Medical University of Graz
Diagnostic & Research Center for
Molecular BioMedicine
Diagnostic & Research Institute of Human Genetics

Institute of Human Genetics

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Consent form for a genetic analysis

I agree that a **genetic analysis** is 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

I was informed by a specialist in accordance with § 69 GTG 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 giving 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 or another centre for medical genetics in Austria [1]. In special cases, the analysis can also be performed at another national or international diagnostic laboratory. The personal data (especially master data, contact details, health data, family data) and the results of the genetic analyses are stored in the institute that carries out the analysis in accordance with the legal provisions. As well as the protection of your rights[2], all legal requirements of data protection and the Austrian Genetic Engineering Act are observed. Further information on this can be received from the medical specialist or on the homepage https://humangenetik.medunigraz.at/.

Replicate analyses

Knowledge of genetic changes is constantly increasing. For this reason, a re-analysis of the samples or data can lead to new knowledge after some time for some medical questions. If such replicate analyses should result in findings that could be of importance to you, we would notify you or your supervising physician. There is, however, no entitlement to a replicate analysis. Please indicate below whether you agree:

I allow my data and samples, if necessary, to be analysed again at a later point in time if it is useful and possible to clarify my medical question.

☐ Yes ☐ No

*If no selection is made, it is assumed that you do **not** agree.*

Additional findings

In the context of a genetic analysis, often a comprehensive genetic data set, which is specifically evaluated for the specific 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 might be useful for you and you wish to be informed. You may specify this below:

1 The list of facilities is available at www.oegh.at [Einrichtungen].
2 You have the right to information, correction, deletion, restriction of processing, data processing, objection and the right not to be subjected to a decision based solely on automated processing.

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I would like to be informed about additional medical findings. ☐ Yes ☐ No

*If no selection is made, it is assumed that you do **not** agree.*

Communication of findings, documentation

The results of the analysis are summarized in a medical report, which, unless otherwise specified, is sent to the referring physician and, if applicable, the attending physician. Other people will only receive the medical report if you explicitly request and allow it.

I ask that the results of the genetic analysis are also sent to the following physician:

....
Name of the physician, discipline Postal code, city

Genetic analyses of the germline are subject to approval according to the Austrian Genetic Engineering Act (GTG):
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 must not be documented in medical reports and medical histories. For results from analyses of types 2 and 3, documentation in doctor's letters and medical histories is usually useful to ensure optimal treatment. However, you may also decline this below:

I object to the documentation of the diagnostic or therapy-relevant findings (Type 2/3 GTG)
- ☐ in medical letters/medical records from my attending physicians
- ☐ in the electronic health record ELGA

Future handling of samples or data, quality assurance

Sample material that is not used is stored after the desired examinations have been completed.
A separate analysis of samples or data can be helpful for quality controls, method development, or training and further education. Samples / data are encrypted (pseudonymized) so that an allocation to a specific person is excluded. Please indicate below whether you agree:

I agree with the encrypted use of my samples or data for quality control, method development, or training and further education. ☐ Yes ☐ No

*If no selection is made, it is assumed that you do **not** agree.*

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

This declaration of consent was developed across the board by the Austrian Society for Human Genetics (ÖGH).
Further information is available on the ÖGH homepage, www.oegh.at.

Password for further enquiries

If you have any questions over the telephone regarding genetic findings, please give us with a password that only you know and that we can use to ensure your identity:

Password (legible in BLOCKLETTERS): .....

Medizinische Universität Graz, Auenbruggerplatz 2, A-8036 Graz. www.medunigraz.at

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Performance of a genetic analysis

Data protection information according to Art 13 DSGVO

The Medical University of Graz is responsible for the processing of your personal data and takes technical and organizational measures to adequately protect them.

Your data will be processed on the basis of your consent and the applicable legal provisions (Art 9 Para. 2 lit a and h EU-DSGVO in conjunction with § 69 GTG) for the purpose of a genetic analysis and, if necessary, also for the purposes of quality controls, method development or training and further education. The data will be stored for as long as the legal requirements allow or as far as it is necessary for the purpose of the genetic analysis.

If this appears appropriate in your interest for medical or other considerations, your personal data will also be transmitted to other approved national or international diagnostic laboratories for analysis purposes. Your data may also be processed in laboratories in countries outside the EU (third country) that are not subject to the DSGVO. An adequacy decision, which guarantees an equivalent level of data protection as in EU countries due to the GDPR does not exist for all third countries. This means that there is a risk that you will not be able to enforce your rights under the DSGVO. In any case, the recipient of the data is obliged to adequately protect your data.

You have the rights to information, correction, deletion, restriction of processing, data portability, objection to data processing and revocation of consent. For this purpose, please either contact your attending physician or the data protection officer (datenschutz@medunigraz.at), who is also available to answer any questions you may have about data protection. We would also like to point out that complaints or claims relating to data protection can be made to the data protection authority of the Republic of Austria.

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