Center for Human Genetics and Laboratory Diagnostics

Dr. Klein, Dr. Rost and Colleagues

Genetic Counseling
Imma Rost, M.D. (Head)
Monika Cohen, M.D.
Prof. J.-U. Walther, M.D.
Dagmar Wahl, M.D.

Declaration of consent (acc. to German Genetic Diagnostics Act)

Surname, First name (pat.): _____

Date of birth: _____ Gender: ☐ Male ☐ Female

Address: _____

Postcode, City: _____

Telephone: _____

Responsible physician (Stamp) - Date - Signature

Request/Indication - (suspected) diagnosis - please copy onto laboratory note

Copies of results to:

permitted only with written consent of patient or legal guardian (see below)

Specimen for investigation (type, quantity, date/time of collection where relevant)

Note: unlabeled material must be discarded

Clinical data/family history

Declaration of consent (according to German Genetic Diagnostics Act, GenDG) – *applicable only for the determination of genetic (hereditary) characteristics*

The GenDG requires provision of detailed **information** and a written **consent** for all genetic investigations, as well as **genetic counselling** prior to both predictive (applies to healthy individuals) and prenatal testing. The German Society of Human Genetics (GfH) and the Association of German Human Geneticists (BVDH) recommend clarifying the issues listed below during the information process. **Please read the declaration of consent carefully** and cross out any statements you do not agree with.

By signing the form below, I confirm that I

- have been fully informed by my physician about the significance and consequences of the genetic investigation, in compliance with GenDG,
- have been given sufficient opportunity to discuss open questions,
- agree to the sampling of specimens needed for investigation (blood, tissue, chorionic villus cells or amniotic fluid for prenatal diagnosis),
- consent to the **genetic test** being carried out in order to clarify the **disease/dysfunction/suspected diagnosis** below

_____

- agree with the evaluation of additional genes in the same indication group as part of the research.
- agree that the remaining **specimens** may be stored for further investigations after the examination is completed, yet not claiming storage,
- agree that the **specimens**, and if applicable DNA sequence information, may be made available anonymously for quality management and scientific purposes,
- agree that the results of the analysis may be used anonymously for scientific publications,
- agree that the **results of the analysis** may be stored for a longer period than the statutory period of 10 years, yet not claiming storage of results,
- agree that the investigation or parts of the investigation may be **forwarded** to collaborating medical laboratories if necessary,
- agree that a copy of the results of the analysis may be sent to the following physician(s):

Dr(s). med. _____
Name Street Postcode/City Country

In addition, I have been informed that

- I may stop the investigation at any time and ask for the results available until that time to be destroyed,
- I may withdraw my consent entirely or in part at any time without giving reasons,
- I will be charged for the costs incurred until the time of withdrawal of consent,
- I may choose not to be informed about the test results (**right not to know**),
- the genetic investigation and evaluation is limited to the requested indication and no statements will be made about other diseases.

Communication of additional findings found during the course of the research

☐ Yes, I wish to be informed about additional findings ☐ No, I do not wish to be informed about additional findings

_____ ✗ _____ ✗ _____

Place, date | Patient's signature/Signature of parent or legal guardian | Responsible physician's signature

Centre for Human Genetics and Laboratory Diagnostics
Lochhamer Str. 29
82152 Martinsried, GERMANY

Medical Directors
Hanns-Georg Klein, M.D.
Imma Rost, M.D.

Tel. +49.89.895578-0
Fax +49.89.895578-780
www.medical-genetics.de

Akkreditiert nach DIN EN ISO/IEC 17025, DIN EN ISO 15189, European Fed. of Immunogenetics

ilac-MRA DAkkS Deutsche Akkreditierungsstelle D-ML-13317-01-00 D-PL-13317-01-00 efi