Parent of a Child With Interstitial Lung Disease

European Management Platform for Childhood Interstitial Lung Diseases

European Children's Interstitial Lung Disease Database, Biobank and Observational Study

Your child is 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 and your child. Please read this leaflet carefully. Feel free to talk about it to anyone else you think can help you make a decision such as other family members or your GP.
The doctor in charge of this study at your hospital is [*insert local PI name*]. The study is taking place across Europe and 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 and (b) An observational study. We have put the two studies into one information sheet because the information required for the observational study will be gathered during the database and biobank study. At the end we will ask if you want your child to take part in both the database/biobank study and the observational study or just the database/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 Interstitial Lung Disease. These vary in severity and can affect children in different ways. Getting the diagnosis right can sometimes be difficult as the information from test results isn't always clear. Because ChILD is uncommon we don't understand these diseases as well as more frequently seen lung disease. There are often too few cases in each country to get a good understanding of the problem and what are the best treatments.
The purpose of these studies is to bring together and look in greater detail at the cases of children's interstitial lung disease (ChILD) occurring across Europe to see if we can gain better understanding of the diseases and hopefully offer better treatment in the future.

Why has my child been invited to take part?
Your child has been invited as your child's doctor suspects that your child has ChILD.

Does my child have to take part?
No. It is up to you and your child to decide. If you do you will be asked to sign a form giving your consent. This means that you agree for your child to take part. You will be given a copy of this information sheet and your signed form to keep. You and your child are free to stop taking part at any time during the research without giving a reason. This does not affect the treatment your child receives in any way.

What will happen to my child if we do take part?

The Database and Biobank Study mostly collects information that is already being collected by doctors caring for your child or from previous samples. To get a better understanding we will place these details into a database with those of other children taking part. The database will store information from your child's medical history (the information that doctors record) and will link this to a biobank. The biobank stores x-rays, lung biopsy (if your child has one) and blood and lung washing samples. The information stored in the database and biobank will be reviewed by an international team of experts. The experts have been chosen as they have particular expertise in ChILD. They will consider what diagnosis they feel is most likely after having seen the information from the database and biobank. The review by the international team of experts will be fed back to your local doctor.

We will also ask you to fill in questionnaires at the start of the study, and again after 3, 6 and 12 months. We can offer you help filling this in if you would like. Children over the age of 8 will also be asked to contribute answers to some of these questionnaires. Once a year further information about your child's progress will be placed in the database. The international review panel will then review the case again.

The Observational Study*:* Following a suspected or confirmed diagnosis of ChILD children are usually in hospital or returning to clinics more frequently. We would like to capture as much information as possible from the first year after diagnosis to better understand what happens and look at why some children may do better than others. The ChILD-EU observational study will gather information at time of diagnosis, and at 1, 2, 3, 6 and 12 months intervals in the first year (i.e. starting now).

All of the measurements we would like to record are routine clinical measurements that would be done by your local doctor. These measurements include heart rate, respiratory rate, oxygen saturation levels, current medicines, blowing tests (spirometry - if capable) and how your child is responding to treatment.

Typically, your child will have a chest x-ray at diagnosis and again after 6 and 12 months as part of the usual care. We would ask your local team to upload these chest x-rays to our database.

The clinical team will ask routine questions for the review of a ChILD case including what medicines have been tried and possible benefits/side effects. In addition we will ask you to fill in a questionnaire every 3 months about how much you need to use health services and the impact this may have on your life.

Are there any additional tests?

Database and Biobank Study: We know that many diseases are affected by our genes and those of our parents. For that reason, as part of this study, we would like to take an extra blood sample from your child (this is the only extra sample for the study) and if possible also take blood samples from both biological parents. These samples will be stored for future research in case a possible genetic test for ChILD is developed to help with diagnosis or treatment.

Observational Study: There are no additional tests for the observational Trial.

What are the possible benefits of taking part?
There are no direct benefits to you or your child taking part in this study. However the information that we get from this study will help us improve the treatment of Children's Interstitial Lung Disease.

What are the possible disadvantages and risks of taking part?
We do not anticipate any risks from these studies. Parents will be asked to provide a blood sample at the start of the study and we will also ask you to complete questionnaires every 3 months. This will be an additional task.

What will happen to any samples I give or my child gives?
The donated research blood sample collected from you and your child will be identified by a code rather than your or your child's name. This is called pseudo-anonymised and means that the genetic information can be linked to your child's clinical information but personal details allowing your child to be identified will be masked. Samples will be put into a 'biobank' for use at a later date by researchers. The researchers will only be able to identify the samples by a code number and will not know your name or your child's name. The pseudo-anonymised samples will be stored in the 'biobank' in Dr. von Hauner Children's Clinic, Ludwig Maximilians University Munich, Lindwurmstr. 2a, 80337 Munich.

Will anyone else know my child is taking part in these studies?
We will keep yours and your child's personal information confidential. This means that only those involved in the study who have a need or right to know will be able to find out who you are. Your child will be given a code (study number) that will be used when looking at the results so that your child's identity does not need to be revealed.

Who will be able to access my child's medical records?
NHS clinical staff treating you child will have access to your child's medical records.
After results from the study are made available there may be other clinicians in the ChILD-EU study team researching childhood lung diseases who want to better understand the clinical symptoms or are interested in finding out more details of the examinations carried out. They would request the NHS trust for access to notes of ChILD patients so that, for example, they could consider if a new medicine used in adults could be given to children. We will ask for your consent to allow other clinicians access to your child's medical records for the duration of the ChILD-EU programme (due to end June 2016).

