European Management
Platform for Childhood
Interstitial Lung Diseases

chILD-EU Register und Biobank

Informed Consent Form and Patient Information

For adult patients

European Management
Platform for Childhood
Interstitial Lung Diseases

Declaration of Informed Consent

I read the patient information and had the opportunity to ask questions. These have been answered satisfactorily and completely. I know that my participation is voluntary and that I can withdraw consent at any time without giving reasons and without incurring any disadvantages.

I consent to my biomaterials and associated data being given to the chILD-EU Register and Biobank, as described in the patient information document, and used for the medical research purposes specified in the information document, including genetic analyses. In particular, I consent:

- that chILD-EU Register and Biobank may collect my personal data, in particular information about my health, may take further personal data from my medical records, and store the data pseudonymized (i.e. coded);
- that the results of previously performed and future diagnostic tests, including raw data of genetic testing, are made available to the chILD-EU Register;
- that all ownership rights to all biomaterials collected from me are transferred to chILD-EU Register and Biobank;
- that the biomaterials will be stored pseudonymously by chILD-EU Register and Biobank;
- the biomaterials with the aforementioned data (including genetic analyses) may be passed on pseudonymously to universities, research institutes and research companies for the purposes of medical research. Under certain circumstances, this also includes the transfer for research projects in countries outside the EU. This is generally permissible if an adequacy decision of the European Commission is available or the guarantee of an adequate level of protection is contractually agreed and implemented

Furthermore, I consent to the transfer of the biomaterialss and data to countries outside the EU also in cases where there is no adequacy decision of the European Commission and no guarantee of an adequate level of protection is contractually agreed or implemented. I have been informed about the possible risks of such transfer.

□ **Yes** □ **No**

I hereby expressly declare my wish to be informed about clinically relevant results and research findings. I agree that my data and biomaterials may be continued in the register in pseudonymized form in the event of death or after withdrawal of participation. On demand, all data and biological samples collected up to then need to anonymized or deleted.

I have received a copy of the patient information and consent form. The original remains with chILD-EU Register and Biobank.

Patient

_____	_____	_____
Last Name in block letters	**First Name** in block letters	**Date of birth**
_____	_____	
Place and Date (to be entered by the patient)	Signature	

I have conducted the informed consent interview and obtained the consent of the patient.

_____	_____	_____
Physician`s Name in block letters	Place and Date	Signature

If more than two relatives of the patient give their consent, print it out this page again and number the relatives!

For relatives:

☐ mother ☐ father ☐ sibling ☐ other: _____

I hereby consent to collection, storage and use of my medical history and biomaterials (blood samples, buccal swabs, and others) for research purposes. I consent to genetic tests are performed using these biomaterial (e.g. exome analyses, genome sequencing)

I would like to be informed about the results of the genetic tests through the informing doctor.

I have the right to stop our/my participation in the chILD-EU register at any time, without giving reasons. On demand, all data and biological samples collected up to then need to anonymized or deleted.

_____	_____	_____
Relative`s Name in block letters	Place and Date	Signature
_____	_____	_____
Physician`s Name in block letters	Place and Date	Signature

For relatives:

☐ mother ☐ father ☐ sibling ☐ other: _____

I hereby consent to collection, storage and use of my medical history and biomaterials (blood samples, buccal swabs, and others) for research purposes. I consent to genetic tests are performed using these biomaterial (e.g. exome analyses, genome sequencing)

I would like to be informed about the results of the genetic tests through the informing doctor.

I have the right to stop our/my participation in the chILD-EU register at any time, without giving reasons. On demand, all data and biological samples collected up to then need to anonymized or deleted.

_____	_____	_____
Relative`s Name in block letters	Place and Date	Signature
_____	_____	_____
Physician`s Name in block letters	Place and Date	Signature

European Management Platform for Childhood Interstitial Lung Diseases

Patient Information and Declaration of Informed Consent for the Research Project "European chILD Register and Biobank" of the European network for rare lung diseases in children (chILD-EU register)

Dear Patient,

You, or one of your relatives, were diagnosed with a rare lung disease. We would therefore like to ask you to participate in the European register and biobank of the chILD-EU project, the aim and procedure will be explained in the following. The participation is voluntary. Please speak to your doctor if you have any questions or would like to know anything further.

