



**Zentrum für Diagnostik
Institut für
Transfusionsmedizin**

**Institutsleiter
Dr. med. Sven PEINE**

Martinstraße 52
20246 Hamburg
Gebäude O38 - 1. OG
Telefon: (040) 7410-53433
Telefax: (040) 7410-55471
E-Mail: hss@uke.de

Patient Identification*

Referring Physician*

Surname First name

Date of birth

Name in block letters*

Street

Postal code City

Signature* Institution stamp*

Informed Consent for Genetic Testing (GenDG-Compliant Template)

Please note: The informations marked with an asterisk (*) are explicitly required under the german Genetic Diagnostics Act (GenDG). If any of this information is missing, molecular genetic diagnostics must not be initiated.

The GenDG mandates for all genetic analyses:

- written informed consent of the person concerned (this form), following comprehensive information
- genetic counselling prior to prenatal and predictive genetic analyses

Please read this declaration of consent carefully and clarify any of the issues listed below with your physician if necessary.

Please ensure that all fields are completed and that one box is checked in each section according to your preferences.

By signing (page 2), I give my consent to the genetic analyses of **HLA characteristics potentially associated with the disease**, as well as to the required collection of blood/tissue samples, which are necessary solely for the diagnostic clarification of the specified **disease / clinical question**.

Disease / clinical question*:.....

I have been informed about the purpose, nature, scope, and significance of the requested genetic test. I have also been informed in detail about the possible consequences that may arise from the results of the genetic analysis for myself and for my family members.

I agree that the results of the analyses may be forwarded by the referring physician to the following physicians / persons:

.....

I wish to be informed about the results of the genetic analysis only to the extent that they are of practical relevance to me and my family for the above-mentioned question. **I waive the disclosure of incidental findings.***

I also request disclosure of all incidental findings from which practical consequences may be derived.*

Please tick as appropriate:
☐ yes ☐ no *

☐ yes ☐ no *

The legislator requires that your personal data and medical results/findings must be completely destroyed after 10 years. However, this information may still be of significant importance to you or your relatives (e.g. your children) beyond this period. With your consent, we may retain these data beyond the legally required retention period of 10 years. Do you agree that data/documents relevant to you or your relatives may be stored for up to 30 years and only then destroyed?	<i>Please tick as appropriate:</i> ☐ yes ☐ no
I agree that collected data/results concerning the disease in question may be used in encrypted (pseudonymised) form for scientific purposes and published in anonymised form in scientific journals.	<i>Please tick as appropriate:</i> ☐ yes ☐ no
I consent to my test material being forwarded to an external laboratory if the UKE HLA laboratory is unable to perform the analyses itself.	<i>Please tick as appropriate:</i> ☐ yes ☐ no
The GenDG requires that unused sample material be destroyed after completion of the analysis. With your consent, however, it may be retained. Please decide whether and how unused sample material may be used: I agree to the storage (multiple selections possible): • for the purpose of verification of the obtained results • for use in future diagnostic options regarding my above-mentioned clinical question • I wish to be informed about clinically relevant findings • for use in quality assurance, medical education, research into the above-mentioned disease, and improvement of diagnostics and treatment of genetic disorders in pseudonymised form Alternatively: I request immediate destruction after final completion of the analysis.	<i>Please tick as appropriate:</i> ☐ yes ☐ no ☐ yes ☐ no ☐ yes ☐ no ☐ yes ☐ no ☐ yes ☐ no
• I have received, read, and understood general written information (and, if applicable, additional specific written information) on genetic analyses pursuant to the GenDG. • I have had sufficient opportunity to discuss any open questions. • I have been informed that I may withdraw my consent in whole or in part at any time without giving reasons and without suffering any disadvantage, and that I have the right not to know the results (right not to know). • I am aware that I may stop initiated analyses at any time before results are communicated and request the destruction of the sample material, including all components derived from it, as well as all results and findings obtained up to that point.	
Place, date * Signature of the patient / legal representative * Genetic analyses in minors: Please note that for genetic analyses performed in minors, the signatures of <u>both legal guardians</u> are required. Place, date * Signature of the mother * Signature of the father * (If you have sole custody, please indicate this next to your signature)	