



CAMPUS GROSSHADERN
 MED. KLINIK UND POLIKLINIK III
 DIREKTOR: PROF. DR. DR. M. VON BERGWELT
 LABOR FÜR LEUKÄMEDIAGNOSTIK



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Consent Form¹ for the Performance of Genetic Analyses Pursuant to the German Gene Diagnostics Law (GenDG) incl. Withdrawal of Consent Form
 FB-PÄ 25

Labor für Leukämiediagnostik
 Med. Klinik und Poliklinik III

patient data:

Marchioninstr. 15

Last name

First name

81377 München

Date of birth

Address

Tel. +49 (0)89-4400 7 4977

Fax +49 (0)89-4400 7 4978

For all genetic analyses, the German Gene Diagnostics Law (GenDG) stipulates a detailed explanation along with a written patient consent and, prior to predictive analyses, additional genetic counselling.

Please read this consent carefully and tick YES or NO.

I, the undersigned, have been given a general explanation in writing (and, if applicable, special written explanations) regarding genetic analyses in accordance with GenDG and I have read and understood the explanation(s). I hereby give my permission for genetic analyses that may be required for clarification of the disease/health disorder/diagnosis:

and I consent to give necessary blood/tissue samples.

I² agree to the results of the analysis/es being passed on to further doctors / persons¹:

yes
 no

I² wish to be informed about the results of the genetic analysis only insofar as these practically are relevant for myself and my family in respect of the above medical problems.
 I waive notification of incidental findings.

yes
 no

I² wish to be informed about any incidental findings from which practical consequences may be derived.

yes
 no

Legislation states that your personalized data and medical results/evidence have to be destroyed completely after a period of 10 years. However, the information obtained may be of continued importance for you or your family (e.g. your children) after expiry of that period.
 If you agree, we will be allowed to keep your data beyond the legally prescribed 10-year period³.

yes
 no

- Do you consent to data/documentation relevant to you or your family being kept for a maximum of 30 years before it is destroyed?

yes
 no

- Do you consent to use medical results/specimen for genetic counseling/analyses for following relatives:

Erstellung:

Konstandin, Nikola

Prüfung:

21.12.2017 Zientara, Ewelina

Freigabe:

22.12.2017 Schneider, Stephanie Dr.

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I give permission for data / results concerning the disease in question to be used in encoded (pseudonymized) form for scientific purposes and to be published in anonymized form in professional journals.	<input type="checkbox"/> yes <input type="checkbox"/> no
<p>The Gene Diagnostics Law requires unused specimen material to be destroyed after examination is finished³.</p> <p>However, it may be stored if you agree. Please decide whether and in which way unused sample material may be utilized⁴</p>	
I wish to have the material destroyed immediately after the end ⁵ of investigations as required by GenDG	<input type="checkbox"/> yes <input type="checkbox"/> no
<p>OR (multiple answers possible): I agree to the samples / data being stored</p> <ul style="list-style-type: none"> • to enable verifiability of the results obtained • stored for use to enable future new diagnostics regarding the medical problems concerned, • I wish to be informed about clinically relevant findings • stored for use in encoded (pseudonymized) form for the purposes of quality assurance, teaching of students, research into the disease and for improved diagnostics and treatment of genetic diseases 	<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> yes <input type="checkbox"/> no
<p>I understand that I am entirely free to withdraw my consent partly or totally at any time and without giving any reason and that this withdrawal will not in any way cause disadvantages for me or affect my right not to know any results of investigations. I further understand that I have the right to stop initiated investigations any time before I will be informed about results and to demand destruction of the sample material including any components derived therefrom and of any and all results and findings obtained.</p>	

I have been able to ask questions, all of which have been answered to my satisfaction.

Place and date

Signature of patient or
patient's legal representative

Name and address of
representative

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¹ This consent form for genetic analyses is intended for use by the responsible doctor who is obliged to provide information and explanation for the patient in conformity to Section 9 GenDG. In case third parties or institutions are entrusted with an analysis these shall be furnished with a copy of the signed consent form.

² If this consent form is used by commissioned persons/institutions, the requirement of communication and provision of findings does not apply, since any reports may ONLY be sent by the responsible doctor and findings may only be communicated by a responsible doctor or a genetics counselor. Commissioned institutions and persons are obliged to provide their results/findings ONLY to the responsible doctor.

³ If the patient's consent has been obtained for a specific storage period (e.g. for 30 years), the relevant documentation must be kept for that same period. It is recommended therefore obtaining this consent for RELEVANT medical documentation only. A declaration of assignment does not provide for discretionary power since neither documentation nor findings constitute any property rights as defined in Section 950 BGB (German Civil Code).

⁴ Although assignment of residual sample material as per Section 950 BGB grants the laboratory a free and uncomplicated right of disposition for such sample material in terms of discarding or up to free research, this is contradictory to the purpose of the law (Section 1).

⁵ Unless otherwise agreed in writing with the patient/s with regard to storage / use of residual sample material, the latter shall be destroyed immediately as and when it is no longer required for the intended purpose/s. Since the law does not say anything about a point in time, the investigator will be more or less free to fix a date.

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**Transmission of Withdrawal of Consent for Genetic Analysis
to Commissioned Institutions and Persons**

**Labor für Leukämiediagnostik
Med. Klinik und Poliklinik III
Marchioninstr. 15**

81377 München

Tel. 089-7095 4977

Fax 089-7095 4978

PATIENT DATA

.....
Last name First Name

.....
Date of birth

.....
Address

.....
Postal Code Place

Dear colleague,

This is to inform you that on
the above patient / the legal representative withdrew consent to genetic analysis which had been given to me on
.....

with respect to
.....

You are kindly requested to make sure that, in accordance with Section 12 Art.1 No. 2 and Section 13, Art.1 of German GenDG, all samples I have sent you for diagnostics and all components, results and findings derived from these samples will be destroyed immediately.

.....
Place and date **Stamp and signature of doctor responsible as per German GenDG**