Summary of the project:
Many lung diseases in children are rare and heterogeneous. In order to investigate the natural course, risk factors, treatment possibilities and to better understand the reasons for the development of rare childhood interstitial lung disease **(chILD)** we would like to store and analyse more detailed information about your symptoms, clinical data, quality of life and biological material taken from you. Your data are secured by the mechanisms provided, i.e. the organization of the database and the handling of your biological material make it impossible for unauthorized persons to identify you. The project was approved by the responsible ethics committee and is explained in detail below.

Who conducts the register?
The **European chILD Register and Biobank (chILD-EU register),** held by the non-profit Kids Lung Register Foundation (KLR e.V.), conducts the clinical trial. The coordinator of this research association is Prof Matthias Griese, who can be contacted at the following address:

Prof Matthias Griese
Dr. von Hauner Childrens´Hospital
University of Munich
Lindwurmstraße 4 Tel ++49 89 4400 5 7878
80336 Munich Fax ++49 89 4400 5 7879
Germany E-mail: matthias.griese@med.uni-muenchen.de

What is the goal of this study?
The primary aim of the register is to characterize as comprehensively as possible the natural course and treatment effects of various forms of rare childhood lung diseases, in particular interstitial lung diseases (children´s interstitial lung disease – **chILD**). This should contribute to a better understanding of the disease and to the development of new and effective treatment methods. In order to achieve this goal, patients with rare childhood lung disease or lung disease that can mimic chronic interstitial lung disease or chronic respiratory symptoms of unknown ethology as well as patients with other lung diseases (chronic bronchitis, pulmonary malformations, and pulmonary hypertension) are included in the **chILD-EU** register. In order to be able to detect underlying genetic changes in the occurrence of frequent familial chILD cases, genetic analyzes of family members of the patients can also be carried out. For this reason, family members can also be included in the **chILD-EU** register.

What biomaterials will be collected? What are they used for?
Blood, lung lavage fluid, urine, sputum, buccal swabs, and/or tissue samples, that were taken from you as part of routine measures or specifically for research purposes will be archived in a central biobank in Munich. For future scientific questions, it may be necessary that the biomaterials to be examined are still capable of division. For this reason, we want to enable cellular components of the biomaterials to divide indefinitely (generation of immortalized cell lines). These cells can be stored long term.
Using the blood samples we can perform genetic studies and gene expression analyses. The aim is to identify factors that enable a reliable diagnostic classification of the disease using a blood test.
In cases of presumably genetically caused cases of rare lung diseases, we may use new genome-wide genetic tests. For this, sequencing techniques are used that cover parts or all of the genome (whole exome and genome sequencing). This should identify the factors / genes responsible for triggering the disease. Even if this knowledge

does not directly improve your treatment options, the detection of certain gene mutations can lead to the development of more targeted, i.e. better forms of treatment that you could possibly benefit from. One or more factors that allow a reliable prognosis of the further course of your disease could also be discovered. On the one hand, this precise prediction of your course of the disease could be quite positive, for example, in the case of a planned lung transplant, but on the other hand, it could also be a burden for you if the result is not positive and treatment options are not yet available. There is a potential risk in genome-wide studies that you can be identified based on the genetic data.

In genome-wide analyses, it is possible to find genes that are likely to cause a different disease that have nothing to do with the reason for which your child was included in the chILD-EU register. For example, this may affect the risk of certain tumour diseases or the status of a carrier for an inherited disease. We do not analyse those genes systematically, and therefore do not collect them systematically. Such findings can be communicated to you on request, but no guarantee of completeness can be given.

As it is expected that some of the **chILD** cases are genetically determined, genetic material from the family members will also be required to reliably identify genetic factors that are responsible for the occurrence of the disease in your family. For this we will either need a blood or oral mucosal sample from them. We also ask for the completion of a patient questionnaire, a clinical examination.

