

Participant Information for adolescents (age 12 and older)

Observational study for children with T-Cell immunodeficiency

Dear

We have asked your parents for their permission to allow you to take part in a clinical study. We would now like to ask you for your agreement, too.

Before you decide, you need to know everything important about this research. So please read this information sheet and ask any questions that it raises for you. Take as much time as you need to decide about taking part.

1. Why is this research being carried out?

As your doctor or your parents probably have told you, your immune system isn't working as well as it should and it's likely this has made you unwell. This is called "immunodeficiency". Usually immunodeficiency is something you are born with, but at the moment doctors often can't say exactly which gene is the problem. There are different treatments available, but we do not know yet which works best in each type of immunodeficiency. Therefore, we want to investigate how children in different countries are treated and how well their treatment works. As well as you, about 200 children and young people, mostly in Europe, will take part in this study.

2. What happens in the study?

First we need to check whether your immunodeficiency fits into the group we are studying. As this disorder is rare this is an important step. The assessment is carried out by your doctor and would be made whether or not you participate in the study. Likewise, you will have regular follow-up visits in the next few years, which would be scheduled with your doctor in any case. As usual, the doctor will ask lots of questions and examine you, only the information will be recorded for the study as well as in your medical notes. Blood samples will be collected for routine tests in the usual way.

To build up a better picture of your general well-being, we would like to ask you to fill in some simple questionnaires from time to time over the coming years. This will help us understand the impact of your immunodeficiency and its treatment on your quality of life. No further tests or treatments are prescribed through the study. You and your doctor will stay in control of your treatment.

3. Will there be any benefits if I take part?

Since this is a fact-finding study about your disease, it is unlikely to bring you immediate benefits. It is possible that the results of the study will help your doctors look after you in the future, as well as other children and young people with the same medical problem.

4. Do I have to participate?

You are free to decide for or against taking part in the study. If you decide to take part and then change your mind, that is completely your right. If you wish to leave before the end of the study, please let your doctor know.

5. Who else knows that I am participating in this study?

A lot of information will be collected for analysis in study, mainly about your disease and results of tests. We don't include your full name or date of birth with this information, only a code number that is unique and private to you. This means that apart from your doctor, only the people running the study are aware of your identity. Your personal information is strictly confidential and will stay private.

6. What else do I need to know?

A coordinating investigator, Professor Stephan Ehl, is in overall charge of this study. You can contact him or your own doctor at any time during the study. He and your doctor will be happy to answer any questions you 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
Participant assent form (12+ 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 participant)

Signature of participant

Date

(to be completed by investigator)

Signature of investigator