To ensure that the study is being run correctly, we will also ask your consent for responsible representatives from the Sponsor [University of Edinburgh & NHS Lothian] and NHS Institution to access your child's medical records and data collected during the study, where it is relevant to you taking part in this research. The Sponsor is responsible for overall management of the study and providing insurance and indemnity

What will happen if I don't want my child to carry on with the study?
You are free to withdraw your child at any time without giving a reason. This will in no way affect the regular treatment you receive.
If you do wish to withdraw, we will ask you to consider whether you wish

(1) All information and investigations currently held to be retained and used

(2) Selected information and investigations currently held can continue to be held and used
(3) All data currently held should be removed and not used
Or (4) Whether you wish the study team to retain your contact details to contact you should a study or treatment of relevance to your child become available in the future

What if there is a problem or something goes wrong?
If you have a concern about any aspect of this study then you can contact the researchers involved (see contacts). In the unlikely event that something goes wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against NHS Lothian but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

Is there anything to be worried about if my child takes part?
We all worry about data security. The research team have worked hard to ensure that the data from your child will be secure.

Detailed information on data security and oversight.
If you agree to your child taking part then your local doctor will provide identifiable details of your child (i.e. name, date of birth, hospital number etc) to be stored on a secure database. Your local doctor is then sent an email with the ChILD study number that is assigned to your child. This study number will not contain any identifiable details of your child.

Whenever your doctor wishes to put clinical information (i.e. medical history, x-rays, results of investigations, pictures of lung biopsies) about your child into the ChILD-EU database they will use the ChILD study number to identify your child. A study number identifies your child rather than a name and this is called pseudo-anonymisation.

The ChILD-EU clinical database (SecuTrial) will be kept separate from where your child's personal details are held. The database containing patient data is based at the University of Mainz, Germany and is covered by European Union Data Protection laws. We may access this information at a later date to contact you should a study or treatment become available that we consider may be of interest to you and your child.

The data would be accessed by clinicians who are part of the study team to investigate ChILD, and also for data validation and monitoring as is standard for any clinical trial.

Management of the study data is by the ChILD-EU study management team (lead by Professor Griese, and includes partners from the UK, Italy and France). The study team and its decisions are overseen by a Data Monitoring Committee lead by Professor Peter Propping, Bonn, Germany. Once the ChILD-EU study has finished the KLR Foundation (Kids Lung Register) will continue to oversee the study database. Details of the study team and the KLR Foundation can be found on the ChILD-EU website (www.childeu.net).

What happens to the results of this study?
Once we have collected data from a large number of children we will report the findings at a Medical Conference and in the Medical Press to other interested scientists and doctors. No personal information will be communicated so that no one else will know you have taken part in this study. You can find out the results of the study if you wish by contacting us, but we will also be distributing the results through ChILD parent organisations across Europe.

Who is organising and funding the research?
This study is being funded by the European Union FP7 Framework.

Who has reviewed this study?
All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee. A favourable ethical opinion has been obtained from South East Scotland Research Ethics Committee 2. NHS management approval has also been obtained.

International Contact Details

The overall lead clinician for the study is:

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

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In the UK, the study is being led by:

Dr Steve Cunningham
Consultant Respiratory Paediatrician
Royal Hospital for Sick Children
Sciennes Road
Edinburgh
EH9 1LF
Tel: 0131 536 0607

Professor Andy Bush
Professor of Paediatric Respirology
Royal Brompton Hospital
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 and title]
Address	[insert address] [insert address]

[insert address]
Phone number – [insert number]
E-mail - [insert email address]

If you would like to discuss this study with someone independent of the study please contact: [contact details, insert name,].
[name of hospital]
[phone number]

If you wish to make a complaint about the study please contact NHS Lothian:

NHS Lothian Complaints Team
2nd Floor
Waverley Gate
2 - 4 Waterloo Place
Edinburgh
EH1 3EG

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

PARENT/CARER CONSENT FORM

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

I wish for my child/ward to participate in:	Please **initial** boxes
The database/biobank study	_ _ _
The database/biobank study AND the observation study	_ _ _

1. I confirm that I have read and understood the attached information sheet. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily	_ _ _
2. I understand that the participation of my child/ward is voluntary and that I am free to withdraw him/her at any time, without giving any reason, without his/her medical care or legal rights being affected	_ _ _
3. I understand that relevant sections of my child/ward's medical notes may be looked at by responsible individuals from the Sponsor, NHS organisation or other authorities and I give permission for these individuals to have access to my child/ward's medical records	_ _ _
4. I understand that data from the study will be stored indefinitely and may be used in the future for other studies	_ _ _
5. I agree to my child/ward's GP being informed of his/her participation in the study	_ _ _

You can withhold consent to this part of the study and it will not affect your child's general participation in this study

Genetic Consent (**optional**) – please initial either the "Yes" or "No" box

		YES	NO
6.	I agree to biological samples from my child (blood, tissue) being collected and stored for the purposes of research into childhood interstitial lung disease and understand that this research will involve genetic testing	☐	☐

Future Research (**optional**)

7.	I agree to biological samples from my child (blood, tissue) being used in future research involving genome wide analysis and future research into ChILD	☐	☐
8.	I agree to be contacted in the future if any relevant tests for diagnosis or treatment of ChILD becomes available	☐	☐
9.	I understand that relevant sections of my child/ward's medical notes may be looked at by ChILD-EU clinicians researching childhood lung disease and I give permission for these individuals to have access to my child/ward's medical records for the duration of the ChILD-EU programme. (*In Scotland - if your child has turned 12 we will ask him/her to agree to provide access to his/her medical records)*	☐	☐

Parent's Name (Print) ……..

Parent's Signature ……

Date ……

Name of person taking consent (Print) ……

Signature of person taking consent ……

Date ……..

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