

Questions can be submitted to:
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INFORMED CONSENT to participate in a research study

Project title:

Study of the clinical course and disease mechanisms of Leukodystrophies

(Metachromatic Leukodystrophy (MLD), Globoid Cell Leukodystrophy (Krabbe disease), Canavan Disease, Alexander Disease, Pelizaeus-Merzbacher Disease (PMD) and similar diseases, Adrenoleukodystrophy (ALD), Vanishing White Matter Disease, other classified and unclassified Leukodystrophies)

CONSENT

I voluntarily give my consent to participate in the following parts of the research study:

1. I agree to receive a **questionnaire** and, if necessary may attend a telephone **interview** on the medical history and the current health situation of myself or my child. I also agree that my data is stored and evaluated at the Department of Paediatrics, University Hospital Hamburg-Eppendorf, Germany. Every scientific processing or evaluation of my data is exclusively performed in a pseudonymised (encoded) way/mode/manner, so that my person (or my child) cannot be assigned to the data.

yes no

2. I agree that MR-Images of me or my child are analysed for the purpose of the research of Leukodystrophies. If this is done in collaboration with other researchers, it will be impossible to associate the data and results/ medical findings with my person.

yes no

3. I agree that already existing biologic material (such as urine, cerebrospinal fluid, skin cells or other cells, etc.) may be used for the research of Leukodystrophies, even by other research scientists, if information about my identity is replaced by a code. In case a **genetic test to confirm the diagnosis** has not yet been performed, I agree that such a test is performed with already existing biological samples.

yes no

I will keep a copy of the informed consent form.

I have been informed about the data-protection-policy (next page).

Signatures:

Name of participant

Date

Patient

Date

Parent / legal guardian

Date

Parent /legal guardian

Date

Investigator

Data-Protection Policy

The personal data collected in the context of this research study, and with the explicit consent of the participant (has been submitted), are subject to medical confidentiality and data protection regulations.

The personal information is recorded, pseudonymised* (encoded) and saved on paper and other data-media provided by the University Hospital Hamburg-Eppendorf for the period of at least 20 years. Evaluation and use of the data by the principal investigator, his assistants and cooperating partners is always performed in a pseudonymised mode, for instance to be able to directly contacting a family if important insights may come up.

Pseudonymisation (encoding) of the information is dual and is done as follows: In the beginning a first pseudonym in form of a code-number is generated by a computer software combining name and date of birth. A key-list with the assignment of names and this code-number is exclusively owned by the principal of investigation and kept in a safe place. Subsequently the first pseudonym is modified in a similar way and changed into a second pseudonym which is saved on a respective list and stored safely as well. A transfer of data to third institutions is only allowed in this dual encoded (dual pseudonymised) form. If the study results are published, the patient's information will be used in an absolutely anonymised mode.

Study participants have the right to ask about their collected personal data and, if applicable, may be informed about the study results. In terms of information about personal study results, participants can request information by handing in attachment-form 6a („Information about the results of the study“).

This research study has been counseled by the ethics committee. It might be possible that competent state authorities are allowed access to study data. As soon as research purpose allows it, the key will be deleted and thereby the correlated data will be anonymised.

In case of your withdrawal of consent the data that have already been collected will be deleted as well or will be anonymised and used in this form. Withdrawing of already anonymised data is impossible.

* Explanation of the terms „pseudonymised“ and „anonymised“:

„Anonymised“ data cannot be assigned to a concrete person by anybody - as there is no key-list existing; „pseudonymised“ data can be assigned to a concrete person by the help of a key-list that is only known to few entitled persons.