician (full name and address, in capital letters):

3. Handling of Samples and Data, Quality Assurance

Existing sample materials will be stored after the requested tests have been completed and will be available for further diagnostic analyses (including for follow-up requests or as reference material for carrier testing of relatives). If you wish to have your sample material destroyed after the tests have been completed, please let us know in written form. In addition, an analysis may reveal findings that limit the quality of the test and are therefore reported, e.g., identifying samples that are not genetically related despite reported family relationships.

To ensure the quality of our medical services, samples and related data may also be used for quality control, method development, scientific purposes, or training and continuing education. In doing so, we strictly ensure that samples are pseudonymized. This means that any information that could directly identify a person is removed or rendered unrecognizable. Please indicate below whether you agree to this.

I consent to the pseudonymized use of my samples and data for quality control, method development, scientific purposes, or education and training:

◯ yes ◯ no

4. Reevaluation / Repeated Analyses (particularly for genome-wide analyses)

Our understanding of human genetics and genetic variants is constantly growing. For this reason, reanalyzing samples or data after a certain period of time may yield new insights regarding certain medical issues. Relevant findings may be communicated to you or your treating physician. Please indicate below whether you agree to this. However, there is no entitlement to reevaluation.

I agree that my data and samples can be re-tested later, if needed, to clarify my medical condition:

◯ yes ◯ no

5. Incidental Findings (particularly for genome-wide analyses)

Numerous genetic tests generate a comprehensive set of genetic data, which is evaluated specifically to address the question at hand. In the process, genetic variants may be identified that are not related to the reported symptoms but may be significant for the health of the person being tested (e.g., increased risk of cancer, severe heart or vascular diseases, or treatable metabolic disorders). Such incidental findings are reported in accordance with national and international guidelines if, based on current knowledge, they are relevant for prevention or treatment and you want to be informed. For minors (who are unable to give consent), incidental findings that are already significant for medical care during childhood will be reported even if the parents object. The reporting of incidental findings does not mean that a full genetic carrier screening was performed; therefore, no complete or targeted examination of additional health-related genes is guaranteed.

I would like to receive information about medically relevant incidental findings:

◯ yes ◯ no

6. International Knowledge Exchange

International scientific databases (e.g., ClinVar, GeneMatcher) are used to interpret genetic variations. In certain cases, we may want to submit pseudonymized information – such as the identified genetic variation, its expert assessment, and selected clinical details – to these scientific, publicly accessible databases. Names, dates of birth, or other directly identifiable personal data are not shared in this process. This supports the advancement of human genetics (data analysis for scientific purposes, discovery of new associations between a gene and clinical conditions) and can thus also benefit other patients. Please indicate below whether you consent to this.

I consent to the submission of my pseudonymized data to scientific online databases or platforms:

◯ yes ◯ no

If you have any questions, you can contact the referring physician or the specialist who provided the consultation.

date	last name, first name of patient or representative (in capital letters)	signature of patient or representative

date	last name, first name of specialist/physician (in capital letters)	signature of specialist/physician

Testing cannot be performed unless all required information, including the clinical indication, has been provided and this form has been signed. Any option left unchecked on the form will be considered declined.

Privacy Notice pursuant to Article 13 of the GDPR (DSGVO): The Institute of Medical Genetics at the Medical University of Vienna is responsible for processing your personal data and takes technical and organizational measures to protect it appropriately. In doing so, it complies with all legal requirements regarding data protection as well as the Austrian Genetic Engineering Act (GTG). Your data is processed on the basis of your consent and the applicable legal provisions (in particular Art. 9(2)(a) and (h) of the EU GDPR in conjunction with Sections 64 et seq. of the GTG) for the purpose of genetic tests and, where applicable, for scientific purposes, quality control, method development, or education and training. The data is stored in accordance with legal requirements. The analysis is generally performed at the institute mentioned above. If it is necessary or appropriate for technical or medical reasons, or in your best interest, the testing may also be conducted at another diagnostic laboratory in Austria or abroad. Personal data (primarily master data, contact information, health data, and family data) as well as the results of the genetic analyses are processed at the institute conducting the analysis in accordance with legal regulations. In doing so, all applicable data protection laws and the Austrian Genetic Engineering Act are complied with, and your rights as a data subject are protected. For research purposes, your data may also be shared in pseudonymized form with other scientific institutions in Austria and abroad. Under certain circumstances, your data may be processed in laboratories located in countries outside the EU (third countries) that are not subject to the GDPR. Not all third countries have been granted an adequacy decision guaranteeing a level of data protection equivalent to that under the GDPR in the EU. This creates a risk that you may not be able to enforce the rights to which you are entitled under the GDPR. However, the recipient of the data is in any case obligated to protect your data appropriately. Any transfer to a third country is carried out solely on the basis of Articles 44–50 of the GDPR. You have the right to access, rectification, erasure, restriction of processing, data portability, objection to data processing, and withdrawal of consent. Withdrawal of consent does not affect the lawfulness of processing carried out prior to such withdrawal. If you have any questions, please contact either your attending physician or the Data Protection Officer at the Medical University of Vienna. (E-Mail: datenschutz@meduniwien.ac.at). We would also like to point out that complaints or claims related to data protection may be filed with the Data Protection Authority of the Republic of Austria.