Immunology of THymectomy And Childhood CArdiac Transplant

Participant Information Sheet – Parents/Guardians

We would like to invite your child to take part in our research study. Before you decide, it is important that you understand why the research is being done and what it would involve.

Part 1 tells you the purpose of this study and what will happen to you and your child if you take part.

Part 2 gives you more detailed information about the conduct of the study.

Please take time to read this information carefully and discuss it with others if you wish. If there is anything that is not clear, or if you would like more information, please feel free to ask us.

Part 1 – To give you initial information about the study

What is the purpose of the study?

After an organ transplant, patients on lifelong anti-rejection medications (known as immunosuppressive treatment) have a small risk of developing post-transplant lymphoproliferative disease (PTLD). This occurs when a group of white blood cells called 'B cells' grow out of control and transform (change) into cancerous cells. Most cases of PTLD are caused by infection of 'B cells' by a very common virus called Epstein-Barr Virus (EBV) which can also cause glandular fever.

Whilst most people with transplants **DO NOT** develop PTLD, the risk is slightly higher after a heart transplant compared to most other organs (1 in every 10 heart transplant patients under 18 years old will develop PTLD). The reason for this increased risk is still poorly understood. Our previous study showed that very early removal of the thymus (a gland in the neck needed to develop a healthy immune system) during major childhood heart surgery might play an important role in this.

The purpose of this study is to examine the quantity and function of different immune cells circulating in the blood just before transplant and at regular periods after transplant. We will also look at how well the immune system is able to produce antibodies and other specific immune cells to fight an EBV infection. We intend to compare the immune cell patterns of patients undergoing a heart transplant with those

receiving other types of organ transplants. This will help us to better understand how the immune system recovers after transplant and identify immune patterns that either protect patients from developing PTLD or increase their risk of getting the disease.

Why have we been invited to participate in this study?

We are inviting patients under 18 years old from around the UK, who like your child, have been put on the transplant waiting list. We aim to involve 40 participants in this study.

Do we have to take part?

No, this study is entirely **voluntary**. It is up to you and your child (wherever possible) to decide to take part in the study. If you agree to take part, we will first ask you to sign a screening consent form. During the screening consent, we will ask if you agree for your child to have their first study sample taken and stored before their transplant. Once your child has been called for their transplant, we will confirm with you that you remain happy to be part of the study and ask you to sign a second consent form. We will not include your child in the study or use their blood sample unless you have signed the second consent form.

If your child is able to understand the research and is happy to take part and can write their name, they will be asked to sign an assent form with you, if they want to

You and your child are free to withdraw from the study at any time without giving a reason why. This will not affect the standard of care your child receives in any way.

Can we take part?

Children with an organ transplant under the age of 18 years are able to take part. In order to be enrolled in the study;

- You must currently live in the UK.
- Your child should be listed on the national transplant list.

You cannot take part in the study if your child:

- Has a pre-existing diagnosis of an inherited or acquired immunodeficiency.
- Has an underlying thymic disorder.
- Has previously received a bone marrow or organ transplant.
- Has had a previous cancer diagnosis.
- Weighs less than 2.5kg.

What will happen if we decide to take part?

We would like to take no more than an extra 3 teaspoons of blood during your child's usual investigations. This will occur during routine appointments with your local transplant team and **will not usually** require additional hospital visits. The first blood samples will be taken as close to the day of your child's transplant as possible. We aim to discuss the study with you and your child before transplant. However, if your child's transplant team thinks that this discussion cannot happen at an appropriate time before your child's transplant, then any blood samples taken for our study will be

stored but not used until you and/or your child have given full consent to be a part of this study. If you and/or your child decide not to participate in the study, your child's blood samples will be destroyed as soon as possible and no further samples will be taken. If you and your child decide to participate, subsequent samples will be taken during routine follow up clinic visits at 3, 6, 12 and 24 months after your child's transplant. At the beginning of the study, we will collect information on your child's medical history from the transplant team. We will continue to follow up with the transplant team about your child's health and clinical progress after each routine clinic visits for up to 2 years after your child's transplant.

