Institut für Humangenetik
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Consent form for genetic analysis

I agree that a **genetic analysis** may be performed on a sample taken from

☐ myself

☐ my child

☐ the person represented by me

……
Last name, first name (IN CAPITAL LETTERS)

Date of birth: ……

with regard to suspicion / clarification of:

……
e.g. disease / gene locus / type of clarification / type of examination

Communication of findings, documentation:

The results of the analysis are summarized in a medical report and will be communicated through a genetic counselling session. Unless otherwise specified, the medical findings will be sent to the referring physician and, if applicable, the attending physician. Other parties will only receive the medical report if you explicitly request and allow for transfer of the data.

I request for the results of the genetic analysis to also be sent to the following physician:

……
Name of the physician, discipline, address

Genetic germline analyses are subject to approval according to the Austrian Genetic Engineering Act (GTG). There are different types of analyses:
Type 2 = determination or clarification of an existing illness
Type 3/4 = determination of a disease risk (predisposition) or a carrier status
Type 3 = for a preventable or treatable disease
Type 4 = for a disease that CANNOT be prevented or treated
Results from a type 4 analysis may not be documented in medical reports and medical histories. For results from analyses of types 2 and 3, documentation in medical notes and medical histories may be useful to ensure optimal treatment. However, you may also decline this below. If you object to the documentation of the analysis results in medical notes and medical histories, please indicate this below; if you agree with the documentation thereof, please do not check the relevant box.

I object to the documentation of the diagnostic or therapy-relevant findings (type 2 or 3 GTG)

☐ in medical letters/medical histories ☐ in the electronical health records ELGA

Additional findings, particularly for genome-wide analyses (e.g. exome-sequencing):

In the context of some genetic analyses, often a comprehensive genetic dataset, which is specifically evaluated for a certain question, is generated. Sometimes genetic variants or changes that are not directly related to the original question, but which could be relevant for preventive measures or therapy for other medical reasons, are also identified. Such additional findings will only be communicated if this may be useful for you and you wish to be informed. If you do not want any communication / information, please indicate this below; if you agree to the notification of any additional findings, please do not check the box.

☐ **I do not** want be informed about any medical relevant additional findings.

Further arrangements / information / **password** for telephone queries etc.:

……

Repeat analyses:

Knowledge of genetic changes is constantly growing. In the case of some medical questions, in rare cases a new analysis of the samples / data can lead to new findings in the course of time. If there were any findings that could be of importance to you, we would inform you or your attending physician. However, there is no entitlement to a repeat analysis. If you do not desire such repeat analyses, we ask you to indicate this below; if you agree to any useful repeat analyses, please do not check the box in the field below.

☐ **I do not** want any possible repeat analysis for further clarification after the current ones have been completed.

Future handling of samples or data, quality assurance:

Unused sample material is stored after completion of the desired analyses and is available for further diagnostic analyses. A separate analysis of samples or data can legally be used for quality control, method development, scientific purposes or training and further education. Attention is paid to pseudonymisation of the samples, i.e. information that allows direct conclusions to be drawn about the specific person is removed or made illegible. If you do not want this, we ask you to indicate this below; if you agree, please do not check the boxes below.

☐ **I do not** agree to the pseudonymized use of my samples or data for quality controls, method development, scientific purposes or training and further education.

I was informed by a specialist about the nature, scope, significance, and consequences of the genetic analysis and, if necessary, about possible risks of sample collection and I agree to the analysis with my free consent. I am aware that I can have the investigation terminated without providing reasons until the findings are communicated or I can renounce the communication of the results. I may also change or revoke the other decisions made in the current declaration at any time by giving written notice to the institute. The decisions apply to me and accordingly also to my child or the person I am representing.
The analysis is usually carried out at the above-mentioned institute. If it is necessary or expedient for technical or medical considerations or in your interest, the analysis can also be carried out at another diagnostic laboratory in Germany or abroad. The personal data (especially master data, contact data, health data, family data) and the results of the genetic analyses are processed in the institute that carries out the analysis in accordance with the statutory provisions. As with the protection of your rights as a data subject, all statutory data protection requirements and the Austrian Genetic Engineering Act are complied with. You can obtain more information about this from the medical specialist or on the following website: https://humangenetik.medunigraz.at/.

Data protection information in accordance with Art 13 DSGVO
The Medical University of Graz is responsible for processing your personal data and takes technical and organizational measures to protect it appropriately. Your data will be processed on the basis of your consent and the applicable legal provisions (in particular Art 9 Paragraph 2 lit a and lit h EU DSGVO in conjunction with § 64 ff GTG) for the purpose of genetic analysis and, if necessary, for scientific purposes, quality control, method development or training and further education. The data is stored in accordance with the statutory provisions. If it is necessary or expedient for medical reasons or in your interest, your personal data will also be transmitted to other approved diagnostic laboratories in Germany and abroad for analysis purposes. In principle, there is no transmission to countries outside the EU (third country); a possible exception is the temporary evaluation of pseudonymous data records in a third country (e.g. USA) with a data protection-checked procedure. Any transmission to a third country takes place only on the basis of Art. 44-50 DSGVO. You have the right to information, correction, deletion, restriction of processing, data portability, objection to data processing and revocation of consent. Withdrawing your consent does not affect the legality of the processing until the withdrawal. Please contact either the supervising doctor or the data protection officer or data protection coordinator, the email address for data protection inquiries is: office.datenschutz@medunigraz.at. We also point out that complaints or claims in connection with data protection can be submitted to the data protection authority of the Republic of Austria.

Addition for Whole Exome Sequencing and Whole Genome Sequencing (WES / WGS) at the Institute of Human Genetics Graz:
Clinical information about you and your family and the genetic changes found are entered in a pseudonymized form in a non-publicly accessible database, which is used both to manage the examination process and the examination data, and also for data evaluation for scientific purposes. You are not recognizable as a person or named in any form. If you would like to delete your data from the database at a later point in time, this can be done by contacting your supervising doctor at the Institute of Human Genetics.

☐ I agree to the inclusion of my data in the aforementioned database.

☐ I prohibit the inclusion of my data in the aforementioned database.

.....	.....	.....
Date	Last name, first name patient / legal representative (BLOCK LETTERS)	Signature patient / legal representative

.....	.....	.....
Date	Last name, first name referring physician (BLOCK LETTERS)	Signature referring physician

Medizinische Universität Graz, Neue Stiftingtalstraße 6, 8010 Graz - www.medunigraz.at