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UNIVERSITÄT LEIPZIG
Medizinische Fakultät

Informed consent

on the study

Genetics of rare diseases based on Next Generation Sequencing

at the Institute of Human Genetics and the Centre for Rare Diseases of the University Medical Centre Leipzig

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Space for individual information / medical labels

General

I have been given the written study information and the informed consent form for the study or have been sent them digitally, have read them and have had sufficient time to consider and freely make the decision to participate in the study. I was adequately informed about the general purpose, procedure and significance as well as advantages and risks of the study. All my questions have been answered to my complete satisfaction. Participation in the study is voluntary and free of charge, and there are no claims for remuneration or compensation, royalties or other participation in financial benefits and profits that may be obtained on the basis of the research with our information.

I agree that the persons mentioned at the beginning or employees of the institutions mentioned at the beginning may have access to original medical records. In this context, personal data, in particular information about health, will be stored pseudonymously on data servers of Leipzig University Hospital for the purposes described in the study information. Disease data may be used under the responsibility of the above-mentioned institution in pseudonymized form for publications of the study results as well as forwarded to cooperating research groups.

Data protection

An insight into the data protection concept of this project is possible upon request. Access, deletion and modification of data (e.g. in the event of a change of name or place of residence, etc.) are also possible at any time without giving reasons and without any disadvantages. Data transfer can also be requested if the undersigned wishes the data to be transferred to a third party (further studies or doctors from other specialist institutions). Data will only be passed on to third parties with a corresponding written order.

Revocation of consent to sample and data use

Consent to the use of the data collected and generated can be revoked at any time and without giving reasons to the institution or person mentioned at the beginning. This has no influence on any further medical treatment. I am aware that I can also revoke this consent in writing at any time without giving reasons and without any disadvantages. The data will only be passed on to third parties who are not connected with the above-mentioned study with the corresponding postal order. I agree that the collected and generated pseudonymized data will be stored securely for an unlimited period until revoked.

Protection of children and persons in need of protection

I have been informed that I have to tell the persons legally represented by me from the age of 14 about the study and, if requested, present it to the project leader or a member of the project staff in person or by telephone in order to answer any questions. If the participating child reaches the age of 18 during the course of the study, a new informed consent form must be completed. In the case of subjects who are unable to give consent independently (the majority of subjects), this will continue to be decided by the parents or legal representatives.

Permission to collect and use samples and obtained information

I hereby consent to the collection, use and storage for an indefinite period of samples taken from me and the persons legally represented by me and hereby leave these in the hands of the above-mentioned responsible persons or the above-mentioned institutions. With regard to the collection of samples, I have made a binding statement in the tabular listing on page 2.

I agree that the samples will be used under the responsibility of the above-mentioned persons in coded form for studies in the context of the identification and characterization of genetic alterations.

I agree that the collected tissue samples and clinical data may be sent pseudo-anonymized to other clinics or institutes in Germany or abroad within the framework of scientific cooperation projects in the context of the identification and characterization of genetic alterations. I agree that the data collected in the course of the study may be entered in variant and phenotype databases in anonymized form.

Place, date: .....

Signature(s) of the test person(s) or legal representative(s): .....

In the case of shared custody, both legal guardians must usually sign. If only one legal representative can give consent, he or she confirms that he or she is acting on behalf of the other by signing this consent.

Informed Consent

With my signature I agree to the sample collection (standard: EDTA blood) and the subsequent genetic testing. I also confirm by checking the options below that I agree to the following. No cross or a missing signature is considered as not given consent.

Participating person(s)				I wish to receive a report on:		I consent to the collection of *additional* samples for the following uses: (for details see the study information)					Date and signature
Name	First name	Date of birth	Degree of relationship to the index (e.g. father, mother, siblings, grandparents, etc.)	Study results (see study information)	Additional findings (see study information)	Collection of blood for the establishment of cell lines	Blood collection: scientific analyses	Oral mucosa swab	Nail or hair sample	Dermal biopsy	
				❑	❑	❑	❑	❑	❑	❑	
				❑	❑	❑	❑	❑	❑	❑	
				❑	❑	❑	❑	❑	❑	❑	
				❑	❑	❑	❑	❑	❑	❑	
				❑	❑	❑	❑	❑	❑	❑	
				❑	❑	❑	❑	❑	❑	❑	
				❑	❑	❑	❑	❑	❑	❑	

If applicable, notes or comments from the informing physician or from the subject or his relatives:

Name/official stamp
of the physician providing the information: .....

Place, date and signature of the informing physician: .....