Are there any possible disadvantages or risks from taking part?

Apart from taking a slightly larger blood sample, this research will not affect your child. It does **NOT** alter your child's treatment. Since the blood samples will be taken during your child's routine transplant tests, there will be no additional pain or discomfort to them from taking part in this research study.

What are the possible benefits of taking part?

Your child will not gain any direct benefit from the study, but the information gathered from our research might help us to better understand how PTLD develops. This is an important step for us to develop future tests that tell us which patients are more likely to develop PTLD. With this knowledge, we could possibly identify ways to reduce the chance of transplant patients getting PTLD and/or create new treatments for this condition.

Will our taking part in the study be kept confidential?

Yes. All information about your child will be kept private. The details are included in Part 2.

Will our family doctor/General Practitioner (GP) be informed of my child's participation?

It is optional for your GP to be informed about your child's participation in the study. If you agree, we will write to your GP to inform them that you and your child have agreed to take part in the study. The letter will explain the aims of the study but will not include any information about your child's specific blood test results.

What if there is a problem?

Any complaint about the way you or your child have been treated during the study or any possible harm your child might experience will be addressed. The detailed information on this is given in Part 2.

Contact for further information

If you would like any further information about this study, or **if you are interested in participating**, you could contact:

Name: Dr Simon Bomken **Designation:** Consultant Paediatrician **Department:** The Sir James Spence Institute, Royal Victoria Infirmary, Queen Victoria Road, Newcastle upon Tyne, NE1 4LP. **Tel:** +44 (0) 191–282–4068	**Name**: Dr Ugo Offor **Designation:** Paediatric Registrar **Department:** The Sir James Spence Institute, Royal Victoria Infirmary, Queen Victoria Road, Newcastle upon Tyne, NE1 4LP. **Tel:** +44 (0) 191–233–6161
Study email: nuth.ithaca@nhs.net	

If the information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making any decision.

Part 2 – More detailed information you need to know if you still want to take part.

What will happen to my child's samples?

Your child's study samples will be analysed in NHS laboratories, Newcastle University research laboratories and other collaborating laboratories in the UK.

If you and your child consent, any leftover blood samples can be stored within the Newcastle University biobank and used for future approved research. This is optional; your child's involvement in this study will not be affected by the decision whether to allow storage and future use of leftover samples. If you or your child request at any time, the remaining blood samples will be destroyed.

What will happen if we don't want to carry on with the study?

If at any time you or your child change your minds about being involved with this study, you are free to withdraw without giving a reason. If you withdraw, we would not perform any more research procedures on your child. Your decision will not affect the standard of your child's care in any way. Unless you state otherwise, any blood samples taken while your child was involved in the study will continue to be stored and used for research as detailed above. You and your child are free to request that their blood samples are destroyed at any time during or after the study. Any data collected and/or generated up to the time of your child's withdrawal may be kept and used for study analysis.

Will my child's taking part in the study be kept confidential?

All information that is collected about your child during the course of this study will be coded with a study number and kept private. The information will be available to the study team, authorised collaborators, ethical review committee, Newcastle University and the study sponsor (The Newcastle upon Tyne Hospitals NHS Foundation Trust), who can ask to access the study data to ensure that we are complying with research study regulations. They are all bound by the same confidentiality rules.

Every effort will be taken to maintain your child's privacy. Information about your child may be stored electronically on NHS secure servers, and paper documents will be kept in a key-locked filing cabinet or restricted access office at the Sir James Spence Institute, Royal Victoria Infirmary. Study results will be published in a scientific journal but nothing that could identify your child will be mentioned in any report or publication.

How will you use information about my child?

