**Information for patients on providing consent**

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

Dear Patient,

Treatment of and research into rare liver disease is one of our clinic’s areas of expertise.

In order to improve the quality of treatment and research into rare liver diseases, we need 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).

This registry is part of the European Reference Network (ERN) for rare liver disease (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 your 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 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 questions you may have in person (Tel.: xxx).

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 your well-being 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 your medical data, 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. Your personal and medical data will be given a pseudonym (encrypted) before being recorded in the database. This means that features which identify you, e.g. your name 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 you 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 have a direct impact on your future medical treatment.

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

In the context of research projects, data transfers of your 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 further treatment.

**Declaration of consent**

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(Patient first and last name) (Patient date of birth)

(Patient address)

(E-mail address)

I agree that my personal and medical data can be recorded, processed and stored in encrypted form in a multi-centre, 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 to undergo a follow-up examination or questioning for research purposes (or if there are important results which are relevant for treatment), I agree that my personal data can be decrypted, (suspension of encryption) so that 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 me at irregular intervals (possibly also by e-mail) so that I can complete an online questionnaire regarding my well-being.

**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 future treatment (For contact details see the first page). My encrypted data transferred to the R-LIVER database will then be made anonymous and destroyed. 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).**

Place, date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Patient signature)

Place, date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Signature of doctor who explained)

**Data protection declaration pursuant to**

**Art. 13, 14 General Data Protection Regulation (GDPR)**

The protection of your personal data is important to us. In addition to the aforementioned measures to ensure that your 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 your personal data 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 the personal data 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 corrected (Articles 16, 19 GDPR).

Right to deletion

You have the right to delete your personal data, 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 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 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