

Participant Information for children (age 9-11)

Observational study for children with T-Cell immunodeficiency

Dear _____

You are with us in the clinic because you don't feel well. Together we want to do everything to make you get better soon. We and your parents think you may like to join in a project that may help, called a "research study". This leaflet will tell you all about it, and what taking part would mean for you. You can ask us questions at any time, we will be happy to answer them.

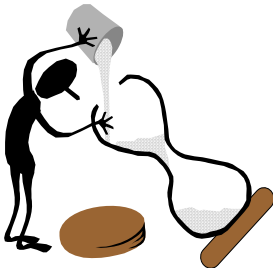


What is research?

Research is how doctors and scientists discover and explain new knowledge. The scientists need to study and investigate carefully to work out the answer to a research question.

1. What is this research study about?

Your doctor or your parents have already explained why you feel ill. Your illness is called "immunodeficiency". This means that your body's defence system against germs is not working well. The idea of this research project is to answer these medical questions about immunodeficiency:



1. why does it happen?
2. what problems does it cause?
3. what is the best treatment?

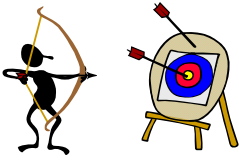
As well as you about 200 children from different countries will take part in this study.

2. What happens in the study?

Most of the work for this study is done by your doctor or nurse, not by you! Whenever you see the doctor, they ask questions, examine you and often ask for blood tests to check on your immunodeficiency. All this stays the same! Here are the differences:

- once a year, information about your illness is sent to the research centre (but not your name or other personal info)

- we will ask you about life in general to get a better picture of what immunodeficiency means for you – this will be a question sheet to fill in



It is important for us to hear about every discomfort you experience, even those which may not be asked about in the questionnaire. So please tell your parents and your doctor if anything is troubling you.

3. Will being in this study make me get better?

During the study, you will be looked after and treated just the same as any other patient. Being in the study won't change your treatment directly. But the results of the study overall may help doctors look after patients with your illness better in a few years' time.

4. Do I have to take part in the study?

You are completely free to decide whether or not to join the study. You can also change your mind later on - it's up to you. If you change your mind, you should let your parents know. We can then discuss together what to do next.

5. What else is important?

- There are laws to make sure research is done properly and safely. Like all research studies that involve patients, this one has been reviewed by an expert committee to make sure it has been set up right.



- We need a lot of info about you for this type of research but not personal things like your name. For the study we will use a code number instead of your name and your date of birth. All the info about you will go under the code number and will be kept private (this is called data protection).

- Here you can find the name of the doctor who is coordinating this study, and the name of the doctor who is responsible for you. They will be happy to answer any questions you or your parents might have.

Coordinating Investigator:	Investigator at hospital (please complete contact data):
Prof. Dr. Stephan Ehl	name
University Medical Center Freiburg	medical center
Center for Chronic Immunodeficiency	department
	station
Breisacher Str. 117	street
79106 Freiburg i.Br., Germany	city, ZIP, country
Phone +49 761 270-77300	phone
Fax +49 761 270-77600	fax

Patient label



Great Ormond Street Hospital NHS Trust

The Newcastle upon Tyne Hospitals NHS Foundation Trust



Observational study for children with T-Cell defect Assent form (9-11 yrs)

Site- and patient No.

patient-name

date of birth

Dr. _____ has explained to me that s/he and others want to find out how different treatments work for children and young people who have the same disease as I have. Therefore s/he asked me if it is OK for me to take part in this research study.

(please initial the boxes below if you agree)

I was able to ask questions. At the moment I have no further questions

I have received an information leaflet about this study. I have read this information/_____ has read this information to me.

I had enough time to think about the study and I spoke with my parents about it.

My doctor explained to me that there are laws regulating how medical studies are carried out and that all relevant laws will be obeyed in this study.

I know that I do not have to take part in the study.

If I agree to participate, it is OK if I change my mind later on.

I have received information about the study and a copy of my consent.

YES, I will participate in the study and I will write my name below.

Date
(to be completed by parents or child)

Name of the child

Date
(to be completed by investigator)

Signature of investigator