As the study sponsor's, The Newcastle upon Tyne Hospitals NHS Foundation Trust is the data controller and is responsible for looking after your child's information and using in properly. We will need to use information from your child's medical records for this research project. This will include identifiable information such as your child's name, NHS number, hospital number, and contact details. People will use this information to do the research or to check your child's records to make sure that the research is being done properly. We will keep such identifiable information about your child for a maximum of 5 years after the study has finished.

People who do not need to know who your child is will not be able to see his/her name or contact details. Your child's data will have a code number instead. We will keep all information about your child safe and secure. We will write our reports in a way that no-one can work out that your child took part in the study. De-identified research data will be stored indefinitely at Newcastle University.

What are my choices about how my child's information is used?

Your child can stop being part of the study at any time, without giving a reason, but we will keep any information about your child that we have already collected.

We need to manage your child's records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about your child.

Where can I find out more about how my child's information is used?

You can find out more about how we use your child's information:

- at www.hra.nhs.uk/information-about-patients/
- by asking a member of our research team
- by sending an email to richard.oliver2@nhs.net, or
- by ringing us on 0191-213-8946.

What will happen to the results of the study?

The results of the study will be published in medical journals which are available via the internet and may also be presented at national/international conferences. This

research will also contribute to the fulfilment of educational requirements (e.g., a doctoral thesis). We will protect your child's privacy by ensuring that no information that could identify them is used when the research results are published. The study is expected to run for at least 2 years.

How have patients and the public been involved in this study?

Potential participants were involved in reviewing the Participant Information Sheet, consent forms and study design. In designing this study we have taken into account patient opinions on the frequency of participant visits and the tests that we will carry out.

Who is sponsoring, organising and funding the study?

The study is organised and sponsored by The Newcastle upon Tyne Hospitals NHS Foundation Trust. The study is funded through financial support from Cancer Research UK and the Lymphoma Research Trust. None of the researchers are paid for recruiting your child into the study.

Who has reviewed and approved the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee to protect your child's safety, rights, wellbeing and dignity. This study has been reviewed and given a favourable opinion by North of Scotland (2) Research Ethics Committee.

What if something goes wrong?

The study team recognise the important contribution that volunteers make to medical research and make every effort to ensure your child's safety and well-being. The Newcastle upon Tyne Hospitals NHS Foundation Trust, as the study sponsor, has arrangements in place in the unlikely event that your child suffers any harm as a direct consequence of participation in this study.

In the event of harm being suffered, while the Sponsor will cooperate with any claim, you may wish to seek independent legal advice to ensure that you are properly represented in pursuing any complaint. The study doctor can advise you of further action and refer your child to a doctor within the NHS for treatment, if necessary. NHS indemnity operates in respect of the clinical treatment which may be provided if your child needed to be admitted to hospital.

Complaint statement

What if I wish to complain about the way in which the study has been conducted?

If you have a concern about any aspect of this study, you should ask to speak to the researcher investigators who will do their best to address your concerns. Alternatively, you may wish to send us an email at **nuth.ithaca@nhs.net**. If you remain unhappy

and wish to complain formally, the normal National Health Service complaints mechanism is available to you. You and your child will not be treated any differently if you decide to make a complaint. You can contact the Patient Advise and Liaison Service (PALS). This service is confidential and can be contacted on Freephone: **0800 032 0202.**

Alternatively, if you wish to make a formal complaint you can contact the Patient Relations Department through any of the details below:
Telephone: **0191-223-1382** or **0191-223-1454**
Email: patient.relations@nuth.nhs.uk
Address: Patient Relations Department
The Newcastle upon Tyne Hospitals NHS Foundation Trust
The Freeman Hospital
Newcastle upon Tyne
NE7 7DN

Further information and contact details
We hope this information sheet has answered all of your questions. If you would like further information about participating in research, please visit the following website: www.crn.nihr.ac.uk/can-help/patients-carers-public/how-to-take-part-in-a-study.
or you could contact the hospital Clinical Research Facility:

nuth.paedoncresearch@nhs.net

01912821893 (Clinical Lead)

01919177591 (Research Nurse)