UCL INSTITUTE OF CHILD HEALTH

The Newcastle upon Tyne Hospitals NHS
NHS Foundation Trust

Great Ormond Street Hospital for Children NHS Trust NHS

Newcastle University

Parent Information sheet

Observational study for children with T-Cell Immunodeficiency (profound combined immunodeficiency : P-CID)

Dear Parents,

Your child has been invited to take part in the study "Observational study on Patients with T-cell Immunodeficiency".

The study will be conducted at the Centre of Chronic Immunodeficiency (CCI) Freiburg, Germany and other European study sites. The study will cooperate with the European database of the "European Society of Immunodeficiencies (ESID)".

This written information is provided to you alongside verbal discussions. Participation in this study is entirely voluntary. Before you and your child decide whether to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Your physician will also be happy to discuss all aspects of the study. If necessary, please do not hesitate to ask for further time to decide whether to take part.

1. What is the purpose of this study?

The study is designed to help us understand combined immunodeficiency (CID) and how best to treat it. CID is rare and has various different causes, which has made it difficult to research. At the moment, it is hard to weigh up the risks of living with profound CID (severe infections, autoimmunity) against a treatment like stem cell transplant (SCT). SCT has the potential to cure CID but carries its own risks.

This study is designed to help us learn from children with CID who are being cared for in many centres across Europe and beyond. Medical findings, treatment and clinical events will be documented regularly for each patient over a period of 5 years. No treatment decisions will be affected by being in the study, which is purely observational. When the experience of many patients is gathered together, we will be able to look for patterns of disease behaviour and treatment response. These might help us choose the right treatment at the right time for individual patients in the future.

2. What data will be collected?

At the start of and during the study, details of your child's medical history, clinical examination findings and results of routine lab tests will be collected with the help of a standardised questionnaire. This information would be collected anyway by your physician during routine visits. In particular we will be looking for signs of infection, autoimmunity and other features typical for patients with P-CID. If a genetic diagnosis is confirmed, this information is also recorded. Data will usually be collected annually for 5 years, and entered in a database. If patients undergo stem cell transplant we ask for additional information at 6 months after transplant, then annually.

3. What are the possible benefits or disadvantages of taking part ?

Participation in the study will probably not help your child directly. However, the aim of the study is to improve the longterm care and outlook for all children with P-CID. This may include advances both in

diagnostic testing and therapy. There is no health risk to your child and no additional costs or doctor's visits if he/she takes part. There is no financial reimbursement for participation.

4. What will happen if my child doesn't want to carry on with the study?

You and your child are free to refuse to participate or withdraw from the study at any time. If you withdraw, all data will be deleted unless you explicitly permit its storage. Your decision will in no way affect the current or future treatment of your child. Your decision will not affect the mutual trust relationship between you and your doctor. Please inform your doctor if you wish to withdraw from the study.

5. Will the participation of my child be kept confidential?

Yes. All personal data (e.g. name, address, date of birth) will be stored confidentially, securely and separately from clinical and research information. For organisational reasons your child's date of birth will be sent to the P-CID central office, which generates a unique code number. Any samples and any medical or research information about your child will be identified only by this code number, and will never carry names, initials or date of birth. The investigation results and identifying data are stored separately to protect your child's data in accordance with data protection guidelines. This means your child will not be identifiable to anyone outside your hospital.

You and your child have the right to see all personal data that has been collected and to correct any errors. After this project has been finished, data will be archived long term in a secure facility. If this observational study is successful, we would like to continue using the existing data as a registry for patients with profound combined immunodeficiency. The data of your child will be saved for 10 years after the end of the study or registry.

6. Contact Details for further questions

In case you or your child have further questions please do not hesitate to contact:

Newcastle upon Tyne:	Great Ormond Street:	P-CID study office:
Dr Sophie Hambleton **Dr Andrew Gennery** Paediatric Immunology Service Great North Children's Hospital Victoria Rd Newcastle upon Tyne NE1 4LP **Tel 0191 282 5234** **Email:** **sophie.hambleton@ncl.ac.uk**	**Professor Bobby Gaspar** Molecular immunology Unit UCL Institute of Child Health 30, Guilford Street London **Tel: 0207 905 2319/2809/2289** **Email: h.gaspar@ucl.ac.uk**	**Professor Stephan Ehl** **Dr Carsten Speckmann** University Medical Center Freiburg, Centre of Chronic Immunodeficiency (CCI) Breisacher Str. 117 2. OG 79106 Freiburg, Germany **Tel +49 761 270-74030** **p-cid@uniklinik-freiburg.de**

Patient label

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Parental Consent Form

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For completion by a parent(s) or guardian(s) of the participant. Please initial the boxes to the left to indicate your agreement with the accompanying statement, and sign below where indicated. The child and a second parent or guardian may also sign.

☐ **I/we agree to the participation of my child in this research study.**

☐ I/we have read and understand the information sheet for the P-CID study (dated 25.10.13).

☐ I/we have had the opportunity to consider the information, ask questions and have these answered satisfactorily.

☐ I/we understand that the personal data of our child will be documented in coded form and kept confidential at all times.

☐ I/we agree that coded data that do not identify our child may be passed on for scientific analysis to the P-CID study team (Prof S Ehl, University Medical Center, Freiburg, Germany) and other investigators or research groups.

☐ I/we understand that participation of our child is voluntary. We are free to withdraw at any time, without giving any reason, and without affecting the medical care or legal rights of our child.

☐ In case of withdrawal, I/we confirm that data already collected could be retained and used for the purposes of the study.

	Name	Signature	Date
Parent/guardian 1			
Parent/guardian 2			
Child (if applicable)			
Physician taking consent			