

Establishing a database as part of the European Reference Network on rare liver diseases (R-LIVER)

Dear ...,

We would like to ask if you are willing to let us collect and store your patient data in a database for patients with rare liver diseases.

The plan is to record and electronically store details about you and your disease (e.g. height, weight, blood test results, medicine, etc.). Other locations in Europe, where liver diseases are treated, will do the same. All these data will be stored centrally at the University Medical Centre Hamburg-Eppendorf, Germany.

Along with your parents, you can decide whether we collect data about your disease. Even if your parents agree, taking part is voluntary. Nobody will force you.

If you decide against allowing us to store your patient data, or if you change your mind later, there will be no disadvantage for you.

You do not have to decide immediately whether you want to participate or not. Feel free to take a few days to think about it. This information should help you make your decision. It is important for you to understand everything. Your parents have also received information from us. When you have read everything, you will talk about it with them.

Your parents will certainly be able to answer most of your questions and your doctor will also talk about it with you. He/she will have enough time to answer your questions.

1. Why should my patient data be stored?

Your liver disease is quite rare, so there are very few patients at individual clinics who have the same disease that you have. But we need to follow disease development of as many patients as possible to research and learn about a disease. This means that it is important that several clinics, which treat rare liver diseases, work together closely and share their information.

For this reason, we have created a patient registry where a lot of clinics can enter and store information about their patients with rare liver diseases electronically. This network is supported by the European Commission.

2. Does taking part have an influence on my treatment?

Whether or not you agree to allowing us store your data in a database, has no influence on your future treatment. Extra examinations will not take place. There will also be no change to your treatment.

3. How will I benefit if my data are recorded and stored in a database electronically?

If you let us record your patient data, there will be no immediate advantages for you. However, in the long term, we hope to gain information which will help us to understand and treat your disease better in the future. We will achieve this by recording the highest number of patients possible.

5. What are the risks if my data are recorded and stored in a database electronically?

Taking part has no influence on your treatment, so there are no direct risks.

6. What will happen to my data?

The plan is that details about you and your disease will be recorded and stored electronically. They will be analysed for research purposes with the long-term aim of offering better treatment options all over Europe. Your name will not be given so that it will not be possible for anybody to find out something about you and your disease. Only certain employees of the clinic can find out your name and look up your contact details if we need extra information about you or if there are new results from research which could be important for your treatment.

We would also like to document your general well-being outside the hospital. In order to do this, we would like to send you an online questionnaire by email at some point during your treatment. This questionnaire helps us to better understand the effects of the treatment on your health.

In order to use our database for research purposes, we have to transfer the data to the researchers. Some researchers work in non-EU countries (e.g. the USA) and are therefore not subject to European data protection law. The European Commission has decided for some of these countries that their level of data protection is compatible with the European level of data protection. Nevertheless, we want to base the data transfer to these countries primarily on your consent.

If you want to stop taking part in the database, the data about you will be deleted. Your parents received more details about this.

Declaration of consent

We need you to agree before you participate. If you agree, we ask that you sign this page. This confirms to us that you give us your consent and permission to store details about you and your disease electronically in the database mentioned above. Your signature also confirms that you know that providing consent is your decision, that all of your questions have been answered, that you are satisfied with the answers and that you have had enough time to think about participating. You can however, tell us later that you no longer wish to participate. This will not result in any disadvantage for your medical treatment.

I declare that I am willing to allow my patient data to be recorded and stored in the database mentioned above.

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

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

Name of minor in block capitals

E-mail address

Place, Date

Signature of minor

I have held the discussion with the minor to explain the above. I am convinced that the minor has understood, that he/she has no further questions, and that *he/she agrees to take part*.

Name of doctor who explained (block capitals)

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