The chILD-EU register generally aims to collect the biomaterials and accompanying medical data listed above at multiple time points. We will therefore also collect samples and medical data at subsequent visits at the treating institution, usually once a year.

What data will be collected? What are they used for?
The pseudonymized biomaterials and corresponding detailed medical data will be recorded and stored in our database and may also be shared with other entities such as universities, research institutes and research companies, including abroad if necessary, for certain medical research purposes in accordance with the chILD EU Register and Biobank Rules of Procedure and Data Protection Regulation. In the process, the data may also be linked to medical data in other databases, provided that the legal requirements for this are met. Biomaterials and data that have been released to other agencies may only be used for the predetermined research purpose and may not be passed on by the recipient for other purposes. Unused biomaterials will be returned to the Biobank or destroyed. Data identifying you will not be passed on to researchers or other unauthorized third parties, such as insurance companies or employers.
Research results will only be published in a form that does not allow any conclusions to be drawn about you.

What are we asking you to do?
We are asking for broad permission to use your biomaterials and data. These are provided for medical research intended to improve the prevention, detection, and treatment of disease. They are to be used for many different medical research purposes in the interests of maximum benefit to the public. These can relate to specific disease areas (e.g. lung diseases, infectious diseases, cancers, cardiovascular diseases) as well as to diseases that are still partly unknown today. Because new questions continue to arise in research, your samples and data may also be used for medical research questions that cannot be foreseen today. The biomaterials and data will not be used for research deemed unethical by the ethics committee evaluating the project.

For logistical reasons, it is not possible for chILD-EU Register and Biobank to make individual restrictions within your consent (e.g., exclusion of certain research, exclusion of the transfer of biomaterials to third parties). If you do not fully agree with the described type and duration of use, consent should not be given.

Risks of participating in this trial
You will not be reimbursed for the transfer of your biomaterials and data. If any commercial benefit is derived from the research, you will not be involved. The Biobank uses your biomaterials and data for scientific purposes only. They will not be sold. However, the Biobank may charge users of the biomaterials and data a reasonable compensation for providing them.
The blood samples are taken as part of routine diagnostics, which means that no additional vein puncture is necessary, so you should not incur any additional risks. The risks of drawing blood during routine diagnostics

include the formation of small bruises at the injection site. In rare cases, permanent nerve damage can occur in the area of the injection site. The amount of blood drawn will not exceed a total of 2/3 of a tablespoon (10 ml).

Your data and biomaterials are secured
The institution responsible for processing your data is the Kids Lung Register Foundation (KLR e.V.). Currently the coordinator of the European **chILD Network** is Prof M. Griese, Ludwig-Maximilian University Munich (for contact details, see above). You can find out at any time who the current data processor is, by visiting the consortium's website (www.childeu.net).
For reasons of data protection, your medical data and identifying data (i.e. the name, address and complete date of birth) will be stored separately at two different sites:

- The above-mentioned and medically relevant data, i.e. your history, your medical findings, the types of treatment, the prescribed medication and your sample data are stored in a medical research database in pseudonymised form (i.e. your identifying data, in particular name and address, are identified by Number replaced) saved. Identification using the pseudonym alone is not possible. This central treatment database is managed on our behalf in a private high-security data centre that specializes in sensitive data. We ensure that the data center complies with an appropriate standard of data protection and data security. This pseudonymized medical data can be viewed by other doctors and scientists registered in the register.
- Your identifying data and your identification number are stored separately from the medical data in the computer centre of the University of Giessen. These personal data (contact details) are treated confidentially and will only be accessed in case contact cannot be made via your treating physician.

Only a very limited number of people have access to your data. These people are bound by a duty of confidentiality. The data are protected against unauthorized access and may only be used for the research project. Only a small, authorized circle of employees has access to the personal data stored separately from the database. The data will only be accessed is contact is necessary for important medical reasons and cannot be made through the treating physician. Your contact details will never be passed on to another third party

For quality assurance, so called monitors can be permitted access to the data for a limited period. Therefore a decision by the management committee of the **chILD-EU register** is necessary. Monitors are bound by a duty of confidentiality. The blood, lung lavage and tissue samples taken from you, i.e. the biomaterials, are collected centrally at the University of Munich under the direction of Prof. M. Griese (see above) and used in the scientific investigations planned within this research project. These samples are also pseudonymized, i.e. stored and processed centrally under an identification number. The data relating to these samples are stored separately in the central treatment database under this identification number.

In order to carry out certain scientific questions, it may be necessary to pass on the biomaterials derived from you - as well as clinical data. Also in this case, this will only be done in pseudonymized form. The management committee of the European **chILD register** and biobank decides on such a transfer of clinical data or biomaterials for scientific purposes after consultation with the ethics committee.

If you are treated at a center other than Dr. Haunersches Children's Hospital, but Dr. Haunersches Children's Hospital already knows your identity as part of a co-treatment (e.g. advice on diagnosis or therapy), the treatment team of Dr. Haunersches Children's Hospital may also support data for the chILD-EU register, knowing your name. The treatment team is subject to medical confidentiality towards third parties and receives a copy of the declaration of consent from the **chILD-EU register** and biobank. Of course, the data is only stored in a pseudonymised manner in the register.

Participation in this study/research is voluntary. You may terminate participation at any time without giving reasons and without affecting your medical care or the relationship of you with your treating physician. Conversely, you may also be excluded from this study should medical or organizational reasons require it. Please notify your treating physician of your withdrawal from participation in the register. . In case of revocation, your data and biomaterials will be used in pseudonymized form for further research projects. In addition, data from already performed analyses cannot be removed.

Additional information according to the European General Data Protection Regulation

You have the following rights with regard to your data

Right to information:
You have the right to information about your personal data that are collected, processed or, if necessary, transmitted to third parties in the chILD-EU register (handing over a free copy).

Right to rectification:
You have the right to have incorrect personal data concerning you corrected.

Right to deletion:
You have the right to have your personal data deleted, e.g. If this data is no longer necessary for the purpose for which it was collected.

Right to restriction of processing
Under certain conditions, you have the right to request that processing be restricted, i.e. the data may only be saved, not processed. You have to apply for this. Please contact your investigator or the data protection officer of the chILD-EU register.

Right to data transfer
You have the right to receive the personal data concerning you, which you have provided to the person responsible for the chILD-EU register. You can use this to request that this data be transmitted either to you or, as far as technically possible, to another body designated by you.

Right to object
You have the right to object to specific decisions or measures to process your personal data at any time. Such processing then generally no longer takes place.

Consent to the processing of personal data and right to withdraw this consent
The processing of your personal data is only lawful with your consent.

You have the right to withdraw your consent to the processing of personal data at any time. However, the data collected up to this point in time may be processed by the bodies mentioned in the patient information and consent declaration of the chILD-EU register.

If you would like to exercise any of these rights, please contact your principal investigator or the data protection officer of your **chILD-EU register** centre directly. You also have the right to lodge a complaint with the supervisory authority (s) if you believe that the processing of your personal data violates the data safety regulations:

Data protection: Contact details chILD-EU register centre

Person (s) responsible for data processing at the chILD-EU Register Center (see page 1 of patient information and patient consent)

Data protection: contact details of head of register of the child register

Data Protection officer		**Data Protection supervisory authority**	
Name:	Herr Gerhard Meyer Official data protection officer Hospital of the University of Munich	Name:	Bayerischer Landesbeauftragter für den Datenschutz (BayLfD) Prof. Dr. Thomas Petri
Address:	Pettenkoferstraße 8 80336 Munich	Address:	Adresse: Post office 22 12 19, 80502 Munich Hausanschrift: Wagmüllerstr. 1, 80538 Munich
Telephone:		Telephone:	Tel.: 089 212672-0 Fax: 089 212672-50
E-Mail	datenschutz@med.uni-muenchen.de	E-Mail	

The Federal Commissioner for Data Protection and Freedom of Information
Husarenstraße 30
53117 Bonn
Telephone: 0228-997799-0
Fax: 0228-997799-550
E-Mail: poststelle@bfdi.bund.de