

Information for patients on providing consent

Recording patient data in the European Reference Network on rare liver diseases (R-LIVER)

Dear Parents,

Your child is undergoing treatment for a rare liver disease in our clinic.

Performing significant clinical studies on these diseases is made difficult due to the rarity and often variable disease progression. In particular, with regard to paediatric patients the amount of data is so scarce because individual centres hardly have enough cases to be able to aim for significant clinical studies.

In order to drive forward the research into rare liver diseases, it is essential to cooperate and exchange with several centres. For this purpose, a multi-centre, international registry was established at the University Medical Centre Hamburg-Eppendorf (UKE), Germany.

This register is part of the European Reference Network (ERN) for rare liver diseases (ERN-RARE-LIVER). European reference networks are supported by the European Commission and they have particular expertise in treating rare diseases. The aim of establishing such networks is to improve treatment of rare diseases within Europe and to create structures for scientific exchange and research.

We would like to ask you to support us in this initiative by providing the consent to use clinical data in a multi-centre, international database (R-LIVER) as part of the ERN for rare liver diseases (ERN-RARE-LIVER).

Providing consent is voluntary. If you do not wish to provide your consent, this will not affect your child's treatment in any way. This document provides information on the organisation and aims of this database and on aspects of data protection. We would be pleased to answer any other questions you may have in person.

The plan is to record personal details and medical data in the medical database every 6 or 12 months. Examples of the type of data include age, gender, height, weight, medical history, progression of the liver disease including complications, laboratory results, findings from ultrasound and X-ray examinations, and information from tissue examination.

In addition, we would like to document the well-being of your child outside the hospital at irregular intervals via an online questionnaire (so-called Patient Reported Outcomes). These data help us to better understand the effects of our treatment approaches. For this purpose, we need an e-mail address where we can contact you and send you the link to the online questionnaire. Each data transfer within the scope of this survey takes place via an encrypted connection, the e-mail address is stored in the database independently of the medical data of your child, can only be viewed by authorized persons and is used exclusively for the purpose of the online survey.

Data gathered as part of the database after you have provided consent is subject to confidentiality and the terms of data protection. For this reason, the database will not be managed based on names. Personal and medical data will be given a pseudonym (encrypted) before being recorded in the database. This means that features which identify the patient, e.g. name of your child and date of birth will be replaced by a code. Only the encrypted data is available in the research facility so that researchers cannot identify the individual patient. Before data is forwarded to other institutions and public or private research institutions outside of ERN, data is made anonymous and if necessary, given a double (additional second) pseudonym (new encryption of code) for research purposes.

Restoring (decrypting) the data about the patient can be necessary in the following cases:

- To ask you further questions or to examine you further if it was necessary for research purposes.
- In addition, we would restore data to be able to inform you if our research findings had a direct impact on your child's future medical treatment.

Encryption takes place using secure and password protected keys by the medical director of the database in the treatment area of our clinic.

In the context of research projects, data transfers of your child's anonymised or double pseudonymised data to non-EU countries (e.g. the USA) that are not subject to European data protection law may occur. In this respect, the European Commission has partly passed resolutions according to which the level of data protection in the third country is appropriate to the European level of data protection. Nevertheless, we want to base the transfer to these countries above all on your consent.

Publication of research findings only takes place in an anonymous form which does not allow identification of individual patients. Consent is voluntary. You have the right to withdraw consent at any stage and it will apply from that point onwards. Withdrawing consent will not lead to any disadvantage for your child's further treatment. It is sufficient if one parent/guardian withdraws consent. If there are two legal guardians, both must provide their agreement to be included in the database.

Declaration of consent

(Legal guardian(s) first and last name(s))

(Patient name and address)

(Date of birth)

(E-mail address)

I agree that my child's personal and medical data can be recorded, processed and stored in encrypted form in a multi-center, prospective database (R-LIVER) on rare liver diseases as part of the European Reference Network "ERN-RARE-LIVER".

Agree Do not agree (please place an "x" on your selection)

If it is necessary for my child to undergo a follow-up examination or questioning for research purposes (or if there are important results which are relevant to my child's treatment), I agree that my child's personal data can be decrypted, (suspension of encryption) so that my child and I can be contacted and sent an invitation.

Agree Do not agree (please place an "x" on your selection)

I agree that the **Institute** may contact us at irregular intervals (possibly also by e-mail) so that we can complete an online questionnaire regarding the well-being of my child.

Agree Do not agree (please place an "x" on your selection)

I am aware that providing consent is voluntary. I have the right to revoke my consent from the clinic with future effect and that this will not result in any negative effects on my child's future treatment (For contact details see the first page). My child's encrypted data transferred to the R-LIVER database will then be made anonymous and destroyed in accordance with my wishes. All of the questions I posed were answered. If I have any further questions, I can ask **Name and Tel No. xxx. I have been provided with a copy of the information and the declaration of consent (to read at home).**

If there are two legal guardians, both signatures are required.

Place, date: _____

(signature of guardian)

Place, date: _____

(signature of guardian)

Place, date: _____

(Signature of doctor who explained)

Data protection declaration pursuant to Art. 13, 14 General Data Protection Regulation (GDPR)

The protection of your child's data is important to us. In addition to the aforementioned measures to ensure that your child's personal data is handled in a manner that complies with data protection regulations, you have the following rights under the GDPR when participating in our research database:

Person responsible for data processing

Contact

Legal Basis

The legal basis for the processing of the personal data of your child at R-LIVER is your voluntary written consent pursuant to Art. 6 para 1 lit a), 9 para 2 lit a) GDPR. We also comply with the Declaration of Helsinki (Declaration of the World Medical Association on Ethical Principles for Medical Research on Human Beings) and the Guideline for Good Clinical Practice.

Rights of the data subject

Right to information

You have the right to be informed about personal data concerning your child which is collected, processed or, if applicable, passed on to third parties within the context of the research database (provision of a free copy) (Article 15 GDPR).

Right to rectification

You have the right to have incorrect personal data concerning your child corrected (Articles 16, 19 GDPR).

Right to deletion

You have the right to delete personal data concerning your child, e.g. if this data is no longer necessary for the purpose for which it was collected (Article 17, 19 GDPR).

Right to limitation of processing

Under certain circumstances, you have the right to request a restriction on the processing, i.e. the data may only be stored but not processed. You must request this (Article 18, 19 GDPR).

Right to data transferability

You have the right to obtain the personal data relating to your child that you have provided to the person responsible for the clinical study. This allows you to request that this data be provided either to you or, where technically possible, to another body designated by you (Article 20 GDPR).

If you wish to exercise any of these rights, please contact the person responsible for data processing:

contact

Guarantee of data protection

We do everything in our power to process personal data in accordance with legal requirements. Should you nevertheless be of the opinion that the processing of your child's personal data is inadmissible under data protection law, you are welcome to contact our data protection officer at:

contact

You also have the option of contacting the competent supervisory authority with a complaint. In addition, you have the option of contacting the responsible supervisory authority with a complaint. The supervisory authority responsible for you depends on the federal state of your residence, your work or the presumed data protection violation. Responsible for **Institute** is:

contact