Child 11-15 years with Interstitial Lung Disease (ChILD)

European Management Platform for Childhood Interstitial Lung Diseases

ChILD-EU Database, Biobank and Observational Study.

You are invited to take part in a research project. Before you decide if you want to take part it is important to understand why the research is being done and what it will involve for you. Please read this leaflet carefully. Feel free to talk about it to anyone else you think can help you make a decision.

The doctor in charge of this study at your hospital is [*insert local PI name*]. The study is being funded by the European Union and is taking place across Europe. The details of the team who are organising the study are given later in this leaflet.

This information leaflet has information about two studies

(a) A database and biobank study – a database is where information is stored on a computer and a biobank stores blood samples and x-rays etc from different people in one place.

(b) An observational study looks at what happens to people over time. We collect the normal information and investigations that doctors request during your treatment.

The database and biobank study will collect information at the start of the study and again after one year. The observational study will collect information more often during this first year of your diagnosis of ChILD. We have put the information for both studies into one information sheet but at the end we will ask if you want to take part in both studies or just the database and biobank study.

Why are we doing this research?

There are a group of diseases of the lung in children that are very uncommon. These are called Children's Interstitial Lung Disease (we abbreviate this to 'ChILD'). It can affect children and teenagers in different ways. Getting the diagnosis right can sometimes be difficult as patients are unwell, or the information from test results is not clear. Because ChILD is uncommon we don't understand these diseases as well as lung disease seen more commonly (like asthma, for example). It can be so uncommon that there may be too few cases in each country to get a good understanding of the problem and what the best treatments are.

The purpose of our research is to look in great detail at all the cases of ChILD in Europe, so that hopefully we can offer better treatment in the future. We hope to improve the knowledge of doctors across Europe who look after children and teenagers with lung problems like yours. When we have some results we will ask ChILD websites to distribute the information so that you can see the results too.

Why have I been invited to take part?
You have been invited as your doctor tells us that you have or may have ChILD.

Do I have to take part?
No. It is up to you. If you want to take part you can sign a form giving your agreement. If at any time in the future you decide you don't want to continue to take part then just tell your parents or hospital doctor or nurse. You don't need to give a reason. Stopping the research won't affect the treatment you will receive in any way.

What will happen if I do take part?
The ChILD-EU Database and Biobank Study mostly collects information that is already being collected by doctors caring for you, and puts that information into a database and biobank. This information is then seen by experts from across Europe who specialise in uncommon lung problems (such as the one you have). These experts will tell your local hospital doctor what they think the problem is and your doctor will let you know. Every year we will update the database on how you are doing.

The ChILD-EU Observational Study: In the first year after someone is diagnosed with ChILD they are often seen more often in hospital clinics. We want to collect information from these visits into the database. Looking at this information from large numbers of children may help us understand why some feel better more quickly than others. The study will collect information from your hospital visits 1, 2, 3, 6 and 12-months from now.

Are there any extra tests?
Database and Biobank Study:
Sometimes people can become unwell because of a problem with their genes. We want to be able to learn whether genes may have caused the problem with your chest. To do this we would like to store some of your blood so we have it ready in case a new test is possible in the future. If you agree, we will try and take this sample when your doctor is already taking blood for another test. You inherit genes from your mum and dad so we will also ask your parents to allow us to collect and store a sample of their blood too.

Observational Study: There are no extra tests as part of the observational study. We will just collect the information that your hospital doctor would collect anyway.

Will anyone be able to find out my information?
The research team have worked hard to make sure that your data will be safe. If you agree to take part then we will store your information in two places. One place will have information such as your name and date of birth. The other place will have the database and biobank information described above. All of your information in the database and biobank will be identified by a study number, not your name. This study number will be unique to you. Using a study number makes sure that information about you is kept secure and confidential. Your parents have more information about the database in their information leaflet if you would like to know more.

Only your GP, local hospital team, and the study research team will know that you are taking part in this research. No one else will know unless you want to tell them.

From time to time there may be a doctor in another hospital who is researching childhood lung diseases who wants to better understand your symptoms and treatments. This doctor would ask the hospital to look at your medical notes.

What are the possible benefits of taking part?
We don't think there will be any direct benefits to you by taking part in this study. The study is to help children and young people in the future who have ChILD.

What are the possible disadvantages and risks of taking part?
We do not think there is any risk from these studies. Other than your normal treatment you and your parents will be asked to complete questionnaires every 3 months. We will also ask your parents to provide a blood sample at the start of the study.

What will happen if I don't want to carry on with the study?
You are free to stop taking part at any time without giving a reason. This will not affect the normal treatment you receive.

If you want to withdraw we will ask you and your parents to consider what you want us to do with the information that we have collected so far. We will discuss these options with you at the time.

Who has reviewed this study?
Before any medical research goes ahead it has to be checked by a Research Ethics Committee. They make sure that the research is fair. This study has been checked by the South East Scotland Research Ethics Committee 2.

Thank you for reading this – please ask questions if you need to.

International Contact Details
The overall lead clinician for the study is:

Prof. Matthias Griese
Dr. von Hauner Children's Hospital
University of Munich
Lindwurmstr. 4
80336 München
Germany

Tel +49 89 5160 7871
Fax +49 89 5160 7872
e-mail: child-eu-office@med.uni-muenchen.de

In the UK, the study is being led by:

Dr Steve Cunningham
Consultant Respiratory Paediatrician
Royal Hospital for Sick Children

Professor Andy Bush
Professor of Paediatric Respirology
Royal Brompton Hospital

Sciennes Road
Edinburgh
EH9 1LF

Tel: 0131 536 0607

Sydney Street
London
SW3 6NP

Tel: 0207 351 8232

Your Local Contact Details

This work is being conducted by the research department at the [insert name of Local Hospital]. You can contact us by phone, e-mail or post and we will be happy to answer any questions that you have.

Local Clinician name and title [insert name of clinician and title]
Address [address]
[address]
[address]
Phone number - [phone nr]
E-mail - [email]

PARTICIPANT ASSENT FORM

Participant's Name	
Study Number	
Title	ChILD-EU database and observational study.
Principal Investigator	

*Child (or if unable parent/carer on their behalf) should **tick/cross box they agree with***	**YES**	**NO**
Has somebody explained this project to you?		
Do you understand what this project is about?		
Have you asked all the questions you want?		
Have you had your questions answered in a way you understand?		
Do you understand it's OK to stop taking part at any time?		
Are you happy to take part?		
Do you agree to let other doctors look at your medical notes?		

If **any** answers are 'no' or you don't want to take part then don't sign your name!
If you **do** want to take part then you can write your name below

Your name ----------

Date ----------

The doctor who explained this project to you needs to sign too

Print name ----------

Signature ----------

Date ----------

Thank you for your help.

1x original – into Site File; 1x copy – to Participant; 1x copy